MSC/M/60/2018
(Adopted in written procedure
on 5 September 2018)

Draft Minutes
of the 60th Meeting of the Member State Committee (MSC-60)
12-14 June 2018

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 60th meeting of the Member State Committee (MSC) (for the full list of attendees and further details see Part II of the minutes).

The Executive Director of ECHA Mr Bjorn Hansen addressed the MSC on the occasion of its 60th meeting and on the occasion of the last REACH registration deadline being over.

Item 2 - Adoption of the Agenda

The Agenda was adopted as modified by the MSC Secretariat (MSC-S) with addition of two any other business-items. The Chairman suggested including an information item in the any other business (Item 12) on possible categorisation of proposals for amendment (PfA) in dossier evaluation with the aim to help MSC members to prioritise their own work. In addition, an item on a substance for which a TPE was agreed on in MSC-57 was added to the any other business (Item 12) based on a request from a member (final Agenda is attached to these minutes as Section III).

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

The Chairman discussed with members the recently initiated lobbying activity related to some ongoing SVHC cases that he had been made aware of. No conflict of interest was identified as a result of this activity and the Chairman concluded that there was no impact on the decision making foreseen at the meeting. However, the Chairman will ensure that appropriate follow-up actions are taken on this issue after MSC-60.

No potential conflicts of interests were declared by any members, experts or advisers with any item on the agenda of MSC-60.

Item 4 - Administrative issues

Outlook for MSC-61 and MSC-62

The Chairman presented an estimation on the potential length of the next meetings, which is expected to be approximately three plenary days for MSC-61 and five plenary days for MSC-62.

Interact

The Chairman updated MSC on the ongoing ECHA IT development project *Interact* presenting its focus and estimated timeline. Members were encouraged to liaise with the designated ECHA's contact point for further information and to volunteer for project involvement to provide occasional input.

Item 5 – Minutes of the MSC-59 meeting

MSC Chairman informed the Committee that the minutes of MSC-59 were adopted by MSC in written procedure and published on ECHA website and in MSC S-CIRCABC.

Item 6 – Substance evaluation

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

SECR introduced the report on the outcome of the written procedure (WP) for agreement seeking on two substance evaluation cases (see Appendix to the Final agenda in Section III for more detailed identification of the cases). WP was launched on 17 May 2018 and closed on 28 May 2018. By the closing date, unanimous agreement was reached on one draft decision (DD). For the second DD, based on request from an MSC member, the MSC Chairman terminated the WP.

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

No cases.

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

SEV-BE-002/2016 Reaction mass of 2,2,3,3,5,5,6,6-octafluoro-4-(1,1,1,2,3,3,3-heptafluoropropan-2-yl)morpholine and 2,2,3,3,5,5,6,6-octafluoro-4-(heptafluoropropyl)morpholine (EC/List No. 473-390-7)

The MSC Chairman had terminated the written procedure for MSC agreement seeking on this SEv draft decision prepared by the BE CA (eMSCA) upon request from a MSC member and the case was brought to the meeting to specifically discuss the issue raised by the member.

The MSC member explained that to date, the number of test concentrations to use in an OECD 305 study has not been specified to a registrant in a Decision (i.e. it is expected that they will follow the technical guidance requirements described in the test guideline with respect to concentration dependence and provide justification as appropriate). Therefore as this DD diverged from that approach, they thought that the DD needed to explain why accumulation in fish may be concentration dependent for this substance. Otherwise the general nature of the current wording suggested that two concentrations would always be required simply because the concentration dependence of every substance is not known. In such case this would contradict the intent of OECD 305 test guideline where single concentration tests are the preferred starting point.

BE-CA captured the concern expressed in a revised text of the DD presented to MSC.

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

4. General topics - Status report on on-going substance evaluation work

SECR provided a brief reminder about the steps for MSCAs to take in Substance evaluation process and the related instructions e.g. on the verification step and for cases at a follow-up stage. SECR also highlighted that for the October meeting round no SEV cases were currently planned whereas for the December there were already eight cases foreseen for the MSCA consultation. In order to understand the reasons for this uneven planning of cases SECR invited MSC members to convey the issue to their MSCA counterparts for input from everyone.

Item 7 – Dossier evaluation

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

SECR introduced the report on the outcome of the written procedure (WP) for agreement seeking on nine dossier evaluation cases (see Section III Final agenda "Appendix to the MSC-60 agenda" for more detailed identification of the cases). WP was launched on 17 May 2018. By the closing date 28 May 2018, MSC reached unanimous agreement on all DDs.

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

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

CCH-032/2018 Cinnamaldehyde (EC No. 203-213-9)
Session 1 (open)

No representative of the Registrant participated in the initial discussion.

SECR explained the two PfAs received to the ECHA's DD, both of which were discussed in the meeting and are outlined below. The first PfA on *in vitro* mutagenicity endpoints (*in vitro* gene mutation study in bacteria; *in vitro* cytogenicity study in mammalian cells or *in vitro* micronucleus (MN) study; and *in vitro* gene mutation study in mammalian cells)

suggested reconsidering the three requests due to the European Food Safety Agency's (EFSA) opinion. Moreover, also ensuring consistency between different European agencies on scientific conclusions on the toxic effects of a substance. This substance was part of an in-depth genotoxicity evaluation by the EFSA Panel on Food Contact Materials, Enzymes, Flavourings and Processing Aids (CEF) performed on the group of cinnamyl derivatives in 2008. The Panel had concluded that cinnamaldehyde should not be regarded as genotoxic.

The second PfA on reproductive and developmental toxicity suggested re-inserting a request for OECD test guidelines (TG) 421 or 422. It pointed out a data gap, because the reported weight of evidence approach did not pass and there was no valid pre-natal developmental toxicity (PNDT) study reported.

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

The Registrant had provided written comments on both PfAs. He agreed with the first one on mutagenicity, but disagreed with the second PfA on reproductive toxicity.

A MSC member summarised the first PfA on mutagenicity and noted that SECR had considered many of the studies as invalid, because they did not conform with good laboratory practices or test guidelines (non-GLP and non-TG). The member argued that this was not a reason to disqualify them and quoted the Panel having judged many of them valid in its assessment. However, the member acknowledged that the Registrant had not updated the dossier with all relevant results. Another MSC member expressed the view that regulatory frameworks and committees have different objectives, and that REACH requires the Registrants to meet the registration obligations by providing the minimum standard information requirements. Other bodies may provide opinions and/or conclusions on the basis of available information, however this does not mean that the REACH standard information requirements are fulfilled. The member concluded by reminding that it is the Registrant's obligation to present all necessary evidence if he considers the requirements as being fulfilled, as detailed out in REACH Regulation. An expert to a MSC member argued that MSC should make use of scientific evaluation carried out in other fora, including work done at national level, and suggested pointing out in the DD that the registration dossier was not yet completed to allow for waiving. The Chairman concluded that MSC seemed to support maintaining the request for mutagenicity.

An expert to MSC member informed that a classification and labelling proposal is being prepared for submission this year on the registered substance with a proposal not to classify the substance for mutagenicity, and questioned whether the Risk Assessment Committee (RAC) deliberations would provide relevant input for MSC. A MSC member considered that it was not possible to wait for future data or deliberations. The member further noted that RAC assessment result might also depend on data availability, while MSC is required by REACH to ensure that information requests are fulfilled. A stakeholder observer argued that the Registrant is to have an opportunity to waive, because one of the uses of the substance is in cosmetics with a link to animal testing avoidance.

On the second PfA on reproductive and developmental toxicity, a MSC member acknowledged the existing data gap and supported to carry out testing in an optimal way. This would mean to first carry out PNDT before possibly continuing with a screening study. MSC agreed to have this PfA implemented in the DD.

Session 2 (closed)

SECR summarised its view that the nature of the EFSA assessment was part of a risk assessment, which is markedly different from REACH requirements. ECHA must ensure that information is present, in a specified form, in the registration dossier meeting the specific information requirements. Therefore, it is possible that different actions may arise from the two Agencies, as a result of the different tasks they perform. In addition, the non-GLP and non-TG studies were not considered as invalid on those grounds, but rather because they did not meet the standard information requirements, among others the robust study summaries.

MSC was of the view that it could not conclude that the information referred to in the PfA, and supported by the Registrant's comments, would allow the endpoint to be fulfilled. MSC

agreed that the request for *in vitro* mutagenicity would be kept. MSC also agreed with the second PfA to re-insert the request for OECD TG 421 or 422.

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

TPE-040/2018 Triethoxy(3-thiocyanatopropyl)silane (EC No. 252-161-3)
and
TPE-046/2018 3-(triethoxysilyl)propanethiol (EC No. 238-883-1)

No representative of the Registrant participated in the initial discussion.

SECR explained the PfAs that were received to the ECHA's DDs for both cases: two similar/same PfAs for both cases and a third PfA submitted only for TPE-040/2018. The PfAs were submitted for *in vivo* mutagenicity requests (*in vivo* mammalian erythrocyte micronucleus (MN) test in mice or rats (OECD TG 474), or *in vivo* mammalian alkaline comet assay in rats (OECD TG 489)).

The first PfA suggested requesting (a) only *in vivo* mammalian alkaline comet assay as the most suitable study to follow up the positive result; (b) rejecting the testing proposal on *in vivo* mammalian erythrocyte MN test; and (c) removing option between MN test and comet assay.

The second PfA suggested to add a provision that the combination of assays (90-d repeat dose toxicity study (RDT; OECD TG 408) - & *in vivo* genotoxicity) should only be considered when the top dose of the 90-d RDT study is not lower than when performing the genotoxicity assay on its own. It pointed out that duration of genotoxicity assays is shorter than 90-d RDT study, hence a combination of both assays may result in a significantly lower dosing which can lead to a false negative result in the genotoxicity assay. Moreover, inclusion of the genotoxicity measurements in a RDT (both in 28-d and 90-d studies) would require additional positive control groups and also (potentially) additional groups to be tested at higher doses.

Hence, combination of assays may provide only limited saving of animals and costs, if any.

The third PfA submitted only for TPE-040/2018, suggested also to remove the option between the MN assay and the comet assay, and request only the comet assay because the registered substance is very reactive and there may be diminished exposure of target tissues distant from the stomach, such as the bone marrow.

SECR had modified the DD in advance of the meeting based on the PfAs. Registrant did not provide comments on the proposals for amendment.

A MSC member acknowledged that SECR had addressed in the draft decision the top dose issue when requesting the combination of a sub-chronic toxicity study with the comet assay.

An expert to MSC member informed, after consultations with CROs and a RAC member, that there is a possibility of combining the two tests (90-d RDT with comet assay). However, there is a concern on the choice of the top dose, of the dosing factor and on tissues to be harvested and analysed in order to minimise possible false negative outcome in the comet assay. He acknowledged that the combination of comet/90-day RDT could lead to false negative results in the comet assay due to differences in the dosing regime for each separate study and the (late) sampling times for rapidly dividing tissues. Moreover, he stated that an alignment of these provisions related to the combination of the two tests might also be discussed in the Member State Committee & Risk Assessment Committee Workshop (planned for October 2018) and to further be introduced in MoD and implemented in the guidelines.

Another MSC member highlighted the aspects as regards top dose which would prevent reasonable and reliable outcome of the integrated comet/90-d RDT.

SECR highlighted that specific statements in the guidelines impose constrains as regards top doses, however the explicit ratio dosing could be established on a case by case basis. It was also acknowledged that the subject of combining 90-d RDT with comet assay (and its details) might be also discussed in the workshop, and that conclusions of the

discussions combined with analysis of database could lead to the improvement of texts in OECD and test guidance documents.

Session 2 (closed)

SECR summarised its proposal to include a possibility for the Registrant to combine the comet assay and 90-day repeat dose toxicity (RDT) study acknowledging the limitations as discussed at the meeting, and suggested some further modification to the DD to reflect these.

MSC supported the integration of comet assay into RDT studies and agreed that further work on this issue at the OECD expert-level would be advised. The DDs were revised in this respect and each one submitted for voting separately.

MSC agreed unanimously to the DDs as amended at the 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 SVHCs

SECR gave a brief report on the outcome of the written procedure for SVHC agreement seeking on the identification of five substances, proposed to be identified as SVHC based on Article 57 of Regulation (EC) 1907/2006, due to their hazardous properties for human health and/or for the environment (see Appendix to the final agenda in Section III for more detailed identification of the substances).

On 31 May 2018, the MSC Chairman terminated the written procedure for agreement seeking on the SVHC proposal for *Lead (EC No. 231-100-4)* following a justified request of an MSC member and the case was brought for further discussion and agreement seeking in the MSC-60 meeting.

MSC agreed unanimously on identification of the other four substances (see the list of substances in the Appendix to the final agenda in Section III) as SVHCs in the written procedure launched on 22 May 2018 and closed on 1 June 2018. SECR explained that the final documents will be published on the ECHA website and in MSC S-CIRCABC and these substances will be included in the Candidate List of SVHCs in the end of June/beginning of July 2018.

Following a written comment of a member about the possibility to discuss in plenary new data in context of SVHC proposal, the MSC-S presented an SVHC communication/ information exchange chart and invited the Committee to consider if any process modifications/adjustments of the MSC SVHC procedures are needed. MSC was requested to send comments/suggestions in this regard to MSC-S by 15 August 2018.

2. Agreement seeking

Octamethylcyclotetrasiloxane (D4) (EC No. 209-136-7)
Decamethylcyclopentasiloxane (D5) (EC No. 208-764-9)
Dodecamethylcyclohexasiloxane (D6) (EC No. 208-762-8)

The dossier submitter (DS) representatives from the German CA and from ECHA introduced jointly their Annex XV proposals for the three substances and explained that the substances were proposed for identification as SVHC under Article 57 (d)&(e) due to their persistent, bioaccumulative and toxic (PBT) & very persistent and very bioaccumulative (vPvB) properties. The DSs presented a brief overview of the comments received in the public consultation on these Annex XV proposals and of the responses provided in the Response-to-comments documents (RCOMs) and the modifications made in this regard in the Support documents (SDs).

Following the SECR's proposal for streamlining the SVHC case introduction in the plenary, the DSs focused on several open issues regarding the substances' B- and T- assessment that in their view required MSC discussion and confirmation. Slides summarising the other issues raised in the public and MSCAs' consultation that DSs considered to be properly addressed/responded either in the MSC Article 77 (3) (c) opinion (2015) on persistency

and bioaccumulation of D4 and D5, or in the relevant SD and/or RCOM, were provided to MSC in advance of the meeting. MSC agreed to follow this approach.

Following the MSC Chair's invitation to the members and observers to highlight any other issues further to the open issues, a member and an ASO observer suggested to discuss some points related to the P-assessment, namely on sediment simulation tests and on information on the fate and persistence in the environment and to address these in the SDs.

In the following discussion on B- assessment of D4, D5 and D6, MSC thoroughly considered the comments regarding the BCF results (that growth correction breaches mass balance and leads to overestimated BCFs) and the need to test the exceedance of the B-criterion statistically. The adviser to the Cefic observer brought some further clarification on these comments. Some members and the DSs indicated that the approach from the recently updated OECD TG 305 had been used for the BCF growth correction, and that statistical assessment of multiple BCF results can be used when data are available for the same species. In conclusion, MSC supported the DSs' conclusions on this endpoint and the response provided in the RCOMs.

As regards the T-assessment, MSC supported the proposed addition from the DSs to further clarify in the substance documentation for D5 and D6 that these substances meet the criteria for identification as PBTs when they contain D4 in amount equal or above 0.1% (w/w).

As regards the P-assessment, MSC also supported the inclusion of additional information from an existing reference (suggested by the adviser to the Cefic observer) and the further clarification proposed on the sediment simulation testing in relevant SDs.

MSC unanimously agreed to the SDs and respective agreements as modified at the meeting and thus identified as SVHCs D4 (as PBT and vPvB), as well as D5 and D6 (as vPvBs and as PBTs, when containing D4 in an amount equal or above 0.1 % w/w) in accordance with Article 57 (d) & (e) of Regulation (EC) 1907/2006. This conclusion was reached on the basis of the application of a weight of evidence approach by taking into account all available relevant information in accordance with Annex XIII of REACH and the previous MSC conclusions made in the context of the MSC Article 77 (3) (c) opinion. Members from CZ, SK and UK abstained from voting on all three proposals. The AT member abstained from voting on the SVHC proposal for D6. The UK member made a statement for the minutes (see Section V).

At the end of the SVHC deliberations, the MSC Chair thanked the DSs and the committee for the successful outcome on these SVHC proposals and asked MSC members to provide feedback on their experience with the new approach for introducing an SVHC proposal within the forthcoming MSC WebEx survey (see item 12.2).

Lead (EC No. 231-100-4)

DS representative from the Swedish CA presented briefly to MSC the Annex XV proposal for identification of lead as an SVHC under Article 57 (c) due to its harmonised classification in accordance with Regulation (EC) No 1272/2008 (CLP) in the hazard class reproductive toxicity category 1A.

Initially the proposal to identify lead as SVHC was put for MSC agreement seeking in written procedure but following a member's request, the Chairman had terminated the written procedure for this proposal and the case was addressed for plenary. In the meeting, the member who requested to stop the written procedure expressed that SVHC identification is hazard based and thus did not disagree with the proposed identification, but doubted if the authorisation route is the best way to regulate this substance, calling for more discussion before moving to Annex XIV stage. Some members and an advisor of an industry observer supported those views, but also noted that SVHC identification is hazard based and hence they could agree to this identification. Some observers from NGOs expressed their concerns over MSC discussing aspects that go beyond its remit, which leads to a reduction in efficiency of the SVHC identification process.

MSC unanimously agreed to the identification of lead as SVHC under Article 57 (c) of the REACH Regulation due to its toxic for reproduction properties. One member abstained from the vote.

The Chairman thanked the dossier submitter for this SVHC proposal and MSC for its deliberations on it and unanimous agreement reached.

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

1) Substances for the 9th recommendation

SECR presented its progress on developing the 9th draft recommendation. SECR suggested to include 13 substances based on high priority and 5 further substances based on grouping considerations to the draft recommendation for public consultation. SECR indicated that it has not yet assigned specific Latest Application Date (LAD) slots in the draft recommendation. The final allocation will be done, using the agreed approach, after the public consultation taking all relevant information received into account. Currently, SECR sees no reason to deviate from the standard LAD slots (range of 18, 21 or 24 months) for all proposed substances.

In the following discussion the inputs were mainly on BPA, the lead substances and DOTE and Reaction mass of DOTE: MOTE, as well on the number of substances considered. A member indicated the possibility of a proposal for risk reduction measures for BPA later on this year. In response, SECR indicated it will closely monitor any regulatory developments on BPA and act accordingly. As regards inclusion of DOTE and Reaction mass of DOTE:MOTE at this stage, two members raised questions of a potential mixed message that this might give given that a proposal to change the reprotoxicity classification of DOTE has been submitted to ECHA (following Articles 37(6) and 37(1) of the CLP Regulation) and Risk Assessment Committee (RAC) is foreseen to adopt its opinion in December 2018. Depending on the outcome of this (de)classification proposal, the inclusion of DOTE (and DOTE:MOTE reaction mass) in the Candidate List may need to be reconsidered. In contrast, a member and an NGO observer considered that not including these two substances in the draft recommendation now would lead to unnecessary delay and give the wrong message. They preferred a reconsideration only once the RAC process has been concluded. Support for dropping these substances from this draft Annex XIV recommendation came from some industry observers who noted that including those substances in the draft recommendation will inevitably lead to a large number of comments, and they were concerned of the workload of ECHA secretariat and MSC.

For lead substances (seven of them), questions on the grouping were raised, and also the perceived overlap with the restriction. An industry observer highlighted that the use of lead as a stabilizer in PVC has been phased out due to industries' voluntary agreement and the restriction proposal will phase out some uses on stabilisers. SECR noted that registration dossier still document evidence of such uses and it is not possible to disregard the information provided by the registrants under their legal obligations. SECR confirmed that any updates of the registration dossiers by the end of public consultation will be considered when finalising the recommendation. However, SECR noted that these substances have been added to the Candidate List several years ago and registrants have had ample time to ensure that their registrations are up to date, which is in any case a legal obligation. SECR clarified that the volume of restricted uses is not included in the priority scoring as this is rather a non-compliance and enforcement issue, however, manufacturing and use for export outside EU is not covered by the restriction. An industry observer argued that intermediate use (as a precursor to stabilisers) is not relevant for priority scoring and if the intention is to regulate workplace exposures this should be covered by other legislation in place. Finally, an observer noted that for the epoxy hardeners (HHPA and MHHPA) there are only industrial uses and the voluntary commitment of industry has led to minimisation of exposures, referring also to a material flow analysis that will be submitted in the near future. SECR indicated that such new information in the registration dossiers would be highly appreciated.

Responding to one question by a member, SECR clarified that for substances placed on the Candidate List due to its impurities, the volume and use of the actual substance as identified is used for prioritisation. It was also noted that it is normally preferred if the impurity itself is also included in the Candidate List. Referring to the long list of substances now proposed, one member inquired if and how SECR has assessed the potential workload to ECHA, its Committees and COM. SECR responded noting that the normal assessment of the workload has been carried out, the number of substances does not directly indicate the workload, considering industries' views that the registration dossiers are not necessarily up-to-date and ongoing reconsideration of some classification there are uncertainties on a number of substances in this round. SECR stressed that the workload is only one aspect to be considered and there is a need to develop a proportionate recommendation.

SECR thanked MSC for the useful reactions and comments and indicated to continue its careful considerations prior to the start of the public consultation. This is tentatively planned to start on 4 September mainly to avoid running the public consultation over summer.

2) Review of the process for Annex XIV recommendations

SECR introduced the ongoing work in reviewing the process for Annex XIV recommendations. Focus of the review is on the documentation produced during the process and its usefulness, and the interactions between ECHA SECR and MSC during opinion forming process. SECR shared some feedback from COM. Based on the feedback the documents are considered generally fit for purpose. SECR also appreciated the feedback so far from a small group of volunteers consisting of MSC members. As regards the opinion forming step it was noted also in the discussion that it would be good to have some clarification of the basis for the work of the MSC Working Group (WG) to ensure the right focus. This in particular as the WG may have felt its efforts being partly in vain.

SECR stated that besides being a legal requirement, the MSC opinion is a valuable input, an enabler, to the process. It continued that no repetition of the assessment that the secretariat has done would be needed but the opinion could be more focussed on adding considerations from MSC's side, and in particular highlighting where MSC does not agree with the assessment or conclusion of the secretariat. SECR, when referring to the comments from public consultation, also appreciated MSC's views on them in addition to its own assessment of them.

Responding to a question from an observer the SECR indicated that further feedback could still be provided until end of June, and the next Rapporteur and WG, together with the existing small volunteer group, could further be involved in fine-tuning of any proposed changes e.g. in the opinion template.

Item 10 – Opinion of MSC on ECHA's draft 9th recommendation of priority substances to be included in Annex XIV Task of the Rapporteur in drafting the opinion of the MSC

1. Task of the (Co-)Rapporteur in drafting the opinion of MSC

2. Appointment of (Co-)Rapporteur

MSC agreed on the tasks of the rapporteur in drafting the MSC opinion on the 9th draft recommendation of ECHA. The Committee appointed one of its members as rapporteur for this opinion preparation.

3. 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 9th draft recommendation of ECHA. Further, MSC appointed three volunteering MSC members and three MSC alternates as the working group members to support the rapporteur in the opinion development. The working group was established for the duration of the drafting of the MSC opinion until its adoption which is expected during MSC-65 in June 2019.

Item 11 – Opinion of MSC on ECHA's draft update of the Community Rolling Action Plan (CoRAP 2019-2021)

1) 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 2019-2021. The Committee also appointed two of its members as rapporteur and co-rapporteur for this opinion preparation.

2) Discussion on possible establishment of a MSC Working Group to support the Rapporteur

MSC noted the need to set up a working group to support the MSC rapporteurs in drafting the MSC opinion on the draft update of the CoRAP for 2019-2021 and mandated the Rapporteur to consider what would be the most appropriate size of the working group once there is more information about the number of substances on the draft CoRAP update. Some members indicated already their interest to join such a working group. SECR promised to launch a written procedure of MSC to set up a working group after summer.

Item 12 – Any other business

1) How to deal with information submitted to the MSC not contained in the proposals for amendment submitted by MSCAs and Registrants' comments on them

The MSC Chairman summarised the meeting document on how MSC could incorporate information that would become available only at a late stage but might affect MSC discussions. This item was presented and discussed at MSC-59. After that meeting some members had provided further views, which the MSC Chairman shared with MSC. Some MSC members welcomed that their observations had been taken well into account. SECR noted that some rephrasing could make the text clearer. MSC took note of the suggestions on how to deal with late information. MSC asked SECR to prepare a revised document, including recent new terminology and taking into account SECR considerations on process related impacts, for discussion in MSC-61.

2) MSC priorities action plan – Action 5 Rethink Webex aim

SECR referred to the meeting document that was describing the current webex aims, timing, structure for SVHC process, DEv process and SEv process. SECR explained that the current webex approach for SVHC and DEv appear to work fine for their goal. SECR continued by presenting a proposal for modification for the SEv webex. This proposed to have the SEv webex at an earlier date so as to allow the evaluating Member State to chair the webex and solve any open issues arising from the proposals for amendment (PfA) or Registrants comments on PfAs, whilst still updating the DD. The first reactions from the MSC members on this revised approach were positive and they were expressing more advantages to the proposed approach than already listed in the meeting document. As next steps, SECR would launch a webropol questionnaire on the webex for the three processes at the end of June to be completed by mid-August. Its outcome would be presented at MSC-61.

3) Update on HESI GGTC discussions regarding somatic and germ cell sampling time in TGR assay, OECD TG 488 (follow-up action from MSC-57)

SECR gave a presentation on an update on the HESI Genetic Toxicology Technical Group (GTTC) discussions on issues specific to transgenic rodent testing (TGR) and related to sampling time for somatic and germ cell. The OECD test guideline (TG) 488 provides recommendations for assessing germ cell and somatic cell mutagenicity, but it is challenging to select one optimal collection time for both cell types. An assessment (soon to be published) concluded that sampling of mature sperm at 28+3 days does not produce meaningful mutagenicity data. For assessing simultaneously the mutagenicity in both cells a 28+28 days collection protocol seems to be practical and could be included in the TG. Additional work is required to determine if the 28+28 days protocol is appropriate for routine evaluation of mutant frequencies in all somatic tissues as well as for rapidly dividing tissues.

MSC took note of the presentation and on past decisions, where the sampling from initial sites of contact was almost always requested. MSC considered that it would need to follow the new sampling timings, when becoming implemented, on a case-by-case basis. MSC asked SECR to keep it informed on the possible update of OECD TG 488 text.

4) Update on appeals and court cases of relevance to MSC

SECR gave the status of recent appeals on evaluation submitted to the Board of Appeal of ECHA, on BoA's decisions and analysis on the decisions, and on the pending cases submitted to the European Court of Justice relating to the authorisation process. MSC took note of the information received.

5) Possible categories for proposals for amendment (PFA) in dossier evaluation

SECR informed MSC on its tentative work to define PfAs into categories, which would help MSC members to prioritise their assessment on issues important to them. The mostly used category has so far been "general item" or "editorial", which has been straightforward to take on board. In recent years when more items have been incorporated in the MSC Manual of Decisions and Opinions, the "alignment" PfAs have been used to harmonise DD requests and justifications. In future, categorising PfAs into scientific aspects and policy approaches could be envisaged.

A MSC member showed appreciation for this initiative and suggested to consider also indicating PfAs where rationale was improved, both liguistically and scientifically, and changing the level of details in justifications. MSC agreed that categories of PfAs would help the members to focus on most important matters during the relatively short preparation time and encouraged to continue the work. SECR asked MSC members to provide further suggestions by end of August 2018 to SECR, who would prepare a document for MSC discussion at MSC-61.

6) Classification of a substance for which a TPE was agreed on in MSC-57

The MSC member from NO informed that RAC had concluded in its June 2018 meeting an opinion on Norway's CLH proposal on dicumyl peroxide (bis(α,α-dimethylbenzyl)peroxide (EC No. 201-279-3) for Rep 2. RAC concluded that the substance fullfills the classification criteria as Rep 1B. In December 2017 MSC-57 had unanimously agreed a testing proposal on PNDT study on a second species (TPE-034/2017).

MSC noted that RAC's conclusion to suggest classification Rep 1B had not been anticipated last year and queried on possibilities to withdraw the decision on TPE-034/2017. SECR informed that the decision had already been sent and did not foresee its withdrawal. MSC took note that the Registrant may consider that the testing is still needed e.g. for risk assessment purposes. MSC noted that this was an unfortunate borderline event and encouraged SECR to pursue ways to avoid such situations in future. MSC concluded to ask SECR to inform the Registrant on the opinion of the Risk Assessment Committee (RAC).

Item 13 – Adoption of conclusions and action points

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

II. List of attendees

Members/Alternate members
AAVIK, Jaanika (EE)
ANDRIJEWSKI, Michal (PL)
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WIJMENGA, Jan (NL)
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Proxies

- CONWAY, Louise (IE) also acting as proxy of DEIM, Szilvia (HU)
- TYLE, Henrik (DK) also acting as proxy of DUNAUSKIENE, Lina (LT) during short periods

Experts and advisers to MSC members

CIESLA, Jacek (PL) (expert to ANDRIJEWSKI, Michal)
COPOIU, Oana (RO) (expert to MIHALCEA UDREA, Mariana)
DE KNECHT, Joop (NL) (expert to WIJMENGA, Jan)
DOBRAK-VAN BERLO, Agnieszka (BE) (expert to VANDERSTEEN, Kelly)
EINOLA, Juha (FI) (adviser to RISSANEN, Eeva)
HJORTH, Rune (DK) (expert to TYLE, Henrik)
INDANS, Ian (UK) (expert to COCKSHOTT, Amanda)

KOZMIKOVA, Jana (CZ) (expert to KULHANKOVA, Pavlina)
KUROVA, Martina (SK) (expert to HORSKA, Alexandra)
MALKIEWICZ, Katarzyna (SE) (expert to LUNDBERGH, Ivar)
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SPURIENE, Otilija (LT) (expert to DUNAUSKIENE, Lina)
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ALLEN, Lisa (adviser to Eurometaux observer)
PLOTZKE, Kathy (adviser to Cefic observer)

Registered to the WEBEX-phone connection:
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ANDERSEN, Sjur (NO)
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GUDBRANDSEN, Marius (NO)
GUTIERREZ, Miriam (DG GROW)
HAUZENBERGER, Ingrid (AT)
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KOBE, Andrej (DG ENV)
PEARSON, Audrey (UK)
PETERS, Oliver (DE)
SAKSA, Jana (EE)
SCHLIEBNER, Ivo (DE)
STOCKER, Eva (AT)
VAN ELSACKER, Paul (BE)
VERBRUGGEN, Eric (NL)

Apologies:
ALMEIDA, Inês (PT)
DEIM, Szilvia (HU)
FRANZ, Michel (FR)
PALEOMILITOU, Maria (CY)
WAGENER, Alex (LU)

III. Final Agenda

MSC/A/060/2018

Agenda
60th meeting of the Member State Committee

12-14 June 2018
ECHA Conference Centre
Annankatu 18, in Helsinki, Finland

12 June: starts at 1 pm
14 June: ends at 1 pm

Item 1 – Welcome and Apologies

Item 2 – Adoption of the Agenda

MSC/A/060/2018
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-59

- Final minutes of MSC-59

MSC/M/59/2018
For information

Item 6 – Substance evaluation

Closed session for 6.3

Decision making process

1. **Written procedure report on seeking agreement on draft decisions on substance evaluation[1]**

ECHA/MSC-60/2018/009
For information

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

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

   None

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

   A case returned from written procedure for agreement seeking in the meeting[2]:

   SEV-BE-002/2016 Reaction mass of 2,2,3,3,5,5,6,6-octafluoro-4-(1,1,1,2,3,3,3-heptafluoropropan-2-yl)morpholine and 2,2,3,3,5,5,6,6-octafluoro-4-(heptafluoropropyl)morpholine (EC/List No. 473-390-7)

   For agreement

4. **General topics**

   Status report on on-going substance evaluation work

   For information

Item 7 – Dossier evaluation

Tentative timing: Start on Day 2
Closed session for 7.3

1. **Written procedure report on seeking agreement on draft decisions on dossier evaluation[1]**

   ECHA/MSC-60/2018/001
   For information

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

   ECHA/MSC-60/2018/002
   For information

   For discussion followed by agreement seeking under 7.3:

   Compliance checks

MSC code	Substance name	EC No.	Documents
CCH-032/2018	Cinnamaldehyde	203-213-9	ECHA/MSC-60/2018/003-4

   Testing proposal examinations

MSC code	Substance name	EC/List No.
TPE-040/2018	Triethoxy(3-thiocyanatopropyl)silane	252-161-3 ECHA/MSC-60/2018/005-6
TPE-046/2018	3-(triethoxysilyl)propanethiol	238-883-1 ECHA/MSC-60/2018/007-8

   For discussion

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

   Cases as listed above under **7.2**

   For agreement

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

[2] Documents are available in the MSC S-CIRCABC folders under substance evaluation.

Timing: start on Day 1

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

ECHA/MSC-60/2018/018

For information

2. Agreement seeking

Substance	**EC Number**	**Documents**[3]
Octamethylcyclotetrasiloxane (D4)	209-136-7	ECHA/MSC-60/2018/012-013
Decamethylcyclopentasiloxane (D5)	208-764-9	ECHA/MSC-60/2018/014-015
Dodecamethylcyclohexasiloxane (D6)	208-762-8	ECHA/MSC-60/2018/016-017
A case returned from written procedure for agreement seeking in the meeting[4]:		
Lead (metal)	231-100-4	

For agreement

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

Tentative timing: Day 2

1) Substances for the 9th recommendation:

   Discussion on the substances suggested for inclusion in the draft recommendation and the respective draft Annex XIV entries prior to public consultation

   ECHA/MSC-60/2018/021-022

   For discussion

2) Review of the process for Annex XIV recommendations

   For information

Item 10 – Opinion of MSC on ECHA's draft 9th recommendation of priority substances to be included in Annex XIV

Invitation for volunteers for the Rapporteurship in drafting the opinion of the MSC on ECHA's 9th draft recommendation for Annex XIV and for Working Group membership

1. Task of the (Co-)Rapporteur in drafting the opinion of MSC

   ECHA/MSC-60/2018/009

   For discussion & decision

2. Appointment of (Co-)Rapporteur

   For discussion & decision

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

   ECHA/MSC-60/2018/010

   For discussion & decision

Item 11 – Opinion of MSC on ECHA's draft update of the Community Rolling Action Plan (CoRAP 2019-2021)

[3] Updated RCOMs (confidential or public version) for cases going to MSC-60 are provided for information in the MSC S-CIRCABC, 01 Meetings/MSC-60/Meeting documents folder

[4] Agreement seeking documentation and RCOMs (confidential or public version) for cases in written procedure are available in the MSC S-CIRCABC, 03 SVHC folder, in corresponding 03 Substance-specific folders

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

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

ECHA/MSC-60/2018/023
For discussion & decision

2) Discussion on possible establishment of a MSC Working Group to support the Rapporteur

For discussion

Item 12 – Any other business

1) How to deal with information submitted to the MSC not contained in the proposals for amendment submitted by MSCAs and Registrants' comments on them

ECHA/MSC-60/2018/020
(Closed session)
For discussion and agreement

2) MSC priorities action plan – Action 5 Rethink Webex aim

ECHA/MSC-60/2018/019

(C*losed session)*
For discussion

3) Update on HESI GGTC discussions regarding somatic and germ cell sampling time in TGR assay, OECD 488 (Follow-up action from MSC-57
4) Update on appeals and court cases of relevance to MSC
5) Possible categories for proposals for amendment (PFA) in dossier evaluation
6) Suggestions from members

For information

Item 13 – Adoption of main conclusions and action points

- Table with conclusions and action points from MSC-60

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

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

APPENDIX to the MSC-60 agenda:

I. List of evaluation cases agreed by MSC in written procedure in advance of the MSC-60 meeting:

Substance evaluation

SEV-IT-016/2016	Ethylene dinitrate (EC No. 211-063-0)

Dossier evaluation

Compliance checks

CCH-019/2018	1-phenylethyl acetate (EC No. 202-288-5)
CCH-021/2018	Dimethoxydimethylsilane (EC No. 214-189-4)
CCH-024/2018	Dibenzyltoluene (EC No. 258-649-2)
CCH-026/2018	Butanoic acid, 4-amino-4-oxo-2(or 3)-sulfo-,N-(C16-C18 (even numbered), C18 to be determined saturated alkyl)), disodium salts (List No. 939-691-7)
CCH-030/2018	(E)-anethole (EC No. 224-052-0)

Testing proposal examinations

TPE-010/2018	1-methylimidazole (EC No. 210-484-7)
TPE-035/2018	Triethoxyoctylsilane (EC No. 220-941-2)
TPE-038/2018	Dimethoxydimethylsilane (EC No. 214-189-4)
TPE-039/2018	[3-(2,3-epoxypropoxy)propyl]trimethoxysilane (EC No. 219-784-2)

II. List of substances agreed as SVHCs by MSC in written procedure in advance of the MSC-60 meeting:

Ethylenediamine	EC No. 203-468-6
Terphenyl hydrogenated	EC No. 262-967-7
Disodium octaborate	EC No. 234-541-0
Benzo[ghi]perylene	EC No. 205-883-8

IV. Main Conclusions and Action Points

Main conclusions and action points
MSC-60, 12-14 June 2018
(adopted at MSC-60)

CONCLUSIONS / DECISIONS / MINORITY OPINIONS	ACTIONS REQUESTED
Item 6 – Substance evaluation **1. Written procedure report on seeking agreement on draft decisions on substance evaluation**	
MSC took note of the report.	**MSC** to consider the decisions uploaded on MSC S-CIRCABC for the written procedure as agreed ones. Final ECHA decisions will become available at ECHA website in due course.
3. Seeking agreement on draft decisions when amendments were proposed by MS-CA's/ECHA	
MSC reached unanimous agreement on the following ECHA draft decision (as modified in the meeting): A case returned from written procedure for agreement seeking in the meeting: SEV-BE-002/2016, Reaction mass of 2,2,3,3,5,5,6,6-octafluoro-4-(1,1,1,2,3,3,3-heptafluoropropan-2-yl)morpholine and 2,2,3,3,5,5,6,6-octafluoro-4-(heptafluoropropyl) morpholine (EC/List No. 473-390-7)	**MSC-S** to upload on MSC S-CIRCABC the agreed decision in the respective case folder. Final ECHA decision will become available at ECHA website in due course.
Item 7 – Dossier evaluation **1. Written procedure report on seeking agreement on draft decisions on dossier evaluation**	
MSC took note of the report.	**MSC** to consider the decisions uploaded on MSC S-CIRCABC for the written procedure as agreed ones. Final ECHA decisions will become available at ECHA website in due course.
3. Seeking agreement on draft decisions on compliance checks and 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): **<u>Compliance checks (CCH)</u>** CCH-032/2018 Cinnamaldehyde (EC No. 203-213-9) **<u>Testing proposal examinations (TPE)</u>** TPE-040/2018 Triethoxy(3-thiocyanatopropyl)silane	**MSC-S** to upload on MSC S-CIRCABC the agreed decisions in the respective case folders. Final ECHA decisions will become available at ECHA website in due course.

CONCLUSIONS / DECISIONS / MINORITY OPINIONS	ACTIONS REQUESTED
(EC No. 252-161-3) TPE-046/2018 3-(triethoxysilyl)propanethiol (EC No. 238-883-1)	
Item 8 – SVHC identification - Seeking agreement on Annex XV proposals for identification of SVHC **1. Written procedure report on seeking agreement on identification of SVHCs**	
MSC took note of the report and on the proposal of the MSC-S for a review of the procedural information exchange aspects, as outlined in the MSC SVHC working procedures.	**MSC-S** to upload on MSC S-CIRCABC the final MSC documents on the substances identified as SVHCs in written procedure and to publish them on the ECHA website. **SECR** to add the newly identified SVHCs to the Candidate List (update foreseen in the end of June/ beginning of July 2018). **MSC** to re-consider the established MSC SVHC procedures and established information exchange practices and submit suggestions for potential modifications, if needed, by 15 August 2018.
2. Agreement seeking	
MSC unanimously agreed to identify the following substances as SVHCs (and unanimously agreed on their respective DA and SD): Octamethylcyclotetrasiloxane (D4) (EC No. 209-136-7) Decamethylcyclopentasiloxane (D5) (EC No. 208-764-9) Dodecamethylcyclohexasiloxane (D6) (EC No. 208-762-8) Lead (metal) (EC No. 231-100-4)	**MSC-S** to upload the MSC agreements, as well as the support documents and RCOMs, on MSC S-CIRCABC and to publish them on the ECHA website. **SECR** to add the newly identified SVHCs to the Candidate List (update foreseen in the end of June/ beginning of July 2018). The abstaining **MSC member** who made a statement and requested for its attachment to the minutes to provide this statement in writing to **MSC-S** by 18 June 2018.
Item 9 – ECHA's recommendations of priority substances to be included in Annex XIV	
3) Substances for the 9th recommendation: Discussion on the substances suggested for inclusion in the draft recommendation and the respective draft Annex XIV entries prior to public consultation 4) Review of the process for Annex XIV recommendations	
MSC took note of the list of substances planned to be included in the 9th draft recommendation of substances for possible inclusion in Annex XIV for a 3 months public consultation. MSC took note of the ongoing review.	**MSC** to provide any feedback by end June 2018.
Item 10 – Opinion of MSC on ECHA's draft 9th recommendation of priority substances to be included in Annex XIV	
Invitation for volunteers for the Rapporteurship in drafting the opinion of the MSC on ECHA's 9th draft recommendation for Annex XIV and for Working Group membership 4. Task of the (Co-)Rapporteur in drafting the opinion of MSC 5. Appointment of (Co-)Rapporteur 6. Establishment of a MSC Working Group to support the Rapporteur	

CONCLUSIONS / DECISIONS / MINORITY OPINIONS	ACTIONS REQUESTED
MSC adopted the mandate and the tasks of the rapporteur, and appointed one member as a Rapporteur for drafting the MSC opinion on ECHA's 9th draft recommendation for Annex XIV. MSC established a working group to support the Rapporteur and appointed volunteering members to it.	**MSC-S** to send the appointment letter to the Rapporteur after the meeting. **Rapporteur** to assess whether there is a need for appointment of a Co-Rapporteur.
Item 11 – Opinion of MSC on ECHA's draft update of the Community Rolling Action Plan (CoRAP 2019-2021)	
Invitation for volunteers for the Rapporteurship in drafting the opinion of the MSC on the CoRAP update and for Working Group membership 3) Draft terms of Reference and possible appointment of the Rapporteur and Co-Rapporteur 4) Discussion on 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 opinion of the MSC on the CoRAP update. MSC mandated the Rapporteur to decide on the size of the working group.	**MSC-S** to send the appointment letters to the Rapporteur and the Co-Rapporteur after the meeting. **Rapporteur** to assess the size of the working group once further information on the draft CoRAP 2019-2021 is available. **MSC-S** to launch a written procedure for the appointment of the WG in September 2018.
Item 12 – Any other business	
1) Information submitted to the MSC not contained in the proposals for amendment and Registrants' comments on them: MSC took note of the suggestions on how to deal with late information. 2) MSC priorities action plan – Action 5: Rethink Webex aim: MSC took note of the presentation. 3) Update on HESI GGTC discussions regarding somatic and germ cell sampling time in TGR assay, OECD 488: MSC took note of the presentation. 4) MSC priorities action plan – Action 3: PfA types: MSC took note of the MSC-S suggestions on categorising PfAs and supported further work to help members prioritise their assessment. 5) Suggestions from members: Classification of a substance for which a TPE was agreed on in MSC-57.	1) **MSC-S** to include recent new terminology, together with SECR, in a revised document for discussion in MSC-61 in October 2018. 2) **MSC-S** to launch a webpropol questionnaire on the webex for the three processes via MSC S-CIRCABC to MSC members and Evaluation S-CIRCABC to eMSCA experts (online from end of June until mid-August 2018). **MSC-S** to present outcome of questionnaire at MSC-61. 3) **MSC-S** to keep MSC informed on the possible update of OECD TG 488 text. 4) **MSC members** to provide further suggestions by end of August 2018 to **MSC-S**, who prepares a document for MSC discussion at MSC-61. 5) **SECR** to inform the Registrant on the decision taken by the Risk Assessment Committee (RAC).
Item 13 – Adoption of main conclusions and action points	
MSC adopted the main conclusions and action points of MSC-60 at the meeting.	**MSC-S** to upload the main conclusions and action points on MSC S-CIRCABC by 15 June 2018.

V. Statements with regard to agenda item 8.2

UK member's statement with regard to the SVHC identification of D4, D5 and D6

The UK member has abstained from the vote because whilst we agree that the substances meet the Annex XIII & consequently Article 57 criteria, the timing of nominations are inconsistent with the UK position paper outlining a strategy for assessing the wider group of siloxane substances, as previously submitted to RiME (April 2016).

If D4, D5 and D6 are added to the Candidate List, many other siloxane substances may become candidates for SVHC identification because they contain one or more of these substances as impurities due to the nature of the manufacturing process. This could create mixed messages to an industry already subject to ongoing Substance Evaluation activities. In addition, manufacturers might react by seeking higher distillation efficiencies to reduce already small impurity levels further (with increased cost and energy consumption) or possibly by producing an increased amount of waste that will need to be disposed of. These issues were not addressed in the risk management options analyses.