MSC/M/36/2014
ADOPTED by written procedure
on 1 September 2014

Minutes

of the 36th Meeting of the Member State Committee (MSC-36)

10-13 June 2014

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 36th meeting of the Member State Committee (MSC) (for the full list of attendees and further details see Part II of the minutes).

Item 2 - Adoption of the Agenda

The Agenda was adopted as provided for the meeting by the MSC Secretariat without further changes (final Agenda is attached to these minutes).

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

One member declared a potential conflict of interest in respect to the dossier evaluation case CCH 050/2014 (based on the annual declaration as published on the ECHA website) and was therefore considered not to be in a position to participate in the vote for this case. No conflicts of interests were declared by other members, experts or advisers with any other items on the agenda of MSC-36.

Item 4 - Administrative issues

SECR thanked for the feedback that was received on the streamlining suggestions as regards notes and documents that are provided to MSC for information in the context of evaluation processes (follow-up from MSC-35). Based on the suggestions a revision of evaluation related working procedures will be prepared by the SECR for discussion in September.

SECR also provided a brief summary of the results from the testing of an IT platform tool that took place with MSC members during March-April. The MSC support for the testing was much appreciated and used among others as input for the ECHA Secretariat decision not to use this tool for Committee purposes.

Item 5 – Adoption of the minutes of the MSC-35 meeting

SECR presented the revised version of the MSC-35 minutes informing MSC that written comments on the draft minutes were received in advance of the meeting. The minutes were adopted with some changes made in the meeting. SECR would upload the minutes on MSC CIRCABC and ECHA website.

Item 6 – Substance evaluation

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

SECR gave a report on the outcome of the written procedure (WP) for agreement seeking on one substance evaluation case (Methanol EC No 200-659-6). Following the evaluating MSCA's (eMSCA) conclusion, after consideration of the proposals for amendment and the Registrants' comments thereon, MSC was requested to agree that no information needs to be requested from the Registrants. Agreement of MSC was sought via WP on a draft agreement document. WP was launched on 15 May 2014 and closed on 26 May 2014. By the closing date, responses to WP were received from 22 members with voting rights and from the Norwegian member. Unanimous agreement was reached on the agreement document on 26 May 2014.

b. Introduction to and preliminary discussion on one draft decision on substance evaluation after MSCA's/ECHA reactions (Session 1, open session)

c. Seeking agreement on draft decisions on testing proposals when amendments were proposed by MSCA's/ECHA (Session 2, closed)

SEV-NL-026/2012 Triclosan (EC No. 222-182-2)

Session 1 (open)

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

The evaluating Member State Competent Authority (eMSCA) expert from the Dutch CA (NL CA) in cooperation with the Danish CA (DK CA) presented the outcome of substance evaluation (SEV) of the above-mentioned substance performed on the basis of the initial grounds for concern: human health/ suspected endocrine disruptor; environment/ suspected PBT/vPvB (Persistent, Bioaccumulative, Toxic/very Persistent, very Bioaccumulative); exposure/ high aggregated tonnage. Additional concern identified during the evaluation process was cardiotoxicity.

During the presentation of the case eMSCA explained that DD was modified for the meeting based on proposals for amendment (PfAs) received. eMSCA accepted and incorporated in the DD most of the PfAs received with as notable exception the PfA related to mollusc toxicity testing and requests for generating information on the degradation product methyl triclosan. The former was not included because the test was not anymore regarded necessary at this stage for further continue the PBT/vPvB assessment or ED conclusion, however, during the follow-up stage this may be revisited if necessary for quantitative risk assessment purposes and/ or for the continuation of the PBT/vPvB assessment if this turns out to be needed in accordance with the revised the PBT assessment strategy, which focuses on the PBT/vPvB assessment of triclosan itself first. This also impacted the potential challenge that the deadline would set for the registrant. As there was a general agreement on these aspects the discussion focused on whether and how to take account of the other PfAs in the DD.

Description of the PfAs discussed

Regarding simulation testing of triclosan on ultimate degradation in fresh water (lake, river) and sea water performed as pelagic test at an environmentally realistic ambient temperature of 10°C, one PfA proposed to perform the test at 12°C instead of 10°C since it is the default temperature in EUSES for both freshwater and seawater, or else provide scientific rational for requesting the test at 10°C. Another PfA proposed to perform the simulation test in marine water since it is expected to result in the longest degradation half-life, or else to first run the test in marine water and if considered necessary to run it in freshwater. A PfA further proposed to request identification and a PBT assessment for any transformation product found to be formed in a relevant environmental compartment at any time at a concentration of ≥0.1% w/w.

Regarding the developmental neurotoxicity study for which none of the PfAs challenged the need, the PfAs received focused mainly on the aspects related to the study design. Furthermore, a PfA proposed to add a sentence requesting careful evaluation of male fertility based on a recent published study.

Regarding the fish sexual developmental test (FSDT) with zebrafish or Japanese medaka, one PfA proposed to clarify that in case the FSDT results do not confirm endocrine disruption in aquatic animals, the eMSCA will evaluate in the follow-up stage the need for further testing in aquatic animals, and to clarify that if the enhanced developmental neurotoxicity study shows clear thyroid disruption effects in rats that further testing on amphibians might not be needed. Another PfA proposed to delete the exact test concentrations, and to use Japanese medaka due to its advantage in relation to additional response parameters (e.g. sexual characteristics).

Other PfAs were received, one of which proposed to request all available data and performed evaluations on the effects on the cardiovascular system and another proposed to request for exposure calculations and updated exposure scenarios for the consumer end use.

Registrant's comments on PfAs of CAs and discussion

The registrant provided written comments on the PfAs submitted and highlighted some of those comments in the discussion.

They agreed to include all the available information on cardiotoxicity effects of triclosan in an update of the dossier. Regarding the Enhanced Developmental Neurotoxicity (DNT) study the registrants questioned the need to perform the study but MSC did not consider

this a comment as a response to a PfA. The Registrant in his clarification of relevant comments on PfAs indicated to understand why direct pup dosing was requested, but challenged that the requested enhancement of the test would add further information beyond that already available.

Regarding the PfAs related to environmental information requirements, the registrant agreed with the PfA asking for more information on the values used to assess the environmental exposure of Triclosan, and with the PfAs not to set the exposure concentrations for the FSDT and keep the choice of the fish species. Regarding the simulation tests at 12°C, the registrant explained that their rooms are set to work under standard condition of 20 – 25°C. Reducing the temperature to 12°C will require additional engineering solutions, and these will likely cause a break down in the system even if a solution with a water bath is used. Furthermore, the Registrant highlighted several EU guidance documents where temperature correction is considered an accepted method when the testing temperature is 20-25 °C.

Regarding the request to determine the degradation products at 0.1%, the registrant clarified that even if radiolabelled material is used, such level of detection cannot be guaranteed for each transformation product apart for the main degradation product i.e. methyl triclosan. Other detection methods might be needed, like Gas-Chromatography coupled with Mass Spectrometry (GCMS) where the detection limit is dependent on the structure and it can go down to several ng/L. Clarifying questions from MSC members were addressed by the Registrant's representatives. The Chairman thanked them for their interventions, and explained that relevant comments would be further considered during the closed session deliberations of MSC.

Session 2 (closed)

MSC generally supported the request for a developmental neurotoxicity study (OECD TG 426), whereas the enhancement with direct dosing of the offspring pre-weaning due to lack of transfer of the substance via mother's milk was discussed, since for rats certain central nervous system (CNS) development occurs post-natal where the comparable human CNS development occurs in the 3rd trimester in utero. MSC agreed to request direct dosing of the offspring and indicated a dosing procedure and dosing solution in accordance with the provision for post-natal dosing from TG 443 (Extended One-Generation Toxicity Study - EOGRTS) and good animal welfare practice.

Regarding simulation testing temperature, MSC considered that temperature correction approaches were applied to soil simulation testing but not validated for aquatic simulation testing, and reconfirmed that environmentally relevant temperatures should be used for such simulation testing and that 12°C was appropriate for freshwater, and focused the discussion mainly on the issue whether a lower temperature was more appropriate for the marine environment. One MS expressed some sympathy with IND regarding practical issues with running the test at 12°C degrees. They also commented about other concerns for conducting the simulation studies at lower temperatures, such as consistency with some earlier decisions and the behaviour of substances known to rapidly degrade. It was also noted that cooling of the sample to 4°C is recommended by the TG (if transport duration exceeds 2 to 3 hours). A noticeable fluctuation of the temperatures was recommended to be avoided. To allow for potential parallel testing in marine and freshwater in this case a maximum temperature for testing at 12°C was agreed.

MSC supported that the needs for later requests for information generation on the degradation product methyl triclosan (suspected vPvB) will be re-evaluated in light of the results from the required information for triclosan.

Based on the above considerations, MSC unanimously agreed to remove the requests for information generation on the degradation product methyl triclosan; to request the simulation testing of triclosan on ultimate degradation in fresh surface water and sea water at an environmentally relevant temperature of at most 12°C; to keep the request for Enhanced Developmental Neurotoxicity Study, with direct dosing of pups post-natally until weaning and to specify the test volume in accordance with OECD TG 443 and animal welfare provisions; to keep the choice of fish species between Medaka and Zebrafish for the fish sexual developmental test, and allow for adaptation of the stipulated exposure

concentrations based on further scientific evidence if available and justifiable; to request for all available information on cardiotoxicity of triclosan and on environmental emission scenario 'Wide dispersive indoor use of reactive substances in open systems'; to modify statement of reasons of the DD on the details and rationale for requesting the information respectively and to set the deadline for submitting the information at 24 months.

MSC unanimously agreed on this SEV DD as modified at the meeting.

d. CoRAP and substance evaluation

1) Scenarios to finalise the substance evaluation decision making process after MSCA consultation

SECR analysed the Polish SEV case and explained the agreement seeking procedure used for this case. SECR also presented different scenarios encountered in DEV cases leading to withdrawal/ termination of the case and assessed whether these analogue scenarios could be possible under SEV.

During the discussion a sub-scenario of cease of manufacture was also presented as being possible i.e. when all the uses except intermediate uses are dropped by the Registrant. Further analysis of this scenario is required to define which conditions apply in order to allow termination of the SEV process.

2) Extended one-generation reproductive toxicity study (EOGRTS) in Substance evaluation

MSC appreciated SECR presentation on ECHA's approach and thoughts on how to deal with EOGRTS during the consistency screening of substance evaluation DDs. A member commented that there are different views of how to tackle the different cohorts under REACH, and that whilst US and Canada use internal triggering for extending the Cohort 1B (OECD GD 117), EU (under REACH) uses external triggering. The Chair invited members to contribute further to this discussion during one of the next meetings as appropriate.

3) Short general update by the secretariat

MSC appreciated the report presented by SECR on the update and on the outcome of the SEV workshop. In the discussion, a stakeholder observer highlighted that it is good for industry if new substances are introduced in the 3rd year of CoRAP and not earlier. He will recommend to the members of his industry association that they inform the eMSCA when all the information requested in the final decision has been submitted in a dossier update.

MSC was also reminded to inform their MSCAs that the eMSCA needs to keep ECHA up to date on their substance specific SEV planning and try to keep the booking table for SEV found on the Evaluation CIRCA BC as up to date as possible while also keeping the substance manager from ECHA well informed. It was emphasised that this table is considered a living document that can be changed once the planning of the eMSCA changes.

4) Update on appeal cases (Closed session)

SECR provided MSC with feedback from the appeal cases on substance and dossier evaluation decisions and substances of very high concern. SECR explained following a question from one of the MSC members that decisions appealed before ECHA's Board of Appeal are suspended for all addressees of that decision even if such addressee has not appealed the decision himself. Information on appeals and decisions by the Board of Appeal are made public on the ECHA website, with confidential information taken out.

Item 7 – Dossier evaluation

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

SECR gave a report on the outcome of the written procedure (WP) for agreement seeking on 46 dossier evaluation cases as decisions resulting from 24 testing proposal examinations and 22 compliance checks (see Section V for more detailed identification of the cases). WP was launched on 15 May 2014 with a closing date of 26 May 2014.

For 22 testing proposal examinations and four compliance checks the draft decisions (DD) were split, thus resulting in two DDs for each case (52 DDs for the 26 split cases) and overall 72 draft decisions resulting from the total of 46 cases.

By the closing date, responses to WP were received from 25 members with voting rights and from the Norwegian member. Unanimous agreement was reached on 46 DD. For the other 26 DDs MSC did not find unanimous agreement due to divergent opinions on the appropriate test method to fulfil the two-generation reproductive toxicity endpoint and these cases will be referred to the Commission to be dealt with in accordance with the procedure referred to in Article 133(3) of REACH Regulation.

b. Introduction to and preliminary discussion on draft decisions on compliance checks after MSCA reactions *(Session 1, open session)*

c. Seeking agreement on draft decisions on compliance checks when amendments were proposed by MSCA's *(Session 2, closed)*

CCH-044/2014 Dichloromethylbenzene (EC No. 249-854-8)

Session 1 (open)

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

SECR explained that seven proposals for amendments (PfAs) were submitted in total to ECHA's DD.

Two PfAs suggested the OECD TG 443 to be requested without F2 and with the developmental neurotoxicity (DNT) and developmental immunotoxicity (DIT) cohorts. One PfA proposed OECD TG 443 excluding the extension of cohort 1B (production of F2 generation). Another PfA suggested keeping the two choices for OECD TG 416 and OECD TG 443, as proposed by ECHA, but excluding from the extended one-generation reproductive toxicity study (EOGRTS) the extension of cohort 1B.

In addition, one PfA suggested rat, one PfA suggested that mice could be used when conducting the EOGRTS but with modifications to section II of the decision, although normally rat is the preferred species, another PfA mentioned a choice for either rats or mice, and one further PfA suggested the study must be conducted using the rat in absence of validation analysis for the EOGRTS for mice, and alpha-2u-nephropathy in male rat to be an insufficient justification in itself for changing the preferred species.

A PfA on the subchronic toxicity study (90-day), oral route, suggested that the study be conducted using rat rather than mice, and that additional investigations on renal pathology in rat are conducted to investigate which of the two potential modes of action gave rise to the hyaline droplet formation observed in male rate in the 28-day study.

With respect to terrestrial toxicity, a PfA suggested not to reject the waiver from the Registrant and remove the terrestrial data requirements and underlying reasoning from the DD. Should this PfA not be followed, the Registrant should be requested to better present their case to avoid further terrestrial testing by refining the exposure and risk assessment in a tiered sequential way.

A PfA suggested to require information on (a) simulation testing on ultimate degradation in surface water, and (b) sediment simulation testing, as the waiving according to Annex IX, 9.2.1.2 by the Registrant was not considered justified. It was also noted that release of the substance and subsequent environmental effects cannot be ruled out, but the derivation of factors and extent of risk management measures (RMM) use appear unclear.

ECHA Secretariat has amended DD based on PfAs and split the DD into two parts prior to the meeting: CCH-044A/2014 and CCH-044B/2014. Part A addresses the information requirement for Annex X, 8.7.3 (two-generation reproductive toxicity study) and part B other information requirements.

Registrant's comments on PfAs of CAs and discussion

The Registrant provided written comments on the PfAs.

At the meeting the Representatives of the Registrant clarified their written comments and explained that the use of the substance could be updated, as after interviewing customers all professional use was found to be well-controlled industrial use. With respect to the choice of species, they emphasized the difficulties to find a no effects level as very low doses caused effects, and preferred to keep the selection of species open. Regarding the biodegradation simulation testing they reiterated that the main pathway of entry into the environment was air and very little would enter soil or water, in particular as new information indicated that no wide dispersive use existed any more. Therefore, they considered the biodegradation simulation testing unjustified.

Session 2 (closed)

During the discussion MSC agreed that there is no definitive information available to attribute the observed hyaline droplet formation in the kidneys of male rats to the alpha-2 microglobulin mode of action, which is known not to be relevant for man. Hence, MSC agreed unanimously to amend the DD part B to conduct the sub-chronic toxicity study (90-day) with rats, modified to include urinalysis and a full histopathological examination, which is to include immunohistochemical investigation of renal pathology to determine, if the pathology is mediated by alpha-2-microglobulin.

The PfA on removing the terrestrial toxicity requests was withdrawn following ECHA's secretariats response to the PfA indicating that exposure of soil is not unlikely, and that the low persistence of the substance in soil is not proven. Furthermore, MSC unanimously agreed to request for simulation testing on ultimate degradation in surface water, to be conducted at a temperature of 12°C; and to request for justification of environmental release factors used in the exposure estimation for relevant exposure scenarios, or to use default release factors of environmental release categories (ERC) for his exposure estimation.

MSC agreed unanimously on ECHA's split of the DD addressing the above studies in part Bwith a change of the deadline for submission of the data due to the splitting of the DD. Furthermore, some modifications were made in the DD (Part B) based on the Registrant's comments on the PfAs.

MSC did not reach unanimous agreement on the DD addressing the two-generation reproductive toxicity study (part A). However, MSC agreed to modify relevant parts of this DD regarding the selection of species (rats) and the deadline due to the splitting of the DD. The Chair invited the disagreeing MSC members to provide written justifications for their disagreement if the justification were different to those provided for previous similar cases (otherwise SECR would use the justification provided in previous similar cases). ECHA will refer the DDs to COM which will prepare a decision in accordance with the procedure of Article 133(3) of REACH.

CCH-045/2014 Prop-2-yn-1-ol (EC No. 203-471-2)

Session 1 (open)

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

Ten PfAs were submitted in total to ECHA's DD.

Two PfAs suggested the OECD TG 443 to be requested without F2 and with DNT/DIT cohorts. One PfA proposed OECD TG 443 excluding the extension of cohort 1B (production of F2 generation). Another PfA suggested keeping the two choices for OECD TG 416 and OECD TG 443, as proposed by ECHA, but excluding from the EOGRTS the extension of cohort 1B.

One PfA did not agree with ECHA that the proposed adaptation of the information requirement by the Registrant through read-across is not acceptable for the pre-natal developmental toxicity study (PNDT; OECD 414). This PfA considers the read-across plausible and indicated that it should be conditionally accepted pending the outcome of the fertility study and thus the request for the PNDT study should be removed.

One PfA suggested to request further justification for the exposure estimation for the manufacturing site, and to address the uncertainty about the basis of environmental

release factors used. Another PfA suggested to request information on (a) the environmental exposure assessment and risk characterisation on regional scale (b) concentrations in groundwater for derivation of daily intake of man via the environment, and (c) concentrations (PEC values) in air. Alternatively, a proper justification about the lack of information should be provided.

One PfA requested to perform long-term toxicity testing on invertebrates as the acute toxicity test on *Daphnia* is suggestive that there may be a higher chronic toxicity.

Regarding personal protective equipment (PPE), a PfA suggested to provide documentation for the recommended material type, its thickness and the typical or minimum breakthrough time for the glove type recommended, with regard to the amount and duration of dermal exposure in the chemical safety report (CSR). Also, another PfA suggested to provide information on the type of material and its thickness, and the typical or minimum breakthrough times of the glove material.

SECR had modified the DD based on PfAs and split the DD into two parts: CCH-045A/2014 and CCH-045B/2014. Part A addresses the information requirement for Annex X, 8.7.3 (two-generation reproductive toxicity study) and part B other information requirements.

Registrant's comments on PfAs of CAs and discussion

The Registrant provided comments on PfAs and supported the PfA to remove the request for an additional PNDT.

Regarding the two-generation reproductive toxicity test, the Registrant continued to disagree with the request for a further fertility study although no PfAs to remove this information requirement from the DD were submitted, however, if requested the Registrant would support the PfAs to perform an OECD 443 without the production of the F2 generation, but disagreed with the PfAs to include the DNT/DIT cohorts which, in his opinion, should be investigated only if triggered by findings.

Regarding the two-generation reproductive toxicity test, the Registrant supported the PfAs to perform an OECD 443 without the production of the F2 generation, but disagreed with the PfAs to include the DNT/DIT cohorts which, in his opinion, should be investigated only if triggered by findings.

With respect to the PfA on use of non-default environmental release factors for relevant exposure scenarios, the Registrant disagreed since he could not justify the use of non-default ERC (Environmental Release Category) release factors with RMMs or operating conditions (OCs) and/or site specific measurements as for these uses no specific data were available. Such non-default ERCs were assumed to be realistic, required to ensure safe use, and communicated via eMSDSs to allow scaling by downstream users.

The Registrant disagreed with the PfAs on the need to provide detailed specifications of the PPEs in CSR and indicated that this information was contained in IUCLID chapter 11 and in the safety data sheets (SDS).

At the meeting the Representatives of the Registrant explained that they had updated the dossier to further justify their proposed read across for the first species, PNDT information requirement.

SECR explained that ECHA had rejected the original proposals for the read across and updates after the start of MSCA consultation could not be taken into account in the ongoing decision making.

Session 2 (closed)

MSC agreed unanimously to amend the DD part B to request for submission in the CSR the predicted concentrations in groundwater, or to provide justification why information on the concentration(s) of the substance in the groundwater is not relevant to be provided in the CSR. MSC concluded that the DD part B did not need to be modified on glove specification and efficiency, as the Registrant had already provided sufficient documentation in IUCLID section 11 of the technical dossier.

It was considered that when submitting a testing proposal a plausible read across approaches may be substantiated with future testing results, however, this would not apply to compliance checks where there has to be sufficient justification and

documentation in the registration dossier when adapting an information requirement. Also considering that for this substance a data gap may exist for the second species PNDT test,

MSC agreed unanimously on the DD (part B) addressing the first species, PNDT information requirement by requesting a test with the registered substance (part B) as modified during the meeting, with a change of the deadline for submission of the data due to the splitting of the DD. Furthermore, some modifications were made in the DD based on the Registrant's comments on the PfAs.

MSC did not reach unanimous agreement on the DD addressing a two-generation reproductive toxicity study (part A). However, MSC agreed unanimously to amend relevant parts of this DD regarding the selection of species (rats) and the deadline due to the splitting of the DD. The Chair invited the disagreeing MSC members to provide written justifications for their disagreement if the justification were different to those provided for previous similar cases (otherwise SECR would use the justification provided in previous similar cases). ECHA will refer the DDs to COM which will prepare a decision in accordance with the procedure of Article 133(3) of REACH.

CCH-048/2014 Ethylenediamine (EC No. 203-468-6)

Session 1 (open)

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

SECR presented two PfAs to ECHA's DD suggesting more detailed information on PPE and on glove material thickness and efficiency to be provided in CSR. Although the glove material is identified in the registration dossier, no specific information is provided on the breakthrough times and the thickness of the glove material.

SECR modified DD for the meeting based on PfAs received.

Registrant's comments on PfAs of CAs

The Registrant provided written comments on the PfAs, and on the DD, the latter not considered for MSC discussion. Motivated by the PfAs, the Registrant agreed to revise and update Part A of the CSR and to provide more specific information on type of PPE to be used.

Session 2 (closed)

In line with the more general discussion on the PPE and glove efficiency for comparable CCH cases discussed at the meeting, MSC concluded that the DD should be modified with a request for further clarification on glove specification and on glove efficiency in both the CSR and IUCLID file.

MSC unanimously agreed on the ECHA's DD as modified at the meeting.

CCH-049A&B/2014 Ethylenediamine, ethoxylated and propoxylated (EC No. 500-047-1)

Session 1 (open)

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

SECR explained that five PfAs to ECHA's DD were submitted. Two PfAs suggested requesting the Registrant to specify the recommended PPE in the relevant documentation (e.g. CSR, SDS), i.e. more detailed information to be provided on gloves (breakthrough time, glove material thickness and efficiency) to be worn when handling the substance or mixture.

Two PfAs received suggested requesting an EOGRTS for Annex X, 8.7.3 only instead of ECHA's proposal to give two options for the Registrant either to perform the two-generation reproductive toxicity test (EU B.35) or EOGRTS (OECD 443) with the second generation. One PfA suggested keeping the two options but excluding from the optional request for EOGRTS the extension of cohort 1B (production of F2 generation).

Registrant's comments on PfAs of CAs and discussion

The Registrant provided written comments on the PfAs and on the DD, the latter not considered for MSC discussion. The Registrant agreed to provide more detailed specification of personal protective equipment (including re-evaluation of the glove efficiency and the model used) and to update the exposure control efficiency information with the next update of the CSR and supported for Annex X the proposed EOGRTS as the preferred test method; however, he disagreed with the inclusion of DNT/DIT cohorts in the study design due to lack of indications of developmental, neurotoxicity or immunotoxicity effects in previous toxicity studies, and disagreed with the production and assessment of a second generation.

The representative of the Registrant explained at the meeting that the latest IUCLID dossier update provided updated information of the manufactured volumes of all concerned registrants. They are well below 1000 t/y since 2011 which does not correspond to the initial dossier registration tonnage band (Annex X) in 2010 and the Registrant asked MSC to re-consider the case in accordance with the criteria for Annex IX.

The MSC Chairman further informed MSC of the REACH-IT notification received by the lead Registrant on his unsuccessful attempt to update the tonnage band of the dossier due to technical problems. It was underlined that if the Registrant considers making a dossier update for a lower tonnage band, a proper justification would be necessary with a clear indication that the total production of the substance has been consistently below the tonnage band of the initial registration dossier.

SECR informed MSC and the Registrant's representative of the splitting of the DD into part A and B where part A addressed the information requirement for Annex X, 8.7.3 (two-generation reproductive toxicity) and part B addressed the other information requirement. Due to splitting of the requirements, the deadlines to be given to the Registrant to submit the required test results had also been modified prior to the meeting.

Session 2 (closed)

In line with the more general discussion on the PPE and glove efficiency for comparable CCH cases discussed at the meeting, MSC concluded that the DD should be modified with a request for further clarification on glove specification and on glove efficiency in both the CSR and IUCLID file.

MSC found unanimous agreement on ECHA's DD, part B addressing information requirements other than the ones for Annex X, 8.7.3., as amended at the meeting.

MSC did not reach a unanimous agreement on the DD, part A, and the Chair invited the disagreeing MSC members to provide written justifications for their disagreement if the justification were different to those provided for previous similar cases (otherwise SECR would use the justification provided in previous similar cases). ECHA will refer this DD to COM which will prepare a decision in accordance with the procedure of Article 133(3) of REACH.

MSC acknowledged the Registrant's declaration for the failure to update the dossier tonnage band to the lower tonnage band where this information requirement is triggered by specific effects observed in other studies. However, as in accordance with the established practices, dossier updates received after the DD referral to the MSCAs are disregarded.

CCH-050/2014 2,2,4(or 2,4,4)-trimethylhexane-1,6-diamine (EC No. 247-063-2)

Session 1 (open)

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

Five PfAs to ECHA's DD were submitted.

SECR explained that regarding short-term toxicity testing on aquatic invertebrates, one PfA considered the aquatic toxicity studies in the chemical safety report (CSR) as not reliable and with numerous shortcomings hence suggests to conduct long-term aquatic toxicity studies for all three taxa (algae, daphnia and fish). A second PfA proposed to request long-term toxicity testing on aquatic invertebrates, although the Registrant waived

this test. The substance is classified with Aquatic Chronic 3, therefore the waiving was not considered appropriate in this case.

A third PfA requested for a test for hydrolysis as a function on pH based on structural considerations, which the Registrant also waived.

A fourth PfA proposed to request a new test on water solubility or to ask for further justifications for the pH value chosen for the studies already provided.

A fifth PfA regarding long-term toxicity testing on terrestrial invertebrates, plants and effects on soil micro-organisms, acknowledged that the Registrant had not provided sufficient justification to waive these terrestrial tests. Hence, a sentence was proposed to clarify that soil toxicity testing is required only in the absence of measured adsorption data and/or sewage simulations study. However, the MSCA submitting the PfA disagreed with ECHA's soil testing strategy that the EPM does not address the risk to soil microbial communities. They feel that further information on fate and exposure of the substance to sewage sludge and soil should be considered first and if soil testing is still required based on refined RCR calculations using EPM, then the three tests should be performed sequentially (soil invertebrates-plants-nitrification), checking the need for further testing after each test.

ECHA Secretariat amended the DD based on all PfAs except the ones on water solubility and long-term terrestrial toxicity testing.

Registrant's comments on PfAs of CAs and discussion

The Registrant provided written comments on the PfAs and clarified those during the meeting. During the meeting the Registrant's representatives re-iterated that they think it is not necessary to perform a hydrolysis study as a function of pH, and suggested using a weight of evidence approach and performing a literature search for hydrolysis of aliphatic amines and perform a read across.

Regarding aquatic toxicity, the Registrant mentioned that they had misinterpreted ECHA's communication inviting the Registrant to provide comments on the PfAs received from MSCAs, and missed the opportunity for written comments. They agreed that a new short term *Daphnia* study is useful since it may result with a lower EC 50 value. However they did not agree to perform a long-term toxicity test in *Daphnia* and fish on the grounds that Annex IX column 2 states that it is only needed when the CSA indicates the need to do so, and long-term toxicity studies can be considered only after the results from the new daphnia study are available. According to the Registrant deficiencies in the algae test are not critical since no hydrolysis and volatility has been observed, and the EC50 for biomass is more conservative.

The Chairman explained that ECHA requests for standard information requirements as stipulated in REACH, however, whether it is possible to build up a scientific argumentation and read across is the responsibility of the Registrant and then it is in the follow-up stage that ECHA can assess its acceptability.

Session 2 (closed)

The MSCA that submitted the PfA on terrestrial toxicity withdrew the PfA and decided to await further data generation for this and other industrial chemicals to be able to do a data-based re-assessment of ECHA's soil testing strategy. Further discussion in the closed session focused on the procedural aspect of whether and how to incorporate the late comments of the Registrant. Since at the moment there is no relevant information in the dossier which would allow considering the information requirements as being fulfilled .

MSC unanimously agreed to request information on long-term aquatic toxicity for plants, invertebrates and fish, and long-term toxicity on terrestrial invertebrates, plants and effects on microorganisms,.

One MSC member had declared a potential conflict of interest for this case and did not vote.

CCH-055/2014 1—vinyl–2-pyrrolidone (EC No. 20-800-4)

Session 1 (open)

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

Two PfAs to ECHA's DD were submitted.

SECR explained that one PfA suggested that the Registrant should provide documentation on PPE in the CSR for the recommended material type, its thickness and the typical or minimum breakthrough time for the glove type recommended, with regard to the amount and duration of dermal exposure.

Another PfA suggested the use of a glove efficacy of maximum 95% (or less) and a revision of the CSR accordingly.

SECR had amended the DD based on PfA related to the PPE in the CSR information requirement prior to the meeting.

Registrant's comments on PfAs of CAs and discussion

The Registrant provided written comments on the PfAs and explained at the meeting that in his view the information on PPE in the CSR is sufficient to calculate risk characterisation ratios, but that for supply chain communication purposes they could agree to update IUCLID's Guidance for safe use. Furthermore, they argued that ECETOC model calculations for determining the efficacy of the gloves can be replaced with higher efficiencies when specific guidance for dermal protection is used.

An expert of one of the MSC members explained the difficulties of gloves efficiency calculations and provided arguments for the justification of higher efficiencies with experimental study results.

Session 2 (closed)

SECR reiterated the conclusions of the open session and justification of the modifications in the DD was provided.

In line with the more general discussion on the PPE and glove efficiency for comparable CCH cases discussed at the meeting, and based on the above considerations, MSC decided not to amend the DD requesting specification of the glove efficiency, but to put in a note for Registrant's consideration that the information provided in the comments should be included in a dossier update in both the CSR and IUCLID file.

MSC found unanimous agreement on ECHA's draft decision as modified in the meeting.

CCH-056/2014 1,2-dichloropropane (EC No. 201-152-2)

Session 1 (open)

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

SECR explained that two PfAs to ECHA's DD were submitted. These PfAs suggested more detailed information on PPE and on glove material thickness and efficiency to be provided in CSR, as although the glove material is identified in the registration dossier, no specific information was provided on the breakthrough times and the thickness of the glove material. Further, the CA requested the Registrant to update the technical dossier and the CSR with the appropriate order of RMMs or to justify why other measures than the use of PPEs are not applicable or could not sufficiently reduce the risks.

SECR modified DD for the meeting based on PfAs.

Registrant's comments on PfAs of CAs

Motivated by the PfAs, the Registrant agreed in writing to revise and update the CSA/CSR according to ECHA request.

Session 2 (closed)

In line with the more general discussion on the PPE and glove efficiency for comparable CCH cases discussed at the meeting, MSC concluded that the DD should be modified with a request for further clarification on glove specification and on glove efficiency in both the CSR and IUCLID file.

MSC unanimously agreed on the ECHA's DD as modified at the meeting.

d. General topics

1) Presentation on ECHA's approach to compliance checks related to CSR (Closed session)

MSC took note of the presentation focusing on PPEs, and a closed session was held to discussthe preferred ECHA approach to compliance checks related to CSR. MSC concluded that DDs can contain a request to further clarify glove specification and glove efficiency, which are to be provided in both the CSR and IUCLID file.

2) Status report on on-going evaluation work

SECR gave detailed statistics and update on the status of dossier evaluation work. The Committee was also informed of the potential workload for the forthcoming MSC meetings. MSC took note of the report.

Item 8 – SVHC identification

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 three substances, as follows: *1,2-benzenedicarboxylic acid, dihexyl ester, branched and linear* and *sodium perborate; perboric acid, sodium salt* proposed to be identified as SVHC based on Article 57 (c) due to their reproductive toxicity and *cadmium chloride* proposed to be identified as SVHC based on Article 57 (a-c) and (f) as carcinogenic, mutagenic, toxic for reproduction and as a substance of equivalent concern (kidney and bone effects) to the substances identified as SVHCs under Article 57 (a)-(e) of the REACH Regulation. It was explained that MSC agreed unanimously on identification of these three substances as SVHCs in the written procedure launched on 20 May and closed on 30 May 2014. SECR indicated that the final documents have already been made available on MSC CIRCABC and on the ECHA website and the substances will be shortly included in the Candidate List of SVHCs.

The member from NL requested the floor and mentioned they had voted 'yes' on all three substances as these substances meet the criteria for identification as SVHC set out in Article 57 of REACH. However, NL had its doubts on identification as SVHC and authorisation as a possible next step for some of the substances, as the RMOAs provided were, in the view of NL, not clear on the preferred regulatory route. The Dutch member gave a statement on the use of RMOAs, which is annexed to these minutes (see Annex VI).

Item 9 – Prioritisation of Candidate List substances for inclusion in Annex XIV

Discussion on ECHA's 6th draft recommendation for inclusion of priority substances in Annex XIV

Discussion of the draft recommendation – prioritisation of the substances on the Candidate List and draft Annex XIV entries of the substances suggested for inclusion in the draft recommendation (2nd discussion).

SECR introduced the further work carried out for the 6th draft recommendation for inclusion of priority substances in Annex XIV since MSC-35 and provided responses to the written comments of MSC during the presentation and through the documents provided for the meeting. In the draft recommendation as presented for the meeting 21 substances were indicated as potential substances for inclusion at the stage of public consultation. SECR clarified that it is not foreseen to include in the final recommendation all 21 substances. This is as the resulting workload in the authorisation application phase would be too high. SECR called for views on when to reduce number of substances, i.e. based on the discussion at MSC-36 before the public consultation starts or taking into account also the comments provided during the public consultation. Furthermore, SECR stressed that the substances having high priority but not recommended in this round will likely have high priority also in coming draft recommendation rounds and suggested that more clear

communication on this would increase predictability and support longer term planning by industry, encourage timely update of registration dossiers and also support the preparation of the MSCAs.

A proposal to postpone the issuing of the 6th (draft) recommendation was made by a member as COM has decided not to move forward with the 5th recommendation this year and work on improvements in the authorisation application phase is ongoing. Supporting views were expressed by a number of other members. MSC exchanged views on that topic. Several members supported to go ahead with the draft 6th recommendation, which is based on the criteria in Art 58(3) and applies the new approach for prioritisation. The SECR emphasised that the smoothness of the process would best be ensured with a steady flow and frequency of updates to the list of substances subject to authorisation. It was noted that the Commission can decide not to proceed with the recommended substances but cannot include substance in Annex XIV without a recommendation. The COM observer reassured that COM is not in favour of stopping the authorisation process. In addition it was noted that the 6th draft recommendation being included in the Management Board approved annual work programme of ECHA, it would require that MSC provides its opinion accordingly. SECR continued that as the authorisation application phase is now successfully implemented for the first cases and work on implementation of further improvements is taking place, for which further discussion is foreseen at the next CARACAL meeting, there should be a good basis to move forward with the 6th draft Recommendation.

The proposal to submit all the 21 substances for public consultation and then to use the information received during the consultation possibly to deselect substances was supported by many speakers. Some members raised concern of the workload during the opinion forming due to high number of substances. In responding to a question SECR explained that the very same criteria would be used for de-selection of any substances after public consultation as have been applied at the prioritisation stage, i.e. to use the updated prioritisation approach. New information regarding aspects relevant for the estimation of the workload or indicating that the grouping is not valid for a certain substance were mentioned as examples of the type of information that could lead to leaving a substance away from this recommendation after closure of the consultation. However, it would not be possible to define in advance the number of substances that would eventually be recommended for the inclusion in Annex XIV.

As part of the discussion MSC commented on several substances and groups of substances in the proposal. Several members stressed the importance of the criteria in Article 58(3) of REACH and the use of the agreed prioritisation approach. It was argued that if there is a need to leave out substances then the lowest scoring substances should be dropped (unless these are in the draft recommendation grouped with high scoring substances). Some MSC members commented on Hydrazine and requested to drop it from the draft recommendation for this round (hydrazine being the lowest scoring substance without grouping considerations). Diverging views were expressed in particular as regards the lead compounds. Regulatory effectiveness with a reference to the existing legislation was mentioned as a reason for hesitation to proceed with lead substances and lack of RMOA was regretted. Current lack of alternatives in some uses was suggested as a reason not to proceed with e.g. boron compounds, however, some MSC members stressed that the authorisation process should drive substitution.

Several stakeholder observers expressed the wish to have RMOAs made available more broadly, and also a comment supporting the launch of public consultation with all 21 substances was made. One stakeholder observer called for a streamlined, efficient and transparent process. While supporting the prioritisation approach itself a stakeholder observer expressed concerns that the level of proof required to challenge the prioritisation, e.g. whether certain lead compounds can be used to replace other ones as basis for recommending lead compounds, seemed too high. In his intervention he also questioned the timelines for the public consultation, which was supported by the Commission observer who spoke in favour of avoiding the summer period for the public consultation.

During the discussion some clarification was provided about a suggestion to use a Call for Information to cover separately aspects related to potential consequences of authorisation. Comments received would then not be addressed by ECHA or MSC but the Commission at the later stage. Furthermore, one member provided some insight in the outcome of the Workshop on the Authorisation process which took place early June in the Netherlands.

It was concluded that all in all longer term predictability in the authorisation process would be much appreciated. Following the discussion in MSC, ECHA Secretariat decided to postpone start of the public consultation of the 6th draft recommendation by 2.5 months until 1 September.

Item 10 – Opinion on the draft recommendation of priority substances to be included in Annex XIV: Tasks and appointment of Rapporteur and possible working group

a. Update to the time plan for the recommendation process and opinion development

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

c. Appointment of (Co-)Rapporteur

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

SECR presented a revised time plan for the opinion development on the 6th draft recommendation and provided further clarification on the some issues raised. However, following the MSC-36 discussion on the 6th draft recommendation and the comments made, and the decision to postpone the launch of its public consultation a further revision of the time plan is required. Thus, MSC agreed that MSC Secretariat would properly reflect the changes in the time plan in consultation with the MSC rapporteur and prior to the MSC-37 meeting.

MSC agreed on the tasks of the rapporteur and on the mandate of the newly-established working group to support the MSC rapporteur in drafting the MSC opinion on the 6th draft recommendation of ECHA. A volunteering MSC member was agreed by MSC to be the rapporteur for the MSC opinion development.

Furthermore, MSC agreed to delay the establishment of the working group supporting the rapporteur due to the postponement of the launch of the public consultation to 1 September. The appointments of a co-rapporteur and of the working group membership will be discussed and agreed in the MSC meeting in September.

Item 11 – Report from other ECHA bodies and activities

Feedback from ECHA Management Board: adaptation of Declaration of Interest-form in MSC RoP's

SECR presented the revised Conflict of Interest (CoI) form in the MSC Rules of Procedure (RoP), available to MSC members in CIRCABC as reference for updating their Declarations of Interest (DoI) where appropriate.

Item 12 – Any other business

No further items under this agenda point.

Item 13– Adoption of conclusions and action points

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

SIGNED

Watze de Wolf

Chairman of the Member State Committee

II. List of attendees

Members/Alternate members
ALMEIDA, Inês (PT)
ANASTASI, Audrey Anne (MT)
ANDRIJEWSKI, Michal (PL)
BASTIJANCIC-KOKIC, Biserka (HR)
COCKSHOTT, Amanda (UK)
CONWAY, Louise (IE)
DEIM, Szilvia (HU)
DUNAUSKIENE, Lina (LT)
FINDENEGG, Helene (DE)
GAIDUKOVS, Sergejs (LV)
HUMAR-JURIC, Tatjana (SI)
KOUTSODIMOU, Aglaia (EL)
KULHANKOVA, Pavlina(CZ)
LULEVA, Parvoleta (BG)
LUNDBERGH, Ivar (SE)
MARTÍN, Esther (ES)
MIHALCEA UDREA, Mariana (RO)
PISTOLESE, Pietro (IT)
REIERSON, Linda (NO)
RUSNAK, Peter (SK)
STESSEL, Helmut (AT)
TALASNIEMI, Petteri (FI)
TYLE, Henrik (DK)
VANDERSTEEN, Kelly (BE)
WAGENER, Alex (LU)
WIJMENGA, Jan (NL)
Representatives of the Commission
GARCIA-JOHN, Enrique (DG ENTR)
KOBE, Andrej (DG ENV)
Observers
ANNYS, Erwin (CEFIC)
BERZANSKIS, Laurel (HCWH)
DEL CASTILLO, Francisco (CONCAWE)
DROHMANN, Dieter (ORO)
HOWARD, Gregory (HEAL)
HÖK, Frida (CHEMSEC)
STAIRS, Kevin (Greenpeace)
TAYLOR, Katy (ECEAE)
WAETERSCHOOT, Hugo (Eurometaux)

ECHA staff
AJAO, Charmaine
ANDERSSON, Niklas
BIGI, Elena
BROERE, William
CARLON, Claudio
CARTLIDGE, George
CESNATIS, Romanas
DELOFF-BIALEK, Anna
DE WOLF, Watze
DREVE, Simina
FEDTKE, Norbert
FEEHAN, Margaret
HUUSKONEN, Hannele
JOHANSSON, Matti
KARHU, Elina
KARJALAINEN, Antti
KARKOLA, Sampo
KORJUS, Pia
MAZZEGA SBOVATA, Silvia
NAUR, Liina
PELLIZZATO, Francesca
PHILLIPS, Andrew
ROBERTS, Julian
RODRIGUEZ IGLESIAS, Pilar
RÖCKE, Timo
RÖNTY, Kaisu
SOBANSKA, Marta
UOTILA, Elina
VAHTERISTO, Liisa
VASILEVA, Katya
VAZQUEZ RODRIGUEZ, Jesus

Proxies

KOUTSODIMOU, Aglaia (EL) also acting as proxy of KYPRIANIDOU-LEONTIDOU, Tasoula (CY)
MARTIN, Esther (ES) also acting as proxy of DRUGEON, Sylvie (FR)
VANDERSTEEN, Kelly (BE) also acting as proxy of VESKIMÄE, Enda (EE)
PISTOLESE, Pietro (IT) also acting as proxy of ANASTASI, Audrey Anne (MT) on Friday
STESSEL, Helmut (AT) also acting as proxy of DUNAUSKIENE, Lina (LT) on Tuesday afternoon and on Friday morning

Experts and advisers to MSC members

ATTIAS, Leonello (IT) (expert to PISTOLESE, Pietro)
AXELSTAD, Marta (DK) (expert to TYLE, Henrik)
BUDASOVA, Jana (EE) (expert to VESKIMÄE, Enda)

GRACZYK, Anna (PL) (expert to ANDRIJEWSKI, Michal)
GOURLAY-FRANCE, Catherine (adviser to DRUGEON, Sylvie)
INDANS, Ian (UK) (expert to COCKSHOTT, Amanda)
KOZMIKOVA, Jana (CZ) (expert to KULHANKOVA, Pavlina)
LONDESBOROUGH, Susan (FI) (adviser to TALASNIEMI, Petteri)
MALKIEWICZ, Katarzyna (SE) (expert to LUNDBRGH, Ivar)
RÜHL, Dana (DE) (expert to FINDENEGG, Helene)
SEBESTYEN, István (expert to DEIM, Szilvia)
TRAAS, Theo (NL) (expert to WIJMENGA, Jan)
VILNISKE, Lina (LT) (expert to DUNAUSKIENE, Lina)
WODLI, Jordane (FR) (expert replacing DRUGEON, Sylvie)
ZELJEZIC, Davor (HR) (expert to BASTIJANCIC-KOKIC, Biserka)

MSCA Expert for SEV case
VERBRUGGEN, Eric (NL)

By WEBEX-phone connection:
During agenda item 6: Ian DOYLE (UK).
During agenda item 7: Susanne BREDENDIEK-KÄMPER (DE), Ann-Carolin DUMKE (DE), Dag ROTHER (DE) and Annika VOGEL (DE).
During agenda items 8, 9 and 10 from the European Commission: Valentina BERTATO, Anna BORRAS HERRERO, Giuseppina LUVARA, Katarina PIRSELOVA, Jacek ROZWADOWSKI and Georg STRECK

Case owners:
Representatives of the Registrants were attending under agenda item 6b for SEV-NL-026/2012 and under agenda item 7b for CCH-044/2014, CCH-045/2014, CCH-049/2014, CCH-050/2014 and CCH-055/2014.

Apologies:
BUSUTTIL, Ingrid (MT)
COSGRAVE, Majella (IE)
DOUGHERTY, Gary (UK)
DRUGEON, Sylvie (FR)
KYPRIANIDOU-LEONTIDOU, Tasoula (CY)
VESKIMÄE, Enda (EE)

III. Final Agenda

ECHA/MSC-36/2014/A/36

Agenda
36th meeting of the Member State Committee

10-13 June 2014
ECHA Conference Centre
Annankatu 18, in Helsinki, Finland

10 June: **starts at 9:00**
13 June: **ends at 13:00**

Item 1 – Welcome and Apologies

Item 2 – Adoption of the Agenda

MSC/A/036/2014
For adoption

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

Item 4 – Administrative issues

- Feedback received on streamlining suggestions (follow-up from MSC-35)
- Feedback from testing of an IT platform tool

ECHA/MSC-36/2014/030
For information

Item 5 – Adoption of minutes of the MSC-35

- Adoption of draft minutes of MSC-35

MSC/M/35/2014
For adoption

Item 6 – Substance evaluation

Closed session for 6c & 6d4
Indicative time plan for 6b is Day 1

a. **Written procedure report on seeking agreement on a draft decision on substance evaluation**

ECHA/MSC-36/2014/001
For information

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

ECHA/MSC-36/2014/002
For information

For discussion followed by agreement seeking under 6c:

- **SEV-NL-026/2012** **Triclosan** (EC No. 222-182-2)

ECHA/MSC-36/2014/003-004
For discussion

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

- Case as listed under 6b

For agreement

d. CoRAP and substance evaluation

1) Scenarios to finalise the substance evaluation decision making process after MSCA consultation

For information and discussion

2) Extended one-generation reproductive toxicity study (EOGRTS) in Substance evaluation

For information

3) Short general update by the secretariat

For information

4) Update on appeal cases *(Closed session)*

For information

Item 7 – Dossier evaluation

Closed session for 7c&d1
Indicative time plan for 7b is Day 1(pm)-Day 2

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

ECHA/MSC-36/2014/005
For information

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

ECHA/MSC-36/2014/006
For information

For discussion followed by agreement seeking under 7c:

Compliance checks

MSC code	Substance name	EC No.	Document
CCH-044/2014	Dichloromethylbenzene	249-854-8	ECHA/MSC-36 /2014/007-008

CCH-050/2014	2,2,4(or 2,4,4)-trimethylhexane-1,6-diamine	247-063-2	ECHA/MSC-36 /2014/015-016
CCH-045/2014	Prop-2-yn-1-ol	203-471-2	ECHA/MSC-36 /2014/009-010
CCH-048/2014	Ethylenediamine	203-468-6	ECHA/MSC-36 /2014/011-012
CCH-049/2014	Ethylenediamine, ethoxylated and propoxylated	500-047-1	ECHA/MSC-36 /2014/013-014
CCH-055/2014	1-vinyl-2-pyrrolidone	201-800-4	ECHA/MSC-36 /2014/017-018
CCH-056/2014	1,2-dichloropropane	201-152-2	ECHA/MSC-36 /2014/019-020

For information and discussion

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

Cases as listed above under **7b**

For agreement

d. General topics

1) Presentation on ECHA's approach to compliance checks related to CSR *(Closed session)*

For information and discussion

2) Status report on on-going evaluation work

For information

Item 8 – SVHC identification

Written procedure report on seeking agreement on identification of SVHCs

ECHA/MSC-36/2014/023 (room document)

For information

Item 9– Prioritisation of Candidate List substances for inclusion in Annex XIV

Discussion on ECHA's 6th draft recommendation for inclusion of priority substances in Annex XIV

Discussion of the draft recommendation – prioritisation of the substances on the Candidate List and draft Annex XIV entries of the substances suggested for inclusion in the draft recommendation (2nd discussion)

ECHA/MSC-36/2014/024-028, 031

For discussion

Item 10 – Opinion on the draft recommendation of priority substances to be included in Annex XIV: Tasks and appointment of Rapporteur and possible working group

a. Update to the time plan for the recommendation process and opinion development

ECHA/MSC-36/2014/029
For information

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

ECHA/MSC-36/2014/021
For discussion & decision

c. Appointment of (Co-)Rapporteur

For decision

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

ECHA/MSC-36/2014/022
For decision

Item 11 – Report from other ECHA bodies and activities

- Feedback from ECHA Management Board: adaptation of Declaration of Interest-form in MSC RoP's

For information

Item 12 – Any other business

- Suggestions from members

For information

Item 13– Adoption of main conclusions and action points

- Table with conclusions and action points from MSC-36

For adoption

Main conclusions and action points
MSC-36, 10-13 June 2014
(adopted at MSC-36)

CONCLUSIONS / DECISIONS / MINORITY OPINIONS	ACTIONS REQUESTED
Item 4 - Administrative issues	
MSC took note on the feedback received on streamlining suggestions (follow-up from MSC-35).	**MSC-S** to revise the MSC working procedures for processing of DEv and SEv draft decisions in line with the feedback received and seek MSC agreement on them at MSC-37
Item 5 – Adoption of draft minutes of MSC-35	
MSC adopted the revised draft minutes of MSC-35.	**MSC-S** to upload final version of the minutes on MSC CIRCABC and ECHA website by 17 June 2014.
Item 6 - Substance evaluation e. **Written procedure report on seeking agreement on a draft decision on substance evaluation**	
MSC took note of the report.	**MSC-S** to upload on MSC CIRCABC the final agreement document agreed in written procedure, as indicated in document ECHA/MSC-36/2014/001.
Item 6 - Substance evaluation **f. Introduction to and preliminary discussion on one draft decision on substance evaluation after MS-CA's/ECHA reactions *(Session 1, open session)*** **g. Seeking agreement on draft decisions when amendments were proposed by MS-CA's/ECHA *(Session 2, closed session)***	
MSC reached unanimous agreement on the following ECHA draft decision as modified in the meeting: **SEV-NL-026/2012 Triclosan** (EC No. 222-182-2)	**MSC-S** to upload on MSC CIRCABC the final ECHA decision of the agreed case.
h. CoRAP and substance evaluation **5)** Scenarios to finalise the substance evaluation decision making process after MSCA consultation	
	MSC-S to upload on Evaluation CIRCABC the template for the agreement document
Item 7 – Dossier evaluation **a. Written procedure report on seeking agreement on draft decisions on dossier evaluation**	
MSC took note of the report.	**MSC-S** to upload on MSC CIRCABC the final ECHA decisions agreed in written procedure, as indicated in document ECHA/MSC-36/2014/005. **MSC-S** to provide COM for further decision making with documents

CONCLUSIONS / DECISIONS / MINORITY OPINIONS	ACTIONS REQUESTED
	(DD, RCOM, outcome of the vote, justifications for NO votes) of cases on which MSC did not reach agreement, as indicated in document ECHA/MSC-36/2014/005.
b. Introduction to and preliminary discussion on draft decisions on compliance checks after MS-CA reactions *(Session 1, open session)* **c. Seeking agreement on draft decisions on compliance checks when amendments were proposed by MS-CA's *(Session 2, closed session)***	
MSC reached unanimous agreement on the following ECHA draft decisions as modified in the meeting: • **CCH-044B/2014** Dichloromethylbenzene (EC No. 249-854-8) • **CCH-045B/2014** Prop-2-yn-1-ol (EC No. 203-471-2) • **CCH-048/2014** Ethylenediamine (EC No. 203-468-6) • **CCH-049B/2014** Ethylenediamine, ethoxylated and propoxylated (EC No. 500-047-1) • **CCH-050/2014** 2,2,4(or 2,4,4)-trimethylhexane-1,6-diamine (EC No. 247-063-2) • **CCH-055/2014** 1-vinyl-2-pyrrolidone (EC No. 201-800-4) • **CCH-056/2014** 1,2-dichloropropane (EC No. 201-152-2)	**MSC-S** to upload on MSC CIRCABC the final ECHA decisions of the agreed cases.
MSC could not reach unanimous agreement on the following draft decisions as modified in the meeting, where appropriate: • **CCH-044A/2014** Dichloromethylbenzene (EC No. 249-854-8) • **CCH-045A/2014** Prop-2-yn-1-ol (EC No. 203-471-2) • **CCH-049A/2014** Ethylenediamine, ethoxylated and propoxylated (EC No. 500-047-1)	**MSC-S** to provide COM for further decision making with documents (DD, RCOM, outcome of the vote, justifications for NO votes) of cases on which MSC did not reach agreement
Item 8 – SVHC identification **Written procedure report on seeking agreement on identification of SVHCs**	
MSC took note of the report, as indicated in document ECHA/MSC-36/2014/023.	**SECR** to add the newly identified SVHC's (in written procedure) to the Candidate List.
Item 9 – Prioritisation of Candidate List substances for inclusion in Annex XIV **Discussion on ECHA's 6th draft recommendation for inclusion of priority substances in Annex XIV**	
MSC took note of the further work carried out for the 6th draft recommendation for inclusion of priority substances in Annex XIV and the responses of SECR to the written comments submitted. MSC provided feedback on the draft recommendation and the number of substances to be possibly included for public consultation stage.	**SECR** to consider further the MSC input on all the substances that are under consideration to be recommended. **SECR** to launch public consultation of its 6th draft recommendation for Annex XIV priority substances on 1 September 2014.
Item 10 – Opinion on the draft recommendation of priority substances to be included in Annex XIV: Tasks and appointment of Rapporteur and possible working group	
a. Update to the time plan for the recommendation process and opinion development b. Task of the (Co-)Rapporteur in drafting the opinion of the MSC c. Appointment of (Co-)Rapporteur	

CONCLUSIONS / DECISIONS / MINORITY OPINIONS	ACTIONS REQUESTED
d. 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 for drafting the MSC opinion on ECHA's 6th draft recommendation. MSC agreed to postpone the establishment of the working group supporting the rapporteur in the MSC opinion drafting, as well as the appointments of a potential co-rapporteur and of the volunteering MSC members and experts for this working group membership for MSC-37 (due to the postponement of the launch of the public consultation).	**MSC-S** jointly with the MSC rapporteur to update the Time plan for the MSC opinion development in line with the new timeframe for the 6th draft recommendation and to communicate it to MSC prior to MSC-37 plenary
Item 13 – Adoption of conclusions and action points	
MSC adopted the main conclusions and action points of MSC-36 at the meeting.	**MSC-S** to upload the main conclusions and action points on MSC CIRCABC by 13 June 2014.

V. Dossier evaluation cases addressed for MSC agreement seeking in WP:

Draft decisions unanimously agreed by MSC in WP:

Testing proposal examinations (TPE)

MSC ID number	Substance name used in draft decision	EC No
Rosin category 1 - 'Rosin, hydrogenated rosin and their salts'		
TPE-003B/2014	Rosin	232-475-7
TPE-004B/2014	Rosin, hydrogenated	266-041-3
TPE-005B/2014	Resin acids and Rosin acids, sodium salts	263-144-5
TPE-006B/2014	Resin acids and Rosin acids, potassium salts	263-142-4
TPE-007B/2014	Resin acids and Rosin acids, calcium salts	232-694-8
TPE-008B/2014	Resin acids and Rosin acids, magnesium salts	270-461-2
TPE-009B/2014	Resin acids and Rosin acids, calcium zinc salts	269-825-3
TPE-010B/2014	Rosin, reaction products with formaldehyde	293-659-0
TPE-011/2014	Resin acids and Rosin acids, reaction products with formaldehyde, potassium salt	295-855-1
TPE-012/2014	Oligomers of rosin	500-163-2
Rosin category 2 - 'Rosin esters'		
TPE-018B/2014	Resin acids and Rosin acids, esters with triethylene glycol	232-478-3
TPE-019B/2014	Resin acids and Rosin acids, esters with glycerol	232-482-5
TPE-020B/2014	Resin acids and Rosin acids, hydrogenated, esters with glycerol	266-042-9
TPE-021B/2014	Resin acids and Rosin acids, esters with pentaerythritol	232-479-9
TPE-022B/2014	Resin acids and Rosin acids, hydrogenated, esters with pentaerythritol	264-848-5
Rosin category 3 - 'Rosin adducts and rosin adduct salts'		
TPE-025B/2014	Rosin, fumarated	266-040-8
TPE-026B/2014	Rosin, maleated	232-480-4
TPE-027B/2014	Resin acids and Rosin acids, maleated, sodium salts	269-228-8
Rosin category 4 - 'Rosin adduct esters'		
TPE-029B/2014	Resin acids and Rosin acids, fumarated, esters with pentaerythritol	305-514-1
TPE-030B/2014	Rosin, fumarated, reaction products with glycerol and pentaerythritol	296-047-1
Individual analogue approach based on testing proposed in other categories		
TPE-033B/2014	Fatty acids, tall oil, oligomeric reaction products with maleic anhydride and rosin, calcium magnesium[..]	500-451-8
Rosin category 5 - 'Isomerised rosins'		

TPE-034B/2014	Reaction mass of hydrogenated and dehydrogenated rosin	911-238-8
TPE-035B/2014	Reaction mass of Resin acids and Rosin acids, hydrogenated, sodium salts and sodium	915-568-3
TPE-036B/2014	Modified rosin salt	915-657-7

Compliance checks (CCH)

MSC ID number	**Substance name used in draft decision**	**EC. No**
CCH-022/2014	Tin	231-141-8
CCH-023B/2014	2-ethylhexylamine	203-233-8
CCH-031/2014	Isopentyl acetate	204-662-3
CCH-033/2014	Hexamethylenediamine	204-679-6
CCH-034/2014	Hexamethylenediamine	204-679-6
CCH-035/2014	Hexamethylenediamine	204-679-6
CCH-036/2014	Hexamethylenediamine	204-679-6
CCH-037/2014	Hexamethylenediamine	204-679-6
CCH-038/2014	Hexamethylenediamine	204-679-6
CCH-039/2014	Hexamethylenediamine	204-679-6
CCH-040/2014	Hexamethylenediamine	204-679-6
CCH-041/2014	Hexamethylenediamine	204-679-6
CCH-042/2014	Hexamethylenediamine	204-679-6
CCH-043/2014	Hexamethylenediamine	204-679-6
CCH-046B/2014	Cyclohexyldimethylamine	202-715-5
CCH-051/2014	2,2',6,6'-tetrabromo-4,4'-isopropylidenediphenol	201-236-9
CCH-052/2014	Ethyl (S)-2-hydroxypropionate	211-694-1
CCH-060/2014	Potassium methanolate	212-736-1
CCH-061/2014	Trizinc dicitrate	208-901-2
CCH-062B/2014	Propylene carbonate	203-572-1
CCH-063/2014	Iodomethane	200-819-5
CCH-064B/2014	Bis(4-chlorophenyl) sulphone	201-247-9

Draft decisions for which no unanimous agreement was reached via WP:

Testing proposal examinations (TPE)

MSC ID number	**Substance name used in draft decision**	**EC. No**
Rosin category 1 - 'Rosin, hydrogenated rosin and their salts'		
TPE-003A/2014	Rosin	232-475-7
TPE-004A/2014	Rosin, hydrogenated	266-041-3
TPE-005A/2014	Resin acids and Rosin acids, sodium salts	263-144-5
TPE-006A/2014	Resin acids and Rosin acids, potassium salts	263-142-4

TPE-007A/2014	Resin acids and Rosin acids, calcium salts	232-694-8
TPE-008A/2014	Resin acids and Rosin acids, magnesium salts	270-461-2
TPE-009A/2014	Resin acids and Rosin acids, calcium zinc salts	269-825-3
TPE-010A/2014	Rosin, reaction products with formaldehyde	293-659-0
Rosin category 2 - 'Rosin esters'		
TPE-018A/2014	Resin acids and Rosin acids, esters with triethylene glycol	232-478-3
TPE-019A/2014	Resin acids and Rosin acids, esters with glycerol	232-482-5
TPE-020A/2014	Resin acids and Rosin acids, hydrogenated, esters with glycerol	266-042-9
TPE-021A/2014	Resin acids and Rosin acids, esters with pentaerythritol	232-479-9
TPE-022A/2014	Resin acids and Rosin acids, hydrogenated, esters with pentaerythritol	264-848-5
Rosin category 3 - 'Rosin adducts and rosin adduct salts'		
TPE-025A/2014	Rosin, fumarated	266-040-8
TPE-026A/2014	Rosin, maleated	232-480-4
TPE-027A/2014	Resin acids and Rosin acids, maleated, sodium salts	269-228-8
Rosin category 4 - 'Rosin adduct esters'		
TPE-029A/2014	Resin acids and Rosin acids, fumarated, esters with pentaerythritol	305-514-1
TPE-030A/2014	Rosin, fumarated, reaction products with glycerol and pentaerythritol	296-047-1
Individual analogue approach based on testing proposed in other categories		
TPE-033A/2014	Fatty acids, tall oil, oligomeric reaction products with maleic anhydride and rosin, calcium magnesium[..]	500-451-8
Rosin category 5 - 'Isomerised rosins'		
TPE-034A/2014	Reaction mass of hydrogenated and dehydrogenated rosin	911-238-8
TPE-035A/2014	Reaction mass of Resin acids and Rosin acids, hydrogenated, sodium salts and sodium	915-568-3
TPE-036A/2014	Modified rosin salt	915-657-7

Compliance checks (CCH)

MSC ID number	**Substance name used in draft decision**	**EC. No**
CCH-023A/2014	2-ethylhexylamine	203-233-8
CCH-046A/2014	Cyclohexyldimethylamine	202-715-5
CCH-062A/2014	Propylene carbonate	203-572-1
CCH-064A/2014	Bis(4-chlorophenyl) sulphone	201-247-9

VI. Statement of the Dutch member in relation to item 8 of the meeting agenda

NL member's observations on the use of the RMO-Analysis in SVHC identification

The Risk Management Options Analysis (RMOA) has been used for quite some time to identify the preferred Risk Management Option (RMO) for a specific substance or a group of substances.

In the process of identification of Substances of Very High Concern (SVHC) under Title VII of REACH, the RMOA has so far been used mainly to describe the pros and cons of each RMO, while the choice to go for identification as SVHC and placement of the substance on the Candidate List was not in every case clear-cut.

With the introduction of the Roadmap on SVHC (adopted by the Commission in February 2013), the RMOA should now be more clear on whether inclusion of a substance on the Candidate List, and subsequent uptake in Annex XIV, is indeed the proper RMO for a substance.

In the Roadmap, it was agreed that in principle only substances for which the RMOA clearly identifies authorisation as the best RMO should be identified as SVHCs and subsequently placed on the Candidate List and Annex XIV.

The Netherlands has noted that some SVHC dossiers that were recently processed by MSC included RMOAs that did not have clear conclusions on whether authorization would indeed be the proper RMO for. The Netherlands would like to bring this to the attention of MSC members, and has also brought this issue to the attention of RiME.

Since the Roadmap has only been adopted recently, there are still dossiers in process which were initiated before the Roadmap was published and which might have RMOs that are not very clear on the best RMO. The Netherlands would like to invite all CAs to consider updating these RMOAs in line with the Roadmap criteria if those dossiers are forwarded to MSC.