MSC/M/01/2010 Final
Adopted at MSC-12, 9 June2010

Final Minutes

Minutes of the 11th Meeting of the Member State Committee (MSC-11)
28-29 April 2010

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 11th meeting of the Member State Committee (MSC).

For this 11th meeting, apologies were received from six MSC members. Five of them had notified the Chair as to their proxies (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 Secretariat (SECR), with the movement of item 13 right after item 6 of the agenda. The Chair proposed to include one information item under AOB regarding the involvement of the MSC in identification of biocidal active substances with PBT properties. The final Agenda is presented in Part III 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 – Adoption of the draft minutes of the MSC-10

SECR reminded the members that the MSC-10 minutes were adopted via written procedure on 22 February 2010 and that the non-confidential version is now published on the ECHA website. As an introduction, SECR explained that as regards the draft minutes for confidential sessions of the MSC-10 meeting, two versions of minutes for those items were drafted. The version of the minutes with the Annex covering some details of the closed session was after adoption placed on CIRCA for the members only.

The action points from the MSC-10 meeting were referred to by SECR. All points had either been carried out or were well on track.

Item 5 - Administrative Issues

a. Results and follow up from satisfaction survey

SECR presented the results of the satisfaction survey to the Committee both in the form of a meeting document and presentation during the meeting. It was concluded that the SECR will proceed with the action points as proposed. Some action points were already put into effect during the preparation phase of the MSC-11 meeting. It was announced that proposals for further improvements are always welcome and that

such survey will be repeated in the end of the year by using the same type of questions so as to be able to derive trends over the years.

b. Annual declarations for 2010

SECR reminded the Committee to hand in the annual declaration and that such declarations of interest will be published on the ECHA website.

c) Use of CIRCA interest groups

SECR delivered a presentation to clarify some issues on the use of CIRCA interest groups. The need for such came out from the results of the survey. The presentation explained the difference between ECHA's different platforms – encrypted (more secure) and non-encrypted, as well as the different interest groups and who leads such groups.

No comments were made by the members on this presentation. The Chair mentioned that there will be the development of a new extranet to replace CIRCA however the timelines when this will be available are not yet known. The members were offered to approach the SECR if they have any problems on the use of CIRCA.

Item 6

- ***Appointment of alternates, modification on handling of minority opinions, next review of the Rules of Procedure***

The SECR explained that the Rules of Procedure (RoPs) were discussed in the Management Board (MB) in its March meeting. The revised Article 5 regarding term of office and replacement of members was approved by the MB with the inclusion of the possibility for Member States (MS) to appoint an alternate member to the MSC. Following this approval ECHA sent an invitation to the MSs to appoint an alternate member through the Permanent Representation (Perm.Rep.). It was explained that responses to this invitation need to be sent through the Perm.Rep. and that there is no time limit.

The Chair clarified that the MSC member will need to inform the SECR about his/her replacement by the alternate for a particular meeting. The alternate member can still be accompanied by an expert and advisor during the meeting. However, when the alternate is accompanying the member during a meeting, he/she can only be reimbursed when in the capacity of an invited expert.

The SECR further explained that the MB had approved the RoPs subject to removing a sentence in Article 19(6) which would have meant that minority positions were part of the MSC opinion. The MSC agreed with the deletion of the sentence as it never was the intention to provide opinions where minority and majority views are mixed creating confusion.

The Chair informed the MSC that during the discussions in the MB the issue on the appointment of co-opted members and their voting rights was raised. The Chair

reminded the MSC that this was already raised before at the MSC. During the MSC-11 meeting, this issue was raised by a member of the MSC. This member stated that as a point of principle, because the MSC is a committee with members appointed by the MS, the co-opted members are really advisors and do not represent a MS. So it seems to be logical that even though their input is highly appreciated, yet they do not have voting rights because the voting rights are to the members appointed by MSs. So it was proposed that before the MSC appoints any co-opted members the voting rights for co-opted members will be changed in the RoPs.

The Chair concluded that there was clear support to this proposal and the SECR will explore this issue of restricting the voting rights of co-opted members together with the Legal Affairs Unit and come back to the MSC with the outcome of the discussion. If the voting rights of co-opted members can be restricted, the RoP would need to be revised. However it was concluded that such revision of RoPs will not take place before next year.

Item 7 – Evaluation tasks

a. ***Introduction and preliminary discussion on draft decisions on a testing proposal and compliance checks. (Closed session)***

b. ***Oral report from the ECHA Workshop on testing proposals (27-28 April)***

ECHA organised on 27-28 April an informal workshop on examination of testing proposals. The workshop was open to MSC members, MSCAs, European Commission and ECHA secretariat. About 65 delegates from the MS, EEA, DG ENTR and DG ENV participated. The examination of testing proposals (TP) process was discussed in the light of an actual TP dossier and presentations on COM, ECHA and MS views.

The SECR gave an oral report of the discussions and proposed way forward of the workshop. SECR explained that the aim was to agree on certain general aspects, so that these need not to be discussed in each individual TP draft decision in the MSC. There is a need to streamline the work of ECHA secretariat and the MSC in view of the increasing number of testing proposal evaluation (TPE) draft decisions to be prepared and discussed in near future.

Especially the scope of TPE and its relation to compliance check (CCH), the tiered testing strategies and use of read across / grouping / QSAR were discussed.

As regards the scope of the TPE and the relation to CCH, the provisions of article 40 and 41 and the efficient use of resources were discussed. It was recommended that the relationship between TPE and CCH should also reflect the overall priorities of CCH.

The MS past experiences on tiered testing strategies, the legal provisions of REACH and the inherent resource question were discussed. When building intelligent testing strategies adequate documentation in the dossier was considered important.

For the use of read across / grouping / QSAR it was acknowledged that such non-testing methods should be used as widely as possible while ensuring that there is reliable enough information available for ensuring a high level of protection of human health and the environment. ECHA already provides guidance, practical guides and guidance in the nutshell on these methods. The acceptability of such information is based on expert judgement and has been done case-by-case. Nevertheless the consistency of such decisions needs to be ensured. The following actions were proposed:

- the MSC is proposed to establish a working group (WG) that would look at the individual draft decisions submitted to MSC. Based on the experiences of this case-by-case analysis the WG would then also assess what kind of more general principles could be developed to ensure consistency.
- the Manual of Decisions of the MSC was proposed to be used to record the principles used
- Workshops between the experts, MSC and RAC will be organised to be able to continue discussion on the use of alternative methods for different regulatory purposes, and also for ensuring consistent approaches
- awareness raising on the state-of-the-art of the use of these methods would be organised. A workshop is planned to take place later in 2010.

The importance of communicating the general evaluation process principles to the registrants was underlined.

c. Organisation of evaluation work in the MSC: Possible establishment of a Working Group (WG)

The Chair opened this agenda item by explaining that since the number of draft decisions is expected to keep on increasing even up to 10 – 15 draft decisions per year the SECR saw the need to establish a WG to discuss in detail the legal aspects and the scientific part of the draft decisions that are referred to the MSC. She explained that perhaps the plenary is not the right place for such a discussion. Such a WG would enable the MSC to come to a faster conclusion during the plenary. A WG would be more informal and easy for discussion. The proposal presented during the meeting by the SECR was for the WG to be composed of volunteering members who can join on an ad hoc basis, based on the topics discussed. Invited experts are also welcome to join the WG.

The members acknowledged the fact that a group of some form is needed for the members to meet and discuss in a more informal setting the draft decisions referred to the MSC, however, they were not in agreement of having a standing working group where the composition is fixed. Especially since there is already the idea of having a WG for another MSC process, and the resources of the Member State Competent Authorities (MSCAs) are limited. There were also proposals for having a different WG per case. However, it was explained by the Chair that such would be very difficult to establish from a practical point of view due to the limited time available for agreement seeking set by the legislation. However, the Chair agreed that the risk of having a circle of members discussing the different cases should be avoided. That is why, an open participation to this working group is being proposed by the SECR. This implies that different member, experts or advisers can join the WG at any time by simply notifying the SECR.

The members showed concerns that the WG would in the end have decision making powers. However, again the Chair explained that this is not the intention, since the decision making powers still remain with the MSC. This would also not effect discussions in the plenary if for example a member was not able to participate in the WG discussions and then has strong views that want them to be discussed during the plenary.

Different suggestions and views were expressed on how to best organise the practical work of the Committee including involvement of the CAs earlier in the evaluation process thus avoiding CA proposals for amendments, as well as, keeping all the preparatory discussions within the whole Committee resulting in longer meetings, as necessary.

The Chair clarified that stakeholder and case-owner participation is still open due to pending discussion at the MB on this issue.

The Chair concluded that in general there was a consensus that some structure is needed for the preparation of the plenary discussion and for making the MSC more efficient. The discussion forum would need to be open for all those that would want to be involved which could result in having an extra day of the plenary, but organised in a more informal setting. However, this needs to be further discussed in the June meeting, and until then the MSC members would need to comment on the draft mandate of the proposed WG and/or to propose possible alternative approaches by 21 May 2010.

d. Status report from other ongoing evaluation work

The SECR gave an overview of the status of the evaluation work as in the end of March. The status was as follows: 26 dossiers were subject for compliance check, 14 Testing Proposals were received out of which 12 Testing Proposals (TP) were being examined. 20 cases for Compliance Check (CCH) were concluded out of which 10 were concluded with a communication letter and the rest without any actions. Out of the 14 Testing Proposals, 4 Draft Decisions were drafted. Agreement was reached on one of these draft decisions in the December 2009 MSC meeting. By the end of March there were 874 dossiers available for evaluation which excludes on-site isolated intermediates to which evaluation is not needed.

It was explained that it does not mean that those dossiers that lead to no administrative action were necessarily perfect, but that the compliance check could have been targeted to some parts of the dossier or else the shortcomings found were not related to safe use. Thus, the dossiers were not considered incompliant leading to administrative actions at this point of time. It would always be possible to open a new compliance check on a dossier if it is seen necessary.

Some members asked ECHA to better inform the MSCAs on the parts of the dossiers that were evaluated. ECHA explained that if ECHA performs a special kind of targeting on the dossier then it would be mentioned in the list that is sent to the MSCAs on the CIRCA site.

A stakeholder observer asked for a clarification on the new Testing Proposal approach brought up in the presentation by SECR. SECR explained that this was a topic also discussed during the TP workshop. It is a procedural and legal issue about the relationship between TP and CCH. When examining a TP other issues in the dossier

need to be looked at to be able to get a full picture about the data gaps, in particular on endpoints related to the testing proposal. If an incompliance is seen in other parts of the dossiers a parallel CCH may be started on those parts. ECHA's legal adviser explained that the reason for ECHA going for this approach is purely based on a strict reading of the scope of Articles 40 and 41 of the REACH Regulation, i.e. Article 40 decisions concern examination of TP and Article 41 decisions concern compliance of all other elements of the registration dossier.

A question was raised on the plans of ECHA for the prioritisation of substance evaluation. The Chair promised to come back on this issue in the next June meeting.

Item 8 – Identification of SVHC

a. Lessons learnt from the previous rounds

The Chair introduced this agenda point by explaining that the intention of this point is to inform the MSC on the developments that took place since the publication of the last candidate list. Two main items were presented under this agenda point:

i. the court cases filed against ECHA at the General Court in Luxembourg
ii. follow-up on the refractory ceramic fibres

i. <u>the court cases filed against ECHA at the General Court in Luxembourg</u>

ECHA's legal advisor gave a brief overview of the court cases that were filed at the General Court in Luxembourg. The first decision under attack was the identification of Acrylamide as SVHC, Case T-1/10. The General Court published a summary of the case filed by the applicant in the Official Journal which can be found at the following link:

http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=OJ:C:2010:063:0048:0049:EN:PDF

ECHA's legal adviser explained that the applicant in parallel to the action for annulment, filed an application for interim measures seeking suspension of the inclusion of acrylamide into the Candidate List until the Court had ruled on the main action (registered as Case T-1/10 R). The applicant argued that inclusion of acrylamide in the candidate list would cause immediate and irreparable harm to the applicant and that therefore its inclusion should be suspended. Due to the apparent urgency of the matter, the Court, without hearing ECHA, ordered the temporary suspension of the effects of the identification of Acrylamide as a SVHC. Therefore, acrylamide was initially not placed on the candidate list when the list was updated in January 2010. After hearing ECHA's arguments, the President of the Court agreed with ECHA that inclusion of acrylamide in the Candidate List will not cause any immediate and irreparable harm. The President of the Court agreed with ECHA that the Candidate List is not a black list. The application for interim measures was therefore dismissed and acrylamide was then included in the candidate list in March 2010 (the Order of the President of the Court in Case T-1/10 R can be found on the Court's website at http://curia.europa.eu/jurisp/cgi-bin/form.pl?lang=en). The main

case filed by the applicant at the General Court is however, on going and will still take some years until the case is closed.

The other cases challenge the identification of Coal Tar Pitch High Temperature (Case T-93/10); Anthracene oil (Case T-94/10); Anthracene oil (low) (Case T-95/10), and anthracene oil paste (Case T-96/10) as substances of very high concern. All the cases were filed on the same day. The General Court did not publish a summary of those cases yet[1]. The applicant's main arguments were the following:

1. A procedural question if the MSC has the power to agree on the classification of anthracene as a carcinogen when this was not mentioned in the Annex XV dossiers submitted by the German CA.
2. Anthracenes are being prioritised over other petrochemicals which create disparity.
3. The identification of a substance as a PBT needs to be based on the substance's intrinsic properties and not on the intrinsic properties of its constituents.

ECHA's legal adviser explained that ECHA is still in the process of preparing its defence in these cases.

ii. <u>follow-up on the refractory ceramic fibres (RCF)</u>

The SECR gave an overview of the case by reminding the MSC, that in the December 2009 meeting, the MSC unanimously agreed that RCF is identified as SVHC and agreement was also found on the identification. Following the publication of the candidate list, ECHA received questions through the helpdesk requesting for a clarification whether their ceramic fibres fit the definition published in the candidate list. This revealed that there are RCF types on the market that fall outside the definition of the types identified as SVHC. The German CA was then contacted by ECHA. Germany showed interest to follow this case but prefers to wait for the registration dossiers to come in, in order to check which other RCF types may need to be addressed in an additional Annex XV dossier.

The Chair took the opportunity to explain to the MSC the procedure that was being discussed in ECHA for the removal of a substance from the candidate list. In situations where new information provides evidence that a substance on the candidate list no longer fulfils the P or B or T or vP or vB criteria of SVHC in order for this substance to be removed from the candidate list, a MS would need to submit an Annex XV dossier stating that the criterion is no longer met. Once agreement is found in the MSC on the basis of the submitted proposal and the normal procedure followed in the identification of SVHCs, the substance can be removed from the candidate list.

On the other hand, where a substance is included in the candidate list because it is a CMR based on the harmonised classification, and new information provides some evidence that the substance may no longer fulfil the C or M or R criterion, the substance should go through the normal classification, labelling and packaging (CLP)

[1] The summaries of cases have since then been published in OJ, C113, p. 63-66, 1.5.2010

process. This implies that a MS would need to submit an Annex VI CL dossier presenting the new information and classification proposal to the Risk Assessment Committee. When the harmonised classification is again agreed at a Community level by the Commission Regulation, then the MS will need to submit an Annex XV dossier to the MSC for the substance to be properly identified or else to be removed from candidate list.

This explanation generated some comments for clarification on the following:

1. whether it is really necessary for the MS to submit an Annex XV dossier to the MSC if the classification of a substance is changed and agreed at a Community level. To this ECHA's legal adviser explained that still such a procedure is needed since they are different processes.
2. whether the MSC can stop the clock for the case of the borates since currently there is some information challenging their classification. It was explained that if the MS that submitted the Annex XV dossier considers that the information at the identification stage is relevant, they can withdraw the Annex XV dossier. If this is not done, the MSC cannot stop the clock, but needs to proceed forward with the agreement seeking based on the criteria of Article 57.
3. whether it is legally possible to remove a substance from the candidate list if there is no legal provision for such. ECHA's legal adviser considered that arguably the identification process set out in Article 59 of the REACH Regulation could be used by the MSC to agree that a substance no longer meets one or more of the criteria for identification as a SVHC.

b. New Annex XV proposals for identification of SVHC

- Presentation of Annex XV proposals for identification of SVHC received in February and the respective work plan

An overview of the comments received during the public consultation was presented by SECR. This was followed by a very short discussion which clarified that if a substance is identified as a CMR through Community legislation, even if the comments received during the public consultation are trying to challenge the classification, yet still the classification cannot be changed.

- Selection of dossiers for identification of SVHC's in written procedure

The SECR presented to the MSC the proposal to seek agreement for the following substances in written procedure:

Trichloroethylene
Sodium chromate
Potassium chromate
Ammonium dichromate
Potassium dichromate

The MSC agreed unanimously to proceed as proposed by the SECR.

Item 9 – Work related to prioritisation and inclusion of substances in Annex XIV

a. ***ECHA's work plan for the 2nd draft recommendation for Annex XIV***

The SECR presented the work plan with the dates for the 2nd draft recommendation of priority substances for Annex XIV, including the steps where the MSC is involved. No major comments were received from the MSC. One of the stakeholder observers asked for the status of the first recommendation. The Commission representative stated that the SCCP will not be proposed to be included in Annex XIV because it is proposed as a Persistent Organic Pollutant. The Commission further said that the guidance on Authorisation would be published soon in the Official Journal as a draft and then later on it would be taken up by ECHA.

In conclusion the MSC agreed on the work plan that was presented by the SECR.

b. ***ECHA's draft document on the prioritisation approach - discussion and responses to comments received from members***

The SECR presented the updated prioritisation approach based on the comments received by the MSC in writing. This presentation was then followed by a presentation from one of the meeting participants representing the European Trade Union Confederation, who was proposing changes to the priority setting approach so as to take into account as well the recognised occupational diseases associated with some SVHC. Even though the MSC acknowledges that occupational diseases are a problem, yet, this approach was not considered appropriate by the SECR, since mere information that a substance can elicit adverse health effects is not a prioritisation criterion, as this applies for virtually all hazardous substances. Data on recent substance related incidences (e.g. case numbers on European/national level by kind of disease and uses of the substance) would be more suitable information to support prioritisation of substances for inclusion in Annex XIV. However, such data are not available to ECHA and have not been provided by stakeholders yet.

The main topics in the discussion raised were that:

1. Article 58 (3) of REACH refers to PBT or vPvB properties; or wide dispersive use; or high volumes. On the other hand, the proposal from ECHA is looking at these three criteria in an additive manner. The SECR explained that the aim of this new approach is to put the focus on the use and volumes and not the inherent properties. Inherent properties are in any case focused on as only substances on the candidate list with specific inherent properties are looked at.

2. The algorithm proposed by ECHA puts more weight on the PBT substances than on the CMRs. Thus some members requested to put equal weight on PBT and CMR substances. A stakeholder representative on the other hand, preferred the approach proposed by ECHA. However, a member stated that this could not be a problem if this new approach is also based on solid arguments, as for the first recommendation. To this the Chair confirmed that since the verbal-argumentative priority setting approach

applied for the first recommendation was well received by the MSC and the outcome was considered positive, it was proposed that for the second recommendation this approach would be run in parallel with the new scoring approach.

3. A zero release of a substance is not possible. To this ECHA referred to the definition of insignificant release that was used for the derivation of the algorithm. It was explained that the 0 score would only be given when it is certain that the releases are negligible in relation to the likelihood that these releases could cause environmental or health affects like for example when substances are used in closed systems.

In conclusion, the MSC supported ECHA's proposal of running prioritisation by using in parallel verbal argumentation and the scoring system. Furthermore the prioritisation would be carried out in two separate tiers: first prioritising substances using the criteria of Article 58(3) as further explained by the priority setting approach document and then applying in tier 2 the regulatory effectiveness criteria against prioritised substances as explained in the priority setting approach document. The SECR would consider the comments made and present the updated priority setting approach to the MSC in mid May. The preliminary draft recommendation with the prioritised substances resulting from application of the priority setting approach document will be sent to MSC at around 19 May. If the time allows the SECR could play around with different options for algorithms thus considering the different suggestions made by members in the discussion. The draft recommendation will then be sent to the MSC on 28 May for discussion in June. All the substances not yet recommended for inclusion in Annex XIV on the candidate list will in Tier I be assessed for priority and ranked by the total score assigned. Final selection of substances, taking in Tier II regulatory effectiveness and coherence considerations into account, will then start from the top of the list. The cut off value of scores is not going to be determined at this stage, since this could then be discussed at the MSC meeting.

c. Discussion on the appointment of Rapporteur and Working Group

The SECR reminded the MSC that an invitation was sent by e-mail on 31 March to request members to volunteer as a rapporteur. One member volunteered as a rapporteur whilst another member volunteered to be part of the WG. Since the rapporteur and WG would need to be appointed in the next June meeting the SECR encouraged the members to show their interest to be part of the WG by 21 May.

Item 10 – Manual of Decision (MoD)

The SECR explained that this has been in written commenting round twice. Only a few comments were received. These comments were taken into account when updating the draft. The first draft edition of the MoD was presented to the MSC for adoption. It was clarified that such document would be a living document, thus, updated as necessary. It applies to all processes of the MSC.

The first version of the Manual of Decision was then adopted by the MSC.

Item 11 – Update on provisional work plan for MSC

- ***Work plan based on compliance checks and testing proposals for 2010, SVHC identification and recommendation process***

Work plan was provided for information.

Item 12– Guidance Issues

The SECR introduced this agenda item by explaining the process for guidance update, and where the MSC fits in this process. The SECR also gave an overview of the guidance documents that still need to be updated and further planning for the MSC involvement. The Chair then explained that the guidance documents that were sent to the MSC for review were chosen based on their link to the three main REACH processes that involves the MSC i.e. identification of SVHC, Recommendation of substances to be proposed for Annex XIV and Evaluation. There is no need for the MSC to reach to a common view on the comments made. The MSC on the other hand, can monitor the responses to the comments made through the response to comments table that is made available on the ECHA website.

Item 13 – Response from other ECHA bodies and activities

- ***Outcome of the MB discussion on participation of stakeholder representatives during evaluation case discussions in MSC***

The Chair informed the MSC that the Management Board (MB) of ECHA was discussing a proposal on how the participation of stakeholder observers and case owners could be organised in the meetings of the MSC during evaluation case discussions. That is, looking for conditions to set the framework for involvement of stakeholder observers during discussion in the MSC. The issue has been addressed in written procedure but would still require discussion in the forthcoming MB meeting.

The SECR continued to explain that the MSC had already started discussing the stakeholder participation in meetings on issue of confidential nature during its 9th meeting, as also documented in the minutes of MSC-9. It was concluded that '*ECHA's policy on the confidentiality-related issues of the upcoming topics in the MSC needs to be established and may need discussion at the MB. As long as such decision is not taken, the MSC will discuss all evaluation cases in closed sessions and inform the stakeholder observers about these cases appropriately.*' The policy issue is therefore, under discussion in the MB. The proposal the SECR made to the MB is to hold a balance between participation and the need to keep Confidential Business Information (CBI). In simple terms, whenever key information in the draft dossier evaluation decision is considered confidential the presence of stakeholder observers cannot be allowed.

Taking into account the independence of the Committees the MSC would still need to discuss whether the policy on allowing stakeholder observers and case owners be present at the evaluation discussions under certain conditions (when agreed by the MB) would be acceptable to the MSC in general.

Item 14 – Any other business

The Chair introduced a possible new task for the MSC based on a letter received from the Commission. The SECR explained that the Commission asked the MSC to start providing scientific opinions on identification of PBT, vPvB or POP characteristics of biocidal substances. This would be an *ad hoc* request under Article 77 (3)(c). The Commission sees particular merits for having the MSC to work on this since all the MSs have members in this committee and consensus view of the MSs would be looked for. However, bilateral discussions with the Commission to further clarify the intentions are expected to commence soon. The Chair explained that because the Committee would be requested for an opinion, then the MSC would need to appoint a rapporteur for these cases.

Some members wondered whether an opinion from an expert group would suffice the purpose. However, the SECR explained that a full scientific opinion from a committee, i.e., the MSC, is being proposed. At this stage the request is only related to biocides..

Other members questioned the legal basis of this request since nothing is mentioned in the Biocide directive, and no mention of such a procedure is being made during the co-decision discussion of the New Biocide Regulation.

The SECR explained that this was one of the questions ECHA raised to which the Commission replied that the basis would be Article 77 (3) of REACH. The Commission in their letter also stated that the evaluation would be substance by substance, with approximately 1-2 substances per year. The MSCA that is Rapporteur Member State for the biocidal active substance would provide a proper dossier to the MSC.

Since there are still some open questions on this issue, it was concluded that the SECR will provide more information in June meeting.

Item 15 – Conclusions and Action Points

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

II. List of attendees

Members
ANGELOPOULOU, Ioanna (EL)
CAMILLERI Tristan (MT)
DEIM, Szilvia (HU)
DOUGHERTY, Gary (UK)
DRUGEON, Sylvie (FR)
DUNAUSKIENE, Lina (LT)
FINDENEGG Helene (DE)
FLODSTRÖM, Sten (SE)
HEISKANEN, Jaana (FI)
KORENROMP, René (NL)
LULEVA, Parvoleta (BG)
MAJKA Jerzy (PL)
MARTIN, Esther (ES)
MIHALCEA-UDREA, Mariana (RO)
PALMA Maria do Carmo Ramalho Figueira (PT)
REIERSON, Linda (NO)
RUSNAK, Peter (SK)
STESSEL, Helmut (AT)
TYLE, Henrik (DK)
VANDERSTEEN, Kelly (BE)
VESKIMÄE, Enda (EE)
WELFRING, Joëlle (LU)
Alternate
HUMAR-JURIC Tatjana (SI)
Representatives of the Commission
BENNINK Dyanne (DG ENTR)
MURPHY Patrick (DG ENV)

Observers
ANNYS, Erwyn - CEFIC
LEENAERS, Joeri - EUROMETAUX
MUSU, Tony – ETUC
REINEKE Ninja - WWF
STOCCO Gianluca - UEAPME
TAYLOR, Katy - ECEAE
WARNON Jacques – CEPE/DUCC
ECHA staff
AJAO, Charmaine
BALOGH, Attila
BRAUNSCHWEILER, Hannu
BROERE, William
BUCHANAN Steven
CHRIST Gabi
DE BRUIJN, Jack
FEDTKE Norbert
GRADZKA, Agnieszka
KARHU, Elina
KOJO, Anneli
KORJUS, Pia
KOULOUMPOS, Vasileios
KUITTINEN, Marko
LEBSANFT, Jörg
LEPPER, Peter
LUTOMSKA, Agnieszka
MALM, Jukka
MÜLLER, Birgit
NAUR, Liina
RUOSS, Jurgen
SUNDQUIST, Anna-Liisa
TISSIER, Chrystele
VAHTERISTO, Liisa
VERSONNEN, Bram
YLÄ-MONONEN, Leena

Replacements

ARTUS Hannela replacing VESKIMÄE, Enda; CONWAY Louise replacing COSGRAVE, Majella;

Proxy's

DUNAUSKIENE, Lina (LT) also acting as proxy of VESKIMÄE, Enda (EE);
CAMILLERI Tristan (MT) also acting as proxy of PISTOLESE, Pietro (IT);
DOUGHERTY, Gary (UK) also acting as proxy of COSGRAVE, Majella (IE);
ANGELOPOULOU, Ioanna (EL) also acting as proxy of KYPRIANIDOU-LEODIDOU, Tasoula (CY);
RUSNAK, Peter (SK) also acting as proxy of GEUSS, Erik (CZ).

Experts and advisers to MSC members

ANDERSEN Sjur (expert to REIERSON, Linda)
ANDERSSON Lars (expert to FLODSTRÖM, Sten)
BALCIUNIENE Jurgita (expert to DUNAUSKIENE, Lina)
BIWER, Arno (expert to WELFRING, Joëlle)
LEONELLO Attias (expert to PISTOLESE, Pietro)
KOZMIKOVA, Jana (expert to GEUSS, Erik)
LUIT Richard (expert to KORENROMP, René)
PECZKOWSKA, Beata (expert to MAJKA, Jerzy)
RÁCZ, Éva (expert to DEIM, Szilvia)
RAMOS Cesaltina (expert to PALMA, Maria do Carmo Ramalho Figueira)
KREUZER Paul (adviser to HEISKANEN, Jana)
MICHEL Cécile and LAGRIFFOUL Arnaud (adviser to DRUGEON, Sylvie)
SCIMONELLI Luigia (adviser to PISTOLESE, Pietro)
HAKKERT Betty (adviser to KORENROMP, René).
MARTINS Lilia (adviser to PALMA, Maria do Carmo Ramalho Figueira)

Apologies:

COSGRAVE, Majella (IE)
FAJFAR, Simona (SI)
GEUSS, Erik (CZ)
VESKIMÄE, Enda (EE)
LUDBORZS, Arnis (LV)
PISTOLESE, Pietro (IT)

Via telephone:

KYPRIANIDOU-LEODIDOU, Tasoula (CY)
EINARSDOTTIR, Gunnlaug (ICE)

III Final agenda

28 April, 2010
Final agenda

Final Agenda
11th meeting of the Member State Committee

28-29 April 2010
ECHA Conference Centre
Annankatu 18, in Helsinki, Finland

28 April**: starts at 14:00**
29 April**: ends at 18:00**

Item 1 – Welcome and Apologies

Item 2 – Adoption of the Agenda

MSC/A/011/2010
For adoption

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

Item 4 –Minutes of the MSC-10

MSC/M/10/2010
For information

Item 5 – Administrative issues

a) Results and follow up from satisfaction survey

ECHA/MSC-11/2010/001

b) Annual declarations for 2010

c) Use of CIRCA interest groups

For information

Item 6 – Feedback from the MB decision on approval of MSC Rules of Procedure

- Appointment of alternates, modification on handling of minority opinions, next review of the Rules of Procedure

ECHA/MSC-11/2010/009 & 010

For discussion & decision

Item 7 –Evaluation tasks

Closed session for 7a

a. Introduction and preliminary discussion on draft decisions on a testing proposal and compliance checks[2].

Three cases with the following MSC identification number will be discussed:

- TPE 001/2010
- CCH 001/2010
- CCH 003/2010

For information & discussion

b. Oral report from the ECHA Workshop on testing proposals (27-28 April)

For information

c. Organisation of evaluation work in the MSC: Possible establishment of a Working Group

ECHA/MSC-11/2010/002

For discussion & decision

d. Status report from other ongoing evaluation work

For information

Item 8 –Identification of SVHC

c. Lessons learnt from the previous rounds

For discussion

d. New Annex XV proposals for identification of SVHC[3]

- Presentation of Annex XV proposals for identification of SVHC received in February and the respective work plan

[2] Evaluation documents are available in MSC CIRCA under 05. Dossier evaluation. For this meeting these are not available in the folder MSC-11.

[3] Annex XV dossiers for the identification of SVHC's and respective comments received are available in MSC CIRCA under 03. SVHC identification. For this meeting these are not available in the folder MSC-11.

For discussion

- Selection of dossiers for identification of SVHC's in written procedure

ECHA/MSC-11/2010/005

For discussion& decision

Item 9 – Work related to prioritisation and inclusion of substances in Annex XIV

a. ECHA's work plan for the 2nd draft recommendation for Annex XIV

ECHA/MSC-11/2010/006

For discussion & decision

b. ECHA's draft document on the prioritisation approach - discussion and responses to comments received from members

ECHA/MSC-11/2010/007 & 008

For discussion

c. Discussion on the appointment of Rapporteur and Working Group

For discussion

Item 10 – Manual of Decisions (MoD)

- Discussion on the format, contents and specific entries for the MoD

ECHA/MSC-11/2010/003

For discussion& decision

Item 11 – Update on provisional work plan for MSC

- Work plan based on compliance checks and testing proposals for 2010, SVHC identification and recommendation process

ECHA/MSC-11/2010/004

For information

Item 12 – Guidance issues

- Feedback from the consultations on guidance updates

For information

Item 13 – Report from other ECHA bodies and activities

- Outcome of the MB discussion on participation of stakeholder representatives during evaluation case discussions in MSC

For information

Item 14 – Any other business

- Suggestions from members

For information

Item 15 – Adoption of conclusions and action points

- Table with action points and decisions from MSC-11

For adoption

IV Main conclusions and action points

MAIN CONCLUSIONS & ACTION POINTS
MSC-11, 28-29 April 2010
(Adopted at the MSC-11 meeting)

CONCLUSIONS / DECISIONS / MINORITY OPINIONS	ACTIONS REQUESTED
5. Administrative issues	
MSC took note of the results of the satisfaction survey.	MSC-S to follow the action plan based on the results of the survey, as presented. Next annual satisfaction survey to be issued at the end of 2010. MSC-S to arrange renewal of badges expiring in May 2010.
6. Feedback from the MB decision on approval of MSC Rules of Procedure (RoP)	
MSC took note of the adoption by MB of the MSC RoP with the option of appointing a formal alternate. MSC agreed on the deletion of the text concerning the recording of minority positions as a part of the Committee's opinion, introduced by the MB in the RoP of MSC. As the MB recommended, MSC has considered the issue of voting right of co-opted members and supported broadly the view that co-opted members shall not have voting rights.	MSC-S to seek legal advice if this limitation is possible. MSC-S to launch the next revision of the RoP in 2011.
7. Evaluation tasks (due to confidentiality reasons, conclusions and action points of 7a) are available only in the confidential version of the minutes of MSC-11)	
7c) Establishment of a MSC WG on Dossier Evaluation	
	MSC-S to take into account the concerns expressed by MSC members that the WG should be open to all Committee members. MSC members to comment on the draft mandate of the proposed WG and to propose possible alternative approaches by 21 May 2010.
8. Identification of SVHCs	
MSC agreed on the substances for identification as SVHC selected for written procedure.	MSC-S to launch the written procedure on 25 May 2010.

CONCLUSIONS / DECISIONS / MINORITY OPINIONS	ACTIONS REQUESTED
9. Work related to prioritisation and inclusion of substances in Annex XIV	
9a) ECHA's workplan for the 2nd draft recommendation for Annex XIV	
MSC agreed with proposed workplan including the timetable for developing the Committee's opinion.	
9b) ECHA's draft document on the prioritisation approach – discussion and responses to comments received from MSC members	
MSC agreed on the use of ECHA's verbal argumentative approach in parallel with the newly developed scoring approach (*option b*) in the current recommendation process of 2010, to test the two approaches.	ECHA to submit the priority setting approach updated on the basis of the comments of MSC members in the first half of May 2010.
9c) Discussion on the appointment of Rapporteur and Working Group	
	MSC members to indicate their interest for membership for the Working Group by 21 May 2010.
10. Manual of Decisions (MoD)	
MSC adopted the MoD as presented by MSC-S and modified in the meeting.	
15. Adoption of conclusions and action points	
The conclusions and action points were adopted.	MSC-S will upload the non-confidential version of the conclusions and action points on CIRCA together with the presentations delivered at the meeting, by 30 April 2010.