MSC/M/017/2011
(Adopted at MSC-18)

PUBLIC

Final Minutes

Minutes of the 17th Meeting of the Member State Committee (MSC-17)
13-14 April 2011

I. Summary Record of the Proceedings

Item 1 - Welcome and Apologies

The Chair of the Committee, Ms Anna-Liisa Sundquist, opened the meeting and welcomed the participants to the 17th meeting of the Member State Committee (MSC).
For this 17th meeting, apologies were received from six MSC members (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 proposed by the MSC Secretariat. The final Agenda is attached to these minutes.

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

No conflicts of interest were declared in respect to any Agenda point of the meeting.

Item 4 - Administrative Issues

a) Results and follow-up from the satisfaction survey

Based on the replies to the satisfaction survey, increasing the efficiency of MSC-meetings and enhancing the involvement of stakeholder observers' could be identified as main action points. ECHA Secretariat (SECR) is committed to take action on these points. As for the second issue, SECR pointed out that significantly more sessions are likely to be opened to stakeholder observers with decreasing number of notified new substances (NONS) in dossier evaluation discussions.
A detailed report on the results of the survey has already been made available to MSC members.

b) Annual declarations for 2011

Annual declarations of MSC members present at the meeting were collected before and during the meeting.

Item 5 – Adoption of the minutes of MSC-16

SECR explained that written comments on the draft minutes of MSC-16 received from one meeting participant had been taken into account. The minutes were adopted without any further changes. The MSC Secretariat will upload the minutes on MSC CIRCA and on the ECHA website. Replying to a question MSC-S emphasised that minutes of MSC-meetings are not intended to be discussion- but rather conclusion-minutes.

Item 6 – Dossier evaluation

a) General topics

1. Update on extended one generation reproduction toxicity study (EOGRTS)

In its introductory presentation SECR reviewed the purpose, design and main features of the study as well as its regulatory relevance for ECHA and MSC. A comparison of EOGRTS and two-generation reproductive toxicity study was given. SECR pointed out that neither the current OECD Test Guidelines nor the current Test Methods Regulation of EU (Council Regulation 440/2008) contains the EOGRTS although negotiations both on OECD and EU level are ongoing.

The current legal requirement under REACH is not the EOGRTS but the two-generation reproductive toxicity study. ECHA needs to ensure with its decisions on testing proposals that this requirement is covered and the information expected from a two-generation reproductive toxicity study is available and adequate for the purposes of risk assessment and classification and labelling. Therefore, ECHA currently can accept EOGRTS as a testing proposal of a registrant only if it is modified/specifically designed to cover the key parameters of a two-generation reproductive toxicity study (EU Test Method B.35).

In the discussion, several MSC members expressed their expectations for the acceptance of EOGRTS on EU and OECD level in the near future and urged ECHA to take EOGRTS into consideration in dossier evaluation as soon as possible. Observers from environmental and animal welfare organisations supported this view, called for reduction of animal tests and emphasised the importance of most efficient use of experimental animals. In the view of an environmental organisation, this should be done by making the additional endpoints of EOGRTS for developmental neurotoxicity and developmental immunotoxicity mandatory. An observer from an industry organisation pointed out that finding agreement in the EU and OECD on the possible acceptance of EOGRTS before the next registration deadline would be very important for the chemical industry as testing proposals to fill in this data gap have to made very frequently. One MSC member expressed his concern that the Member States' experts of the topic could not be present.

Replying to questions SECR explained that in its view REACH currently does not allow for acceptance of EOGRTS without involvement of the second generation of animals. In ECHA's view, developmental immunotoxicity and neurotoxicity - contrary to involvement of the second generation - are not part of standard information requirements in REACH therefore these can not be required in dossier evaluation decisions.

SECR clarified that ECHA's current approach (as presented at the meeting) to EOGRTS versus two-generation reproductive toxicity test is reflecting the current legal situation. ECHA has to carry on its work both on testing proposal examinations (TPEs) and compliance checks (CCHs) to fulfil its legal obligations under REACH. The Chair concluded that ECHA will continue its work on dossier evaluation in the same transparent way as it did so far. Member State Competent Authorities (MSCAs) and MSC members will be consulted on the dossier evaluation draft decisions and the full supporting documentation, and can propose amendments according to REACH also in the future. It is common interest of ECHA and the Member States to find unanimous agreements on these cases. ECHA has to meet tight legal deadlines set by

REACH for TPEs and legal targets for CCHs. However, ECHA will explore legally possible options that may be considered to take EOGRTSs into account. As the next step, CARACAL under the leadership of the Commission will have to discuss further whether the Test Methods Regulation will be changed concerning EOGRTS and if any changes to REACH Annexes were needed or if there were other options available to clarify the position on EOGRTS; MSC is not the appropriate forum for these discussions.

2. Assessment factors deviating from guidance

SECR in its presentation introduced the topic highlighting that based on ECHA's experience with dossier evaluation, registrants tend to use alternative assessment factors (AFs) without any justification instead of the default AFs laid down in the REACH Guidance document. Default AFs are important instruments to ensure high level protection of human health, and they are rather based on consensus than on scientific evidence. If substance specific AFs can not be derived, the default AFs of the REACH Guidance document shall be used on which consensus with industry was found in the Guidance development process. These default AFs can not be replaced by other non-substance specific AFs without justification as their values are largely in line with the practice of national and international regulatory bodies and reflect the development of regulatory toxicology since the 1950's.

In ECHA's view, registrants are challenging the AFs of the REACH Guidance document and the consensus behind, often by using non-substance specific AFs derived e.g. by ECETOC which deviate significantly from those in the Guidance. As these AFs provide less protection for the human health, ECHA's current practice is to reject in draft decisions or quality observation letters the use of any AFs deviating from the REACH Guidance if no appropriate justification is provided.

In the discussion, several MSC members and the environmental NGO observer expressed their disappointment with the industry's practice and at the same time their strong support for ECHA's view that the use of AFs deviating from the REACH Guidance without proper justification shall not be allowed and registrants should be called in draft decision to correct these values. Some MSC members recommended recording the issue in the Manual of Decision of MSC.

Some industry observers stated that the default AFs of the REACH Guidance are too conservative and overprotective. They are based on old historical values which are outdated according to the current scientific knowledge. They questioned that the AFs of the REACH Guidance were developed in consensus with the chemical industry and considered that the AFs were not really discussed and the consensus could be considered rather passive from their side. They suggested to be considered whether it would not be appropriate now to re-evaluate these AFs.

The Chair concluded that there should always be a proper scientific justification in the registration dossiers if the AF used is deviating from the default values of the REACH Guidance. If substance specific AFs can be derived, these default AFs should normally be used. MSC members supported the idea that the use of inappropriate AFs should always be addressed in draft decisions. ECHA will have to further consider this view as well as the recording of this issue in the MoD of MSC. As a summary it

could be stated that industry is challenging the consensus concerning AFs reached with industry's active or passive consent.

3. Status report on ongoing evaluation work

SECR gave a summary report on the current situation and on future challenges of dossier evaluation work in ECHA. Estimates for the increasing workload of the next MSC meetings were given. Multi-annual dossier and substance evaluation planning of ECHA for the period 2011-2013 was presented. MSC took note of the report.

Replying to questions SECR made clear that the preliminary results of ECHA's communication policy with registrants will be presented for MSC-18 meeting. Preliminarily and generally it can be concluded that during the communication with registrants, some issues can be solved but only seldom the whole draft decision can be dropped. Report on the public consultations carried out on vertebrate testing proposals is also being prepared.

Some MSC members were concerned of the high number of compliance checks resulting in draft decisions and/or quality observation letters and the low numbers of planned substance evaluation cases while others found MSCA consultations scheduled by ECHA for the summer period inappropriate. Positive feedback on ECHA's pilot project on communication with MSCAs was also expressed. One MSC member called for a more coordinated approach of MSCAs to review ECHA's draft decisions and proposed a meeting to this end. Another MSC member emphasised the importance of sufficient information given by ECHA to MSCAs on the results of dossier evaluation as an important basis for MSCAs prioritisation for substance evaluation.

SECR explained that the high numbers given for future dossier evaluation cases already include compliance checks of joint registration dossiers. This approach approved by the Management Board and a successful communication between ECHA and MSCAs can hopefully lead to reduced number of proposals for amendment and consequently less work for MSC. ECHA highlighted that compliance checks of members' dossier of a joint submission has added value in terms of verifying the substance identity issues and therefore ensuring that the hazard endpoint information and other information provided by the lead registrant covers also the member registrations. Also verification of adequacy of any deviations from the lead registrant's data (e.g. different chemical safety reports) provides added value for ensuring the safe use of chemicals.

It was also pointed out that the rather low number of substance evaluation cases is the result of the MSCAs' notifications indicating willingness to deal with substances determined by their resources. Concerning the increasing workload of MSC which affects also summer breaks and the workload of the MSCA commenting round preceding each MSC meeting, it was highlighted that dates of four out of six MSC meetings per year are defined by other REACH processes where MSC is involved. As a response to higher workload, longer MSC meetings are planned but the number of meetings are preferred to be kept as six if possible. The MSC meeting dates define the dates of the MSCA commenting due to the timelines specified by the legislation. To make planning for MSCAs better and MSC members possible, the schedule of dossier evaluation processes for 2012 will be provided by SECR soon.

b) Written procedure report on seeking agreement on two draft decisions on dossier evaluation

SECR gave a short report on the written procedure of the two substances, 3,6-bis(4-chlorophenyl)-2,5-dihydro-pyrrolo[3,4-c]pyrrole- 1,4-dione (C.I. Pigment Red 254) and 12-hydroxyoctadecanoic acid, reaction products with 1,3-benzenedimethanamine and hexamethy-lene-diamine (E96095). By the closing date 31 March 2011, responses were received from 23 and 24 MSC members with voting rights, respectively. All responses were in favour and none were against the proposed decisions and agreements. Also the Norwegian member responded positively for both cases. It could be concluded that unanimous agreement on both of the above draft decisions and respective agreement documents has been reached by MSC on the 31 March 2011. ECHA will continue processing the agreements and the decisions. The final documents will be made available on MSC CIRCA.
One MSC member that did not vote in the written procedure for Pigment Red 254 expressed his concerns in a statement.

MSC took note of the report.

c) Introduction to and preliminary discussion on draft decisions on compliance checks and a testing proposal after MSCA reactions and

d) Seeking agreement on draft decisions on compliance checks and testing proposals when amendments were proposed by MS's

CCH 004/2011 (12-hydroxyoctadecanoic acid, reaction products with 1,3-benzenedimethanamine and hexamethylenediamine (E96095))

Session 1 (open)

SECR explained that the registrant accepted the invitation to participate in this session (Session 1) but due to unforeseen circumstances eventually the registrant cancelled participation. The registrant agreed to the presence of stakeholders, therefore an open session was held.

SECR introduced the case which was a NONS. Six proposals for amendment to ECHA's draft decision were submitted to ECHA by five MSCAs. Two of the proposed amendments could be considered rather as clear support than a real amendment to the draft decision. Concerning a proposed amendment to extend the deadline for submission of the requested information from 18 to 24 months, ECHA was of the view that the draft decision as notified to MSCAs and referred to MSC needs to be amended. However, ECHA did not amend the draft decision in advance of the meeting. In ECHA's view, other proposals for amendment regarding the data gap on reproductive toxicity exceeded the information requirements pursuant to Dangerous Substance Directive, and therefore an amendment of the draft decision was not needed in this regard.

The registrant provided comments on the proposed amendments supporting another proposed amendment.

In the detailed discussion of the case, replying to some MSC members' remarks SECR clarified that including suggestions/recommendations in decisions is from practical, legal, clarity and workability point of view not appropriate. Some other MSC members supported ECHA's opinion on this. SECR also explained that if the issues to be dealt with outside the decision are rather complex and lengthy, ECHA prefers sending a quality observation letter (QOBL) to registrants, in addition to the decision and notification letters. Only requirements for which a legal basis is provided in the legislation can be included in the decisions. For this and technical reasons, submitting everything in one document to the registrant is not feasible. ECHA will make sure that QOBLs and notification letters are being made available for MSCAs'/MSC members' information and they are followed up in a similar way as the final decisions. The information on the results of this follow-up will be provided to MSCAs/MSC members too.

Session 2 (closed)

One MSC member having not been present during the agreement seeking in Session 2 expressed his concerns in a statement.

MSC found unanimous agreement on ECHA's draft decision as referred to MSC, after amending it by extending the deadline for submission of the requested information from 18 to 24 months, and adopted the formal agreement.

MSC also concluded that the combined requirements of REACH and Directive 67/548/EEC do not allow requiring a two-generation reproductive toxicity study for the case at hand. ECHA, however, has recommended the registrant in a QOBL to fill in the data gap regarding reproductive toxicity (fertility).

CCH 003/2011 (TACT)

Session 1 (open)

The case owner of the registration dossier did not accept ECHA's invitation and was not present at the initial discussion (Session 1) but informed MSC-S that stakeholder observers can be present at the same discussions. Therefore an open session was held.

SECR informed that the registration dossier was one of the NONS and that one CA proposed two amendments to ECHA's draft decision.

The registrant communicated to ECHA in its comments on the proposed amendments that the granulometry study requested in one of the proposed amendments was already available. This statement is in line with the information which was available to ECHA and was confirmed in the meeting by the MSC member representing the MSCA to which the study was submitted as part of the notification dossier under Directive 67/548/EEC.

The registrant also agreed in his comments to the performance of the 90-day study requested in the draft decision. The registrant also commented on the need to provide *in vitro* gene mutation study. However, this comment did not concern the proposed amendments and in ECHA's view should not be taken into account at this stage of the decision making process.

In conclusion, ECHA considered that the draft decision as notified to MSCAs and referred to MSC does not need to be amended.

Replying to questions, SECR confirmed that the granulometry study in question was indeed performed with the registered substance. SECR also clarified in its response to a question that the *in vitro* gene mutation study is required because *in vivo* mammalian gene mutation study is not available. The available *in vivo* micronucleus test does not replace the gene mutation study in mammalian cells as it aims at testing a different endpoint.

Session 2 (closed)

One MSC member having not been present during the agreement seeking in Session 2 expressed his concerns in a statement.

MSC found unanimous agreement on ECHA's draft decision as referred to MSC without amending it, and adopted the formal agreement.

CCH 002/2011 (HS3520)

Session 1 (closed)

SECR explained that the registrant accepted the invitation to participate in this session (Session 1) with one representative and one accompanying expert. The session was kept closed, due to confidentiality reasons.

SECR informed that the registration dossier was one of the NONS and that two MSCAs proposed ten amendments to ECHA's draft decision. The main proposed amendments were the following.

One amendment was proposed to require ready biodegradability test although inherent biodegradability test was provided. After SECR explained that the Directive 67/548/EEC does not specify which test should be used to provide information for the biodegradation endpoint and that the MSCA responsible for the NONS had accepted the inherent biodegradability test, the MSC member representing the proposing MSCA agreed to not requiring the ready biodegradability test.

Another proposed amendment concerning the likelihood of indirect exposure of the aquatic environment to the substance could be disregarded as the MSCA to which the dossier under Directive 67/548/EEC was notified stated based on its risk assessment that exposure of aquatic environment to the substance is likely.

The third proposal on reproductive toxicity has been reflected in the notification letter addressed to the registrant.

The fourth significant proposal for amendment was related to the rate of hydrolysis of the substance stating that if the substance hydrolyses rapidly, the bioaccumulation study should be requested with the hydrolysis products and not with the parent substance.

In its comments on the proposed amendments the representatives of the registrant mentioned that it is in the process of updating the dossier to provide firmer arguments that exposure of aquatic and terrestrial environment is unlikely. Based on these argu-

ments, the registrant would like to waive the short-term toxicity tests on terrestrial plants and invertebrates. According to ECHA's view these comments of the registrant cannot be considered in this step of the process as the registration dossier was not updated with any new information before consultation of MSCAs was launched.

The registrant informed MSC in the meeting that in his view, based on a screening hydrolysis study the parent substance may be considered to hydrolyse rapidly and that depending on the appropriate rate of hydrolysis applied, the hydrolysis products shall be taken into account for assessment of bioaccumulation in aquatic environment. It was concluded that current information did not define the rate of hydrolysis that had to be achieved in order to base further assessment on hydrolysis products and not the parent material. The Registrant confirmed that the potential for substance to hydrolyse rapidly was based on in-house data from the non-EU manufacturer; it was not possible to confirm from the information available that the study was conducted in accordance with current OECD methods or to GLP standards.
In addition, the representatives of the registrant stated that in their view the bioaccumulation potential of the hydrolysis products is low. They confirmed also in the discussion that further exposure information is being collected currently and the registrant will update the registration dossier with the new data.

In ECHA's view the draft decision as presented to the MSCAs and referred to MSC did not need to be amended in advance of the meeting. Nevertheless, SECR invited MSC to discuss the proposed amendments for possible modification of the draft decision and to consider the registrant's comments on the proposed amendments, particularly regarding those relating to the bioaccumulation study in aquatic environment.

In the detailed discussion MSC found preliminary agreement that, as the available information from the registrant is not sufficient to conclude on the exact rate of hydrolysis of the registered substance, clarification of this issue should be requested in the draft decision. It was also agreed that the bioaccumulation test in aquatic environment should be requested in the draft decision unless substantial new evidence is included in the dossier that substantiates the registrant's claims

Session 2 (closed)
One MSC member having not been present during the agreement seeking in Session 2 expressed his concerns in a statement.
Taking into account the preliminary conclusions reached in Session 1, SECR prepared and presented an amended version of the draft decision. MSC found unanimous agreement on ECHA's draft decision with a revised wording of the parts of the draft decision referring to the bioaccumulation test in aquatic species. As quantitative information on the rate of hydrolysis of the substance was not available/clear from the registration dossier, the performance of the bioaccumulation study in aquatic species was required depending on additional information that the registrant must provide. The information required for the above test and the relevant part of the Statement of Reasons of the decision was changed accordingly.
MSC also adopted the formal agreement.

Item 7 – Substance evaluation

a. Update on the work on CoRAP (Community Rolling Action Plan)

In its first presentation, SECR informed about the current status of development of CoRAP criteria. During the development of the draft criteria, comments received from 12 MSCAs were taken into account. The earlier version of CoRAP criteria was updated in particular by giving more emphasis to suspected effects besides known effects, to combined effects of substances having a similar mode of action and to a more risk-based approach. Both the draft criteria and MSCAs comments with ECHA's responses to them were made available for MSC members. Further discussion on the criteria is foreseen in the 2nd Substance Evaluation Workshop on 23-24 May 2011. ECHA's intention is to adopt the criteria after the workshop as a decision of the Executive Director of ECHA.

The main focus of the workshop was presented as lessons learned from the application of CoRAP criteria, ranking of substances from the candidate list of CoRAP substances, follow-up of substance evaluation including links to identification of risk management options, format and content of necessary documentation (reports/assessments, draft decisions, justification for CoRAP notifications), and training and support needs. The workshop is being prepared by a preparatory working group consisting of representatives of five MSCAs, COM and ECHA. Contributions from Member States (MSs) have already been received.

SECR gave an overview also on MSCAs' indications on their capacity to perform substance evaluations in the years 2012-2014. The indicative number was around 40 per year (1-2 per MS). However, at the time of the MSC-17 meeting, close to the 15 April deadline, only few notifications had been received for the Registry of Notifications for CoRAP substances. MSCAs were kindly invited to submit their CoRAP notifications for 2012 to ECHA as soon as possible. COM expressed its concerns at the low number of notifications and indicated the need to further discuss this issue with MSCAs.

In the discussion, SECR replied to questions that although REACH requires ECHA to submit to MSs a draft annual update to the CoRAP by 28 February each year, ECHA's intention is to adopt and publish already the final CoRAP by this date. According to the plans, the first final CoRAP should be published by 28 February 2012 while the first annual update by 28 February 2013. It was also clarified that normally the notifying MS will be responsible for the evaluation of the substance if it is placed on the final CoRAP.

Notifications from MSs do not necessarily need to follow the CoRAP criteria, but a risk based justification is needed robust enough for the MSC to give an opinion. CoRAP criteria should be considered rather open and they can cover many concerns but probably not all. They will be further developed each year based on the experience gained. However, now ECHA's main focus is more on the timely finalisation of the first final CoRAP than on further refinement of CoRAP criteria for 2012. Lessons learned during the current CoRAP process will be used for refinement of criteria for 2013. How this rolling refinement process should be done in the future will still need to be discussed with MSs. One of the first steps of this discussion will take place already in the next Substance Evaluation Workshop in May 2011.

SECR clarified to a question of a stakeholder observer that the Substance Evaluation Workshop in May 2011 was meant to be a rather technical meeting for MSs, COM and ECHA and stakeholders were not meant to be invited. However, ECHA wants to

ensure maximum transparency and therefore the main outcome documents will be provided for stakeholders' information as well.

The Chair concluded that it will be important to discuss at the Workshop also the justification for CoRAP notifications as this issue will be probably one of the main issues in the MSC discussions when preparing the MSC opinion on the first draft CoRAP. Discussions on other CoRAP related issues also will continue on the Workshop as well as at the MSC-18 meeting.

In its second presentation, SECR described the process and the rationale behind how substances were identified as CoRAP candidates by ECHA using the CoRAP selection criteria. As screening methods, flagging during dossier evaluation IT tools (ProSP and CASPER) and expert verification were used. It was introduced how the different selection criteria were applied by the IT tools. It was explained which exclusion criteria how and on which basis were applied. As a result of the screening, 220 substances were identified as possible candidates for the CoRAP based on potential human health risk, environmental risk and endocrine disruptor properties. These substances were then further screened from regulatory efficiency point of view.

It was emphasised by SECR that many steps of the current screening process were determined by the tight timeframe available for the preparation of the first CoRAP. After screening, by the time of the MSC-17 meeting 49 CoRAP candidate substances were about to be proposed by ECHA and the screening is still ongoing. In the future, where more time and more experience will be available, a more comprehensive (and more resource consuming) screening can be made, resulting in a longer list of CoRAP candidate substances.

Replying to questions, SECR explained that substances on which a testing proposal examination is performed currently were excluded from the screening because in ECHA's view their substance evaluation should be postponed until the required tests are available. NONS were excluded they are very difficult to screen with IT tools; this is due to difficulties with the migration of data from the New Chemicals Database to REACH-IT (IUCLID) and differences in the reporting standards. UVCB substances were excluded because in many cases their substance identity is not clear. Inorganic substances in relation to PBT properties were not screened because it would have been very difficult and time consuming for MSCAs to evaluate them. Risk characterisation ratio (RCR) being close to one was not used as an absolute selection criteria because this can be so for several reasons and time did not allow to go into very detailed analysis. It was also highlighted that the same selection criteria were applied by the IT tools and in the flagging of substances during dossier evaluation. SECR pointed out that the current exclusion criteria were established on a very pragmatic way and time and IT applicability played a very important role in this regard. The groups of substances excluded now will be included in the screening for the next selections.

Furthermore, SECR pointed out that NONS with a CA decision requesting further information are regarded as being chosen (Article 135(2) of REACH) and they go automatically to the CoRAP. The same applies to the substances evaluated under Regulation (EEC) 793/93 for which further information has been requested (Article 136(2) of REACH). Similarly, substances notified to ECHA for substance evaluation on the basis of Article 45(5) of REACH with justification will go automatically to the draft CoRAP, without being further ranked by ECHA from the candidate substances. However, if the substance is notified by MSCAs without justification, it will go through the ranking procedure before possibly being placed on the draft CoRAP.

One MSC member called for close cooperation in substance evaluation among MSCAs to avoid duplication of work and to reach the best use of resources. Stakeholder observers were concerned of the low numbers of CoRAP candidate substances proposed by ECHA.

The Chair concluded that although very ambitious goals can be set, the substance evaluation process is just in the starting phase now and number of substances will hopefully grow with more experience gained.

b. Planning of substance evaluation work in MSC - Time plan for MSC work on providing the opinion on CoRAP

SECR introduced the detailed schedule for MSC on providing its opinion on the first draft CoRAP. MSC agreed upon and adopted the time plan.

Item 8 – SVHC identification

a) New Annex XV proposals for identification of SVHC

1) Brief introduction of Annex XV proposals for identification of SVHCs, the comments received and the respective work plan

SECR gave a presentation analysing the comments received by ECHA during the public consultation on the eight Annex XV proposals for substances to be identified as SVHC for which the consultation closed on 7 April 2011. It was mentioned that due to an administrative error the public consultation for cobalt dichloride needed to be restarted and that it will end on 3 May. Therefore, in case the agreement seeking process of MSC would be prompted due to comments challenging the addition of another hazard on the existing Candidate List entry for cobalt dichloride, MSC will need to address the case in the 18th MSC meeting and not by written procedure.

Reacting to questions, SECR confirmed that inclusion of a substance in the Candidate List does not necessarily require an authorisation process (inclusion in Annex XIV) to be commenced as follow-up nor does such listing preclude imposition of restriction on the substance. However, if a substance has been included in Annex XIV, new restrictions shall not be imposed on the use of a substance arising from the intrinsic properties specified in Annex XIV. SECR also confirmed that the Candidate List is normally updated twice a year.

2) Selection of dossiers for identification of SVHC's in written procedure

Taking into account the results of the analysis of the comments received, SECR proposed to seek unanimous agreement in written procedure for the following four substances: 2-ethoxyethyl acetate, strontium chromate, 1-methyl-2-pyrrolidone and 1,2-benzenedicarboxylic acid, di-C6-8-branched alkyl esters, C7-rich.

The written procedure will be launched on 10 May and closed on 20 May 2011.

Unanimous agreement will be sought on 2-benzenedicarboxylic acid, di-C7-11-branched and linear alkyl esters and hydrazine at the MSC-18 meeting. For these two substances, comments questioning the description and scope of the substance identity have been received during the public consultation. Therefore a meeting discussion seemed to be necessary. In case MSC involvement would be prompted by comments

on cobalt dichloride, MSC will need to address cobalt dichloride in the 18th MSC meeting as well.

The final decision on the procedures will be taken by SECR based on a detailed assessment of the comments received during public consultation and from the MSCAs.

MSC agreed on the proposed way forward.

b) Update on topics related to SVHC identification - Update on REACH Annexes

The agenda item was postponed to MSC-18 meeting.

Item 9 – Manual of Decisions (MoD)

- **Discussion on next new entries for the MoD**

SECR introduced text proposals for two issues to be included in MoD. After discussion, due to lack of quorum, the adoption of the two entries was postponed to MSC-18 meeting.

Item 10 – Work related to prioritisation and inclusion of substances in Annex XIV

a) ECHA's work plan for the 3rd draft recommendation for Annex XIV and time plan for MSC work

SECR presented a detailed time schedule regarding ECHA's development of the 3rd draft recommendation for inclusion of substances in Annex XIV and for MSC to provide its opinion on this recommendation. In 2011 the same approach will be followed as in 2010. The opinion is scheduled to be adopted by MSC at MSC-21 on 7-9 December 2011.

MSC agreed upon and adopted the detailed schedule of the MSC process without any changes.

b) Discussion on the prioritisation of substances from the Candidate List

SECR introduced the draft results of prioritisation of substances from the Candidate List for ECHA's 3rd recommendation. The same prioritisation methods were used as in the 2nd recommendation process: a verbal argumentative and a scoring approach combined with regulatory effectiveness considerations. Information on the substances was gathered from registration dossiers and from the same sources as in 2010 (Annex XV dossiers, comments received in the public consultation, reports prepared by external consultants). After consideration of the available information and the criteria, ECHA was proposing to prioritise and to include in the draft recommendation for public consultation the following 13 substances: trichloroethylene, chromium(VI) compounds (seven substances) and cobalt compounds (five substances). Available information on 2-methoxyethanol and in particular uncertainties in the volumes used in the scope of authorisation and in the wide-dispersiveness of uses had pointed towards but not allowed to draw firm conclusions that this substance should not be prioritised. Therefore, SECR is looking for further information to reduce the uncertainties and to be able to apply the prioritisation criteria in a sound manner. On borates (three substances) SECR presented only interim results of the prioritisation work and noted that the assessment of available information is still on-going. On the basis of

currently available information, in ECHA's view other substances on the Candidate List (as of December 2010) do not qualify for prioritisation in this prioritisation round.

The Chair opened the detailed discussion addressing each substance of the current Candidate List.

Trichloroethylene
No issues for discussion were raised.

Chromium(VI) compounds ((1)chromium trioxide, (2) sodium dichromate, (3) potassium dichromate, (4) ammonium dichromate,(5) potassium chromate, (6) sodium chromate, dichromate, (7)chromic acid, oligomers of chromic acid and dichromic acid, dichromic acid)
SECR clarified reacting to a remark as to whether it would be possible to apply for authorisation of uses of individual substances out of a group (e.g. chromium VI compounds) that applications for authorisation are substance based. Therefore application of the "grouping approach" for identifying groups and prioritising them together should not cause problems in the authorisation phase. The grouping approach is used in the prioritisation phase for treating similar substances together and thus avoiding the possibility to substitute the substance subject to authorisation with another closely related substance. No other issues were raised for discussion.

Cobalt compounds ((1) cobalt(II)sulphate, (2) cobalt(II)chloride, (3) cobalt(II)dinitrate, (4) cobalt(II)carbonate, (5)cobalt(II)diacetate)
SECR stated reacting to questions of an observer and two MSC members that all information from registration dossiers was taken into account when volumes and releases from uses for the five cobalt compounds were considered. The same observer also questioned how cobalt as an essential element can be considered as a non-threshold substance in the Annex XV dossiers. He also pointed out some inconsistencies in Annex XV dossiers of different cobalt compounds concerning intermediate uses and description of uses resulting in inclusion in matrices. He further asked ECHA to delete references from Annex XV dossiers on future increasing market shares. One MSC member questioned whether the five cobalt compounds in question might really be capable to replace each other in their uses.

SECR replied regarding intermediate use that registration dossiers often do not provide enough technical details to decide on the nature of a certain use. With regard to the uses resulting in inclusion of the substance in matrices there may be completely different technical processes involved, which are not necessarily the same in the different cobalt dossiers. However, some of the cobalt compounds are used as dryer or as pigment in colours. SECR also stated that based on the use information available in the registration dossiers, mutual substitution of the five cobalt compounds appears to be possible for the majority of their uses and that from this perspective application of the grouping approach is deemed justified.
Considering the complexity of different industrial uses of cobalt compounds, two MSC members proposed a technical meeting with industry on the role of cobalt (and other metallic compounds) in glass, ceramic and frits production. Industry observers interested in the issue warmly welcomed the idea. Details of a possible meeting will be considered further by ECHA, MSC members and industry observers.

Borates ((1)disodium tetraborate (2) boric acid (3) tetraboron disodium heptaoxide, hydrate)
The representative of EBA (European Borate Association) questioned the proportionality of a prioritisation of boron compounds for Annex XIV. He stated that only 10 percent of the volume of boron compounds on the EU market would fall under authorisation because the other 90 % are either uses as intermediate or are resulting in products in which the boron compounds are contained in concentrations below the SCLs. He also argued that the boron compounds represent a relatively low hazard, which also can be inferred from their relatively high SCLs. Volumes allocated to uses potentially falling under authorisation are low and exposure from these uses are also low.

Furthermore, he expressed his sympathy for ECHA's grouping approach for boron compounds and pointed out that some other boron compounds which could relatively easily substitute the compounds in question now are not covered by the current grouping.

SECR replied that other similar boron compounds can not be part of the current group if they are not included in the current Candidate List. All boron compounds currently on the Candidate List are covered by the current grouping approach.

2- ethoxyethanol and 2-methoxyethanol
An observer expressed his concerns as to why these two substances are not proposed for prioritisation by ECHA. He argued that both substances are reprotoxic and causative agents for occupational diseases as it is recognised in a COM document listing occupational diseases and their causes. Another observer pointed out that the currently applied conditions for uses of these substances are not the same that are listed in the document cited. SECR emphasised that the same prioritisation criteria are applied for all substances on the Candidate List. If application of these criteria justifies, these substances can also be prioritised.

Aluminosilicate and zirconia-aluminosilicate refractory ceramide fibers (RCFs)
The MSC member representing the MSCA having prepared the Annex XV proposal for these substances informed the meeting that they would prepare a new Annex XV dossier on substances which have been registered as RCFs so far but not covered by the current Candidate List entry.

For the other substances currently on the Candidate List, including acrylamide (that was left out of the document because of an editorial mistake) no discussion points were raised. SECR informed that all currently available information has been examined but none of these substances qualified for prioritisation for the time being. All meeting participants were invited to submit their written comments on ECHA's document concerning prioritisation of substances from the Candidate List by 21 April 2011. SECR will consider the comments and based on them and any available information will further refine the document for further discussion in MSC-18 meeting.

c) Discussion on the appointment of Rapporteur and Working Group

SECR reported that so far two MSC members volunteered to be a rapporteur for the next preparation of MSC opinion on ECHA's 3rd draft recommendation. Eight additional MSC members indicated their willingness to be member of the working group supporting the rapporteur. The appointment of the rapporteur and members of the working group will take place at the MSC-18 meeting.

MSC took note of the oral report.

Item 11 – Report from other ECHA bodies and activities – Feedback from Management Board meeting

SECR reported on the last meeting of the Management Board (MB) on 24-25 March 2011. From MSC point of view, the most relevant issue was the follow-up of the discussion which took place in the previous MB meeting concerning the increasing workload of Committees. MB was provided now with ideas how to tackle this high workload such as more support for Committee members, increased efficiency via more use of ICT tools and written procedures, better structuring of meetings, streamlining of ECHA' internal procedures, equal share of work within a Committee and reaching the maximum capacity of the ECHA Secretariat.

MB welcomed the proposals and concluded that based on the proposals, the Committees have to consider and implement practical measures to increase efficiency of their work. Later on, the results should be reviewed and presented to MB.

The Chair pointed out that currently and for the near future, the key issue for MSC is how to reduce the number of proposals for amendment for dossier evaluation draft decisions and consequently the number of draft decisions to be handled by MSC. Better communication between ECHA and MSCAs and also better preparation of meetings should be considered. Following the conclusions of MB, SECR will prepare a paper on this topic for discussion in MSC-18.

Item 12 – Any other business

SECR informed that the German CA has recently submitted a letter to ECHA raising questions related to dossier evaluation. SECR will prepare a reply to these questions and present them in the MSC-18 meeting.

With the approval of the submitter, SECR will make the letter available to MSC on MSC CIRCA.

Item 13 - Adoption of conclusions and action points

The conclusions and action points of the meeting were provisionally adopted after discussion (see Annex IV). As the quorum was not any more present the conclusions and action points will be adopted together with the minutes.

Signed

Anna Liisa Sundqvist
Chair of the Member State Committe

Members/Alternate members
ANDRIJEWSKI, Michal (PL)
BIWER, Arno (LU)
COSGRAVE, Majella (IE)
DOUGHERTY, Gary (UK)
DUNAUSKIENE, Lina (LT) (second day)
FANGUET, Céline (FR) (alternate member)
FINDENEGG, Helene (DE)
FLODSTRÖM, Sten (SE)
HEISKANEN, Jaana (FI)
HUMAR-JURIC, Tatjana (SI)
KORENROMP, Rene (NL)[1]
KOUTSODIMOU, Aglaia (EL)
KULHANKOVA, Pavlina (CZ)
KYPRIANIDOU-LEONTIDU, Tasoula (CY)
LUDBORZS, Arnis (LV)
LULEVA, Parvoleta Angelova (BG)
MARTIN, Esther (ES)
MARTINS, Ana Lilia (PT) (alternate member)
MIHALCEA-UDREA, Mariana (RO)
PEDERSEN, Finn (DK) (alternate member)
PISTOLESE, Pietro (IT)
RÁCZ, Éva (HU) (alternate member)
REIERSON, Linda (NO)
RUSNAK, Peter (SK)
STESSEL, Helmut (AT)
VANDERSTEEN, Kelly (BE)
VESKIMÄE, Enda (EE)

Representatives of the Commission
BINTEIN, Sylvain (DG ENV)
GARCIA JOHN, Enrique (DG ENTR)
KOBE, Andrej (DG ENV)
Observers
ANNYS, Erwyn – CEFIC
BOHDAN, Dmytrasz – CONCAVE
CASALENGO, Carlotta - ECEAE
DOOME, Roger – IMA-Europa, EBA (European Borates Association - only for agenda item 10b)
LIESIVUORI, Jyrki - EUROTOX
NAMEROFF, Tamara - ECETOC
MUSU, Tony – ETUC
REINEKE, Ninja - WWF
WAETERSCHOOT, Hugo - EUROMETAUX
ECHA staff
BALOGH, Attila
BERCARU, Ofelia
BROERE, William
CARLON, Claudio
DE BRUIJN, Jack
DE WOLF, Watze
DE RAAT, Karel
FEDTKE, Norbert
HEIKKILA, Minna
HUUSKONEN, Hannele
KARHU, Elina
KARJALAINEN, Antti
KNIGHT, Derek
LEPPER, Peter
MALM, Jukka
MULLER, Birgit
NAUR, Liina
PREVEDOUROS, Konstantinos
ROCKE, Timo
RUOSS, Jurgen
SUNDQUIST, Anna-Liisa
VAHTERISTO, Liisa
YLÄ-MONONEN, Leena

[1] Not present during agreement seeking on CCH002/2011, CCH003/2011 and CCH004/2011 (Item 6d)

Proxy's

-

Experts and advisers to MSC members

ANDERSSON, Lars (expert to FLODSTRÖM, Sten)

ARTUS, Hannela (expert to VESKIMÄE, Enda)
ATTIAS, Leonello (expert to PISTOLESE, Pietro)
GRACZYK, Anna (expert to ANDRIJEWSKI, Michal)
KOZMIKOVA, Jana (expert to KULHANKOVA, Pavlina)
MICHEL, Cécile (expert to FANGUET, Céline)
SCHWAGLER, Mark (expert to FINDENEGG, Helene)
SCIMONELLI, Luigia (adviser to PISTOLESE, Pietro)
TRAAS, Theo (expert to KORENROMP, Rene)
TALASNIEMI, Petteri (adviser to HEISKANEN, Jaana)

Case owners (attending only to agenda item 6c, case CCH002/2011):
A representative of the registrant
An accompanying expert of the registrant

Apologies:
CAMILLERI, Tristan (MT)
DRUGEON, Sylvie (FR)
DEIM, Szilvia (HU)
PALMA, Maria do Carmo (PT)
TYLE, Henryk (DK)
DUNAUSKIENE, Lina (LT) (first day)

III. Final agenda

ECHA/MSC-17/2011/A/17 Final agenda

Final Agenda
17th meeting of the Member State Committee

13-14 April 2011
ECHA Conference Centre
Annankatu 18, in Helsinki, Finland

13 April**: starts at 9:30**
14 April**: ends at 17:00**

Item 1 – Welcome and Apologies

Item 2 – Adoption of the Agenda

MSC/A/017/2011
For adoption

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

Item 4 – Administrative issues

a) Results and follow-up from the satisfaction survey

ECHA/MSC-17/2011/013

b) Annual declarations for 2011

For information

Item 5 – Draft minutes of the MSC-16

- Adoption of the draft minutes of MSC-16

MSC/M/16/2011
For adoption

Item 6 – Dossier evaluation[1]

Partly closed session for 6c, closed session for 6d

a) General topics

1. Update on extended one generation reproduction toxicity test[2]

2. Assessment factors deviating from guidance[2]

3. Status report on ongoing evaluation work

ECHA/MSC-17/2011/017

For information

b) Written procedure report on seeking agreement on two draft decisions on dossier evaluation

For members only: ECHA/MSC-17/2011/011

For information

c) Introduction to and preliminary discussion on draft decisions on compliance checks (and a testing proposal) after MS-CA reactions *(Session 1, partly closed)*

ECHA/MSC-17/2011/001

For discussion followed by agreement seeking under 6d:

Open session

- CCH 004/2011 – 12-hydroxyoctadecanoic acid, reaction products with 1,3-benzenedimethanamine and hexamethylenediamine

ECHA/MSC-17/2011/002-003

- CCH 003/2011 – TACT

ECHA/MSC-17/2011/005-006

Closed session

- CCH 002/2011 – HS3520

ECHA/MSC-17/2011/008-009

For information and discussion

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

- CCH 004/2011 – 12-hydroxyoctadecanoic acid, reaction products with 1,3-benzenedimethanamine and hexamethylenediamine

ECHA/MSC-17/2011/002-004

- CCH 003/2011 – TACT

ECHA/MSC-17/2011/005-007

- CCH 002/2011 – HS3520

[1] Indicative time plan for 6c is Day 1 (1:30 pm - 5 pm), for 6d Day 2 (morning)
[2] Presentation

For agreement

Item 7 – Substance evaluation

a) Update on the work on CoRAP development

For information

b) Planning of substance evaluation work in MSC
Time plan for MSC work on providing the opinion on CoRAP

ECHA/MSC-17/2011/012
For discussion and decision

Item 8 – SVHC identification

a) New Annex XV proposals for identification of SVHC

1) Brief introduction of Annex XV proposals for identification of SVHC, the comments received and the respective work plan

For discussion

2) Selection of dossiers for identification of SVHC's in written procedure

ROOM DOCUMENT
For discussion& decision

b) Update on topics related to SVHC identification

- Update on REACH Annexes

For information

Item 9 – Manual of Decisions (MoD)

- Discussion on next new specific entries and new topics for the MoD

ECHA/MSC-17/2011/016
For discussion & decision

Item 10 – Work related to prioritisation and inclusion of substances in Annex XIV

b) ECHA's work plan for the 3rd draft recommendation for Annex XIV and time plan for MSC work

ECHA/MSC-17/2011/014
For discussion & decision

b) Discussion on the prioritisation of substances from the Candidate List

ECHA/MSC-17/2011/015
For information and discussion

c) Discussion on the appointment of Rapporteur and Working Group

For discussion

Item 11 – Report from other ECHA bodies and activities

- Feedback from MB meeting

For information

Item 12 – Any other business

- Suggestions from members

For information

Item 13 – Adoption of conclusions and action points

- Table with action points and decisions from MSC-17

For adoption

IV. Main conclusions and action points

MSC-17, 13-14 April 2011
(Provisionally adopted at the MSC-17 meeting)

CONCLUSIONS / DECISIONS / MINORITY OPINIONS	ACTIONS REQUESTED
5. Adoption of the minutes of MSC-16	
The confidential and non-confidential version of the minutes was adopted without any changes made during the meeting.	MSC-S to upload the adopted versions on MSC CIRCA and to publish the non-confidential version of the minutes on the ECHA website.
6. Dossier evaluation **6a) General topics**	
(1) Update on extended one generation reproduction toxicity test (EOGRTS)	
MSC took note of ECHA's presentation. The presentation reflected a technical short-term solution to deal with EOGRTSs. The policy discussion will be continued on COM level.	SECR to consider different options how to deal with the EOGRTSs in testing proposals and compliance checks.
(2) Assessment factors deviating from guidance	
MSC took note of ECHA's presentation and supported ECHA's view that deviation from default assessment factors should always be justified case-by-case in registration dossiers and can be addressed in draft decisions. Industry seems to challenge the consensus laid down in ECHA Guidance concerning assessment factors.	ECHA to continue its current practice of asking for justification in case of deviation from default assessment factors.
(3) Status report on ongoing evaluation work	
MSC took note of the report of ECHA.	
6b) Written procedure report on seeking agreement on two draft decisions on dossier evaluation	
	MSC-S to upload in MSC CIRCA the final ECHA decisions and agreements on cases CCH 001/2011 and TPE 001/2011.
6c) Introduction to and preliminary discussion on draft decisions on compliance checks after MSCAs' reactions *(Session 1, closed session except for CCH 002/2011)* **6d) Seeking agreement on draft decisions on compliance checks when amendments were proposed by MSCAs *(Session 2, closed)***	
<u>CCH 004/2011</u> **Discussion (6c, Session 1)** MSC discussed the case based on ECHA's draft decision, the proposed amendments of MSCAs and the registrant's comments on the proposed amendments. The only change sug-	

CONCLUSIONS / DECISIONS / MINORITY OPINIONS	ACTIONS REQUESTED
gested by MSC members to the draft decision for discussion in Session 2 (agreement seeking) was the extension of the deadline for the prenatal developmental toxicity study from 18 to 24 months. MSC concluded that the combined requirements of REACH and Directive 67/548/EEC do not allow requiring a two-generation reproductive toxicity study for the case at hand. ECHA however has recommended the registrant to fill in the data gap regarding reproductive toxicity (fertility) in its quality observation letter. **Agreement seeking (6d, Session 2)** MSC reached unanimous agreement on ECHA's draft decision (as amended in the meeting). MSC adopted the formal agreement. **<u>CCH 003/2011</u>** **Discussion (6c, Session 1)** MSC discussed the case based on ECHA's draft decision, the proposed amendments of MSCAs, registrant's comments on the proposed amendments. No changes on the draft decision as originally submitted to the registrant were suggested by MSC members for further discussion in Session 2 (agreement seeking). **Agreement seeking (6d, Session 2)** MSC reached unanimous agreement on ECHA's draft decision (as referred to MSC). MSC adopted the formal agreement. **<u>CCH 002/2011</u>** **Discussion (6c, Session 1)** MSC discussed the case based on ECHA's draft decision, the proposed amendments of MSCAs and the registrant's comments on the proposed amendments. The following change to the draft decision was suggested by MSC members to be discussed in	

CONCLUSIONS / DECISIONS / MINORITY OPINIONS	ACTIONS REQUESTED
Session 2 (agreement seeking): • As quantitative information on the rate of hydrolysis of the substance was not available/clear from the registration dossier, the performance of the bioaccumulation study in aquatic species would depend on additional information that the registrant must provide. This information refers to exposure consideration, to the exact rate of hydrolysis and the bioaccumulation potential of any hydrolysis products. **Agreement seeking (6d, Session 2)** MSC reached unanimous agreement on ECHA's draft decision including the revised wording when referring to the bioaccumulation test. MSC did not introduce other amendments on the draft decision. MSC adopted the formal agreement.	MSC-S to upload in MSC CIRCA the final ECHA decisions and agreements on cases CCH 002/2011, CCH003/2011 and CCH004/2011.
7. Substance evaluation **7a) Update on the work on CoRAP**	
MSC took note of the two reports of ECHA.	ECHA to prepare the discussion on the process of further refinement of CoRAP criteria for the future preparation of CoRAPs (at the workshop on substance evaluation on 23-24 May 2011).
7b) Planning of substance evaluation work in MSC - Time plan for MSC work on providing the opinion on CoRAP	
MSC agreed upon and adopted the detailed time plan of the process of providing the opinion of MSC on CoRAP.	
8. SVHC identification **8a) New Annex XV proposals for identification of SVHC** **1) Brief introduction of Annex XV proposals for identification of SVHC, the comments received and the respective work plan**	
MSC took note of the presentation given.	
2) Selection of dossiers for identification as SVHC in written procedure	
MSC agreed on the SVHC Annex XV dossiers to be agreed on in written procedure as proposed by SECR.	
8b) Update on topics related to SVHC identification - Update on REACH Annexes	
Postponed to MSC-18.	

CONCLUSIONS / DECISIONS / MINORITY OPINIONS	ACTIONS REQUESTED
9. Manual of Decisions (MoD) - Discussion on next new entries for the MoD	
MSC postponed the decision on the two entries proposed for MSC-18.	
10. Work related to prioritisation and inclusion of substances in Annex XIV **10a) ECHA's work plan for the 3rd draft recommendation for Annex XIV and time plan for MSC work**	
MSC agreed upon and adopted the detailed time plan of the process of ECHA's 3rd recommendation.	
10b) Discussion on the prioritisation of substances from the Candidate List	
MSC took note of the presentation.	SECR to consider the comments provided in the discussion in the MSC-17 meeting. MSC members to submit their further comments in writing on ECHA's document concerning prioritisation of substances from the Candidate List by 21 April 2011. ECHA to further refine the document based on the comments received and available information for further discussion in MSC-18 meeting.
10c) Discussion on the appointment of Rapporteur and Working Group	
MSC took note of the outcome of the invitation to express interest to act as Rapporteur and working group member.	
11. Report from other ECHA bodies and activities – Feedback from Management Board meeting	
MSC took note of the report.	MSC to consider how to handle the increasing workload in MSC particularly due to dossier evaluation work. MSC-S to prepare a paper on this topic for discussion in MSC-18.
13. Adoption of conclusions and action points	
The conclusions and action points were adopted.	MSC-S to upload the conclusions and action points on MSC CIRCA together with the presentations delivered at the meeting, by 15 April 2011.