European Chemicals Agency

MSC/M/014/2010
Adopted at MSC-15, 1-3 December 2010

Final Minutes

Minutes of the 14th Meeting of the Member State Committee (MSC-14)
20 October 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 14th meeting of the Member State Committee (MSC).
For this 14th meeting, apologies were received from eight MSC members (for the full list of attendees and further details see part II of the minutes).
The future Head of Unit (HoU) for Committees & International Relations Unit from 1 November 2010, Pilar RODRIGUEZ IGLESIAS (current HoU for Guidance and Helpdesk Unit), introduced herself to MSC.

Item 2 - Adoption of the Agenda

The Agenda was adopted with slight changes proposed by the MSC Secretariat. The final Agenda is attached to these minutes (see part III of the 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 draft minutes of the MSC-13

ECHA Secretariat (SECR) explained that written comments on the draft minutes of MSC-13 received from several meeting participants had been taken into account. Providing general comment in clarification of MSC-13 discussion captured in the minutes, Commission (COM) recalled the role of MSC in implementing REACH. Discussions on changes to REACH are beyond its scope. The minutes were adopted with some further changes proposed by participants in the current meeting. A non-confidential version of the minutes will be placed on ECHA website.

All actions from MSC-13 had been carried out, are in progress or were to be covered at this meeting.

Item 5 – Evaluation tasks

***a)* Reporting back on seeking agreement in written procedure on a draft decision on a compliance check (CCH 009/2010 – Vegeflux soy)**

SECR gave a short oral report on the above written procedure with the conclusion that MSC found unanimous agreement on ECHA's amended draft decision as presented at MSC-12. There were 22 (plus Norway) positive responses on the amended draft decision which exceeds the 60 % quorum needed for favourable vote. None opposed the amended draft decision. Also MSC agreement on the case was approved by written procedure with the same figures. ECHA has included further guiding information in the cover letter to the registrant as suggested by one member in the context of the response to the written procedure. ECHA's final decision and the cover letter will be sent to the registrant and together with the MSC document on the agreement will be uploaded on MSC CIRCA soon after the meeting.

b) **Oral report from expert workshop 'Dealing with uncertainty of Non-test methods under REACH' held in ECHA**

SECR gave a presentation on the objectives and outcomes of the workshop. Main focus of the expert workshop was the regulatory acceptance of non-test methods and how to assess and how to deal with their scientific uncertainty. The workshop provided an excellent forum for about 70 experts from member states, third countries, industry and ECHA to exchange their views on the topics. Among the conclusions drawn was mentioned that acceptance of the use of non-test methods is very often case-dependent and experts tend to find agreement easier on specific cases than on drawing general conclusions based on specific cases which seems to be a more challenging task. The workshop proved to be useful also in bridging the differences in scientific views of experts of read-across/category approach and QSAR experts.

Setting up an Expert Forum of experts from ECHA and member states to facilitate decision making at European and national level and developing an Assessment Framework to assist authorities to assess and registrants to improve the quality of registration dossiers in terms of non-test data were mentioned as two possible ways forward. Review the ECHA guidance on non-test methods based on experience from the registration dossiers submitted by the first registration deadline and dissemination of registration data to help developing further QSAR models were also identified as long term goals.

In the discussion, it was raised by meeting participants that non-test methods in many cases are providing the only available information. This fact and also the regulatory context should be kept in mind when talking about uncertainty and regulatory acceptance of these methods. It was mentioned that OECD has developed a reporting format for use of QSARs, which could be studied and maybe made use of also by ECHA. The use of several different toolboxes to assess the use of non-test methods was flagged as desirable despite the fact that some toolboxes e.g. the OECD toolbox try to be comprehensive and merge all the positive features of other currently used methods. Regarding human health endpoints, it was highlighted that pharmaceutical industry might be a source for data on how to use non-test methods. Therefore, this knowledge should be more incorporated in future discussions on these topics.

ECHA thanked for the useful contributions and referred to the planned workshop on the topic of non-testing methods to be organised by ECHA in spring 2011 where experts from member states intended to be involved in the discussions.

c) **Status report on ongoing evaluation work**

SECR gave an overview on the situation of the dossier evaluation work in ECHA. Details of this work are available on the Evaluation CIRCA. It was highlighted that there will not be any draft decisions for seeking agreement on by MSC in the next meeting in December but after this meeting the workload of MSC is likely to become gradually higher. It was also explained that after the CARACAL meeting at the end of October 2010 and a following written commenting round with Member State Competent Authorities (MSCAs), ECHA is planning to launch a pilot project on its new practice to communicate with MSCAs in the context of dossier evaluation work.

d) **Brief report from the workshop on prioritisation criteria for dossier and**

substance evaluation

SECR presented the objectives and outcome of the workshop held on 18-19 October 2010. Main focus of the workshop was on the scope of and finding consensus on prioritisation criteria for substance evaluation. A written commenting round for MSCAs on the prioritisation criteria proposed for and refined after the workshop by ECHA will be launched soon. The process of developing the first and the following Community Rolling Action Plans (CoRAPs) was discussed also in the workshop. One of the conclusions of the workshop was that MSCAs' access to information included in the registration dossiers allowing them to contribute sufficiently to these processes and to propose substances for substance evaluation was considered crucial. MSCAs are invited to communicate to ECHA by March 2011 how many substances they are willing to evaluate in the period of the first CoRAP (2012-14). IT tools developed by ECHA to assist the selection of substances for dossier and substance evaluation (CASPER, ProSP) were also shortly presented.

Some MSC members strongly emphasised the view expressed already at the workshop that in accordance with Article 45(5) MSs may notify ECHA at any time of a substance not on the CoRAP and ECHA should then update the CoRAP on the basis of MSC opinion. According to these views the additions based on MSs' notifications should be made independently from the criteria defined in Article 44 of REACH. One MSC member expressed the view that these MSCA proposals should be based on the same criteria.

A MSC member proposed that MSC should be involved in the discussions where the final criteria for substance evaluation will be developed and agreed upon because MSC is the body which gives its opinion on the draft CoRAP and because the draft CoRAP will be based on these criteria.

SECR replied that attempt will be made to elaborate all these issues in the final report of the workshop which will then be distributed to MSCAs. The Chair concluded that MSC would be kept informed about development of the criteria, if possible at the meeting in December 2010, after the written commenting round of MSCAs on the prioritisation criteria. A more targeted and detailed discussion on MSC's role in the process of refining the prioritisation criteria for substance evaluation will be scheduled. The Chair also pointed out that MSC has to establish its working procedures for the substance evaluation process and the first draft might be presented by MSC Secretariat (MSC-S) for discussion in February 2011.

Item 6 – Identification of SVHC

a) Brief introduction of the comments received on the new Annex XV dossiers for SVHCs

Before the introductory presentation to the topic, one MSC member raised that due to a software change (Document Management System, Documentum), the comments provided during the public consultation were submitted to MSC in XML format which was not technically readable to all members. ECHA stated that it will change XML format to Word format thus ensuring that all members will have access to the necessary documents.

SECR gave a presentation analysing the comments received by ECHA during the public consultation on the 11 Annex XV proposals for substances to be identified as SVHC for which the consultation closed 14 October 2010.

It was pointed out that there were comments received in the public consultation for chromium trioxide and the four cobalt compounds proposing their identification as SVHC under Article 57 (f) of REACH. The reasons brought forward as to why it should be considered to identify the substances also as being of equivalent level of concern are their respiratory and skin sensitising properties, and neurotoxicity and autoimmmune diseases, respectively.

SECR explained that in cases where a new basis for identification as SVHC is proposed for which there is no scientific argumentation available in the original Annex XV dossier explaining how the criteria for this new identification (under Article 57 f) are met, this new basis for identification is not advisable to be taken into account. The main reason for this is that interested parties could not provide comments in the public consultation on the new identification basis that would change the outcome significantly from the original proposal. As identification of a SVHC under Article 57 (f) would always need discussion on a case by case basis it would be problematic to document this discussion after the Annex XV dossier was in the public consultation without such justification. The comments provided this time during the public consultation suggesting identification under Article 57 (f) were very general and did not give further justification as to why the mentioned properties should be considered as presenting equivalent level of concern to those listed under Article 57 (a) to (e).

The Chair concluded that on this basis, the comments provided in the public consultation for these substances proposing additional identification under Article 57 (f) should not be taken into account as challenging the identification because the scientific argumentation for identification under Article 57 (f) was not part of the original Annex XV dossier. In addition, such scientific argumentation was not provided in the comments, either.

Other comments provided did not make a meeting discussion on the substances (Co compounds and chromiumtrioxide) necessary. Therefore, depending on the final conclusions of the MSCA evaluating the comments, MSC-S will launch a written procedure for finding unanimous agreement on the identification as SVHC for the substances in question.

One MSC member pointed out that it is up to a MSCA to decide which basis they include in the Annex XV dossier as basis for identification as SVHC for a certain substance. It is possible that a certain property is not included in the Annex XV dossier on purpose because e.g. based on the other properties the given MSCA intends to propose other actions like restrictions.

ECHA replied that exactly this kind of cases has not yet been discussed in the MSC before and that these situations need further legal clarification. There have been cases where the MSC has concluded in its discussions and based on the comments provided in the public consultation that a substance should also be identified under another cri-

teria of Article 57 than proposed in the Annex XV dossier (for example a PBT substance which fulfils also the criteria to be a vPvB, should be identified both under Article 57 d and Article 57 e) but in these cases the scientific justification was part of the Annex XV dossier. However, also the consequences of not addressing certain SVHC properties in the identification process have to be borne in mind. One of the important consequences could be that a company applying for authorisation would need to take into account in its application only the properties of the given substances which are covered by the identification as SVHC in Annex XIV.

One MSC member reminded that a careful analysis of the possible consequences and presentation of a solid basis for the proposal should be essential before substances are proposed by MSCAs to be identified as SVHCs. SECR replied that the analysis of risk management options (RMO), the practice of which is generally supported by MSCAs, has exactly the same purpose and that the COM is proposing a subgroup under CARACAL to discuss exactly these type of issues.

b) **Discussion on application of Article 57(f) criteria for current proposals**

MSC is discussing for the first time Annex XV dossiers (three trichlorobenzene isomers) that propose identification of SVHCs under Article 57 (f) (equivalent level of concern) as PBT like substances. SECR presented its views on how Article 57 (f) criteria may be applied in the context of such proposals. The main conclusions of the presentation were that the Annex XV dossier/report needs to demonstrate scientifically solid argumentation supported by relevant data that the hazard profile of the substance gives rise to an equivalent level of concern to the hazard profiles listed under Article 57 (a)-(e) and that there is evidence of probable serious effects to human health or to the environment. In ECHA's view, the Annex XV dossiers of trichlorobenzenes isomers would need to be improved so that the scientific argumentation is fully documented and the case discussed using weight of evidence approach and expert judgement.

In the discussion, one MSC member challenged particularly the bioaccumulation potential (B) of the substance in question. Data like BCF (BioConcentration Factor) and log Kow in his view do not support criterion B so that the substance can not be identified as SVHC under Article 57 (f). Furthermore, presentation of BCF data in relation to BCF cut-off values is not consistent which also adds to the uncertainty of the identification.

Another MSC member reminded that the substance was identified as PBT-like substance in the EU Risk Assessment Report prepared by Denmark as rapporteur and also by the TC NES (Technical Committee of New and Existing Chemicals) Working Group. Although the case is not clear-cut one in his view, he was not directly opposing the identification.

Long range transport (LRT) potential of the substance as possibly leading to danger of pristine environments has been mentioned several times as an argument supporting the substance being of equivalent level of concern. In the view of the representative of the Member State having prepared the Annex XV dossier, the clear fulfilment of P criterion supported by high BCF, high toxicity (T) values for aquatic organisms, and by LRT potential based on modelling data justifies the proposal, though BCF and T formally does not exceed or reach the trigger values of Annex XIII of REACH.

A stakeholder observer clearly supported the identification of the substance under Article 57 (f) emphasising that the properties of the substance are very close to fulfilling the PBT criteria and therefore the substance should be considered as PBT-like substance. They had also provided some further supporting data during the public consultation.

Another stakeholder observer pointed out that the data provided in the Annex XV proposal are not conclusive enough for identification as SVHC under Article 57 (f).

During the discussion the regulatory effectiveness was mentioned by MSC members as an argument for not pursuing the particular substance under 57(f). It was argued by another member that the role of MSC is not to question regulatory effectiveness but assess validity of the arguments for inclusion.

COM added to the discussion that at the moment still the "old" Annex XIII is in force and the substances in question shall be discussed on this basis.

The Chair concluded that after hearing all the arguments for and against the identification of the substance as SVHC under Article 57 (f), it is now up to the dossier submitter MSCA to decide what to do with the Annex XV proposal. If the proposal will not be withdrawn, it will be discussed at the next MSC meeting in December and then a unanimous agreement will be sought. It was proposed that it would be advisable to update the support document with more solid argumentation for the identification, besides replying in the RCOM to comments received in the public consultation.

c) **Selection of dossiers for identification of SVHCs in written procedure**

Based on earlier agreements of MSC saying that identification of recognised CMR substances as SVHCs can be agreed upon in written procedure and based on the conclusions drawn under agenda item 5(a), SECR proposed to seek unanimous agreement in written procedure for the following seven substances: cobalt (II) sulphate, cobalt (II) nitrate, cobalt (II) carbonate, cobalt (di) acetate, methoxyethanol, 2-ethoxyethanol and chromium trioxide. The written procedure will be launched on 15 November and closed on 25 November 2010.

Unanimous agreement will be sought on acids generated from chromium trioxide and their oligomers at the December MSC meeting. Although they are recognised CMR substances, comments have been received during the public consultation challenging the substance identification. Therefore, a meeting discussion in the presence of ECHA's substance identity experts seemed to be necessary.

Based on the discussions under agenda item 5 (b), 1,3,5-, 1,2,3- and 1,2,4 trichlorobenzenes will also be discussed at the next MSC meeting in December with the aim of finding unanimous agreement on their identification as SVHC.

The final procedure to be chosen by the MSC-S depends on the decision of the dossier submitters based on the assessment of the comments received in the public consultation.

MSC agreed on the proposed way forward.

Item 7 – Draft recommendation for inclusion of priority substances in Annex XIV

a) Oral report on the outcome of the public consultation on ECHA's Draft Recommendation and Draft Annex XIV entries for prioritised substances

SECR gave an overview on the comments received in the public consultation and on ECHA's draft responses to them as far as already available. As comments have been received from MSCAs on the proposed time periods for transitional arrangements requesting to keep the time periods at the required minimum, it was emphasised by ECHA that the guidance sets 18 months as standard time after publication of Annex XIV until the application date. However, ECHA is open to discuss this issue while at the same time emphasising the need to take into account the limitations set by its resources, resources needed by industry and ECHA's work plan.

For four substances (DIBP, lead chromate, TCEP, 2,4-DNT), there were no comments received challenging the recommended inclusion in Annex XIV or the exemptions of uses or categories of uses from authorisation. For diarsenic trioxide and pentaoxide, some relevant information has been provided in the public consultation on new and discontinued uses and amounts used on the European market. According to industry arsenic metal is used instead of arsenic oxides in production of electrical devices. Arsenic trioxide is also used in purification of zink metal. Industry is considering both the use in glass industry and in purification of zink metal as intermediate uses. Even with this new information in ECHA's view prioritisation is still justified.

On lead sulfochromate yellow and lead chromate molybdate red requests have been received to exempt the substances from authorisation for PPORD and to exempt a range of uses from authorisation based on Article 58 (2) of REACH supported by reference to a number of pieces of EU legislation. Examination by ECHA of both the PPORD request and the legislation referred to is ongoing and conclusions can be drawn only after the assessment of this is finalised.

Replying to concerns of a stakeholder representative, ECHA reconfirmed that in its view, based on the available information on the processes, the use of arsenic trioxide in zinc purification and in glass production is not an intermediate use. It was also stressed that the question whether authorisation or restriction is the better risk management option is not a subject of the current discussions in MSC.

b) Outcome of REACH Committee on the first entries of Annex XIV

COM reported that the REACH Committee at its meeting on 20-21 September 2010 gave a favorable opinion on the draft COM Regulation which will include six substances (MDA, musk xylene, HBCDD, BBP, DBP, DEHP) into Annex XIV and thus make them subject to the authorization regime. The main change compared to the recommendation prepared by ECHA was that the latest application date and sunset date for HBCDD was nine months postponed to 36 months (instead of 27) and 54 (instead of 45), respectively. After the favorable vote of the REACH Committee, the next step of the process is a scrutiny period of three months which will end on 1 January 2011. During this period, the European Parliament and Council can oppose the Regulation in three cases: when they feel either that COM exceeds its implementing power under REACH or the principles of proportionality and subsidiarity are not respected or the draft measures are not compatible with the aim and content of REACH. Assuming that neither of the two institutions are opposing, COM will adopt the Regulation at the beginning of next year.

At the same meeting, the REACH Committee gave its favorable opinion also on the draft revision of Annex I (amended in order to adapt it to the CLP Regulation), Annex XIII (revised criteria for identification of PBT/vPvB substances) and Annex XVII (in PFOS and penta-BDE would be deleted given that they are now covered by the POPs Regulation). For the adoption of these Annexes, the same procedure and a very similar timeline apply as for the Annex XIV.

SECR added complementing the report of COM that SCCPs were taken of the draft Annex XIV because they are handled by the UNECE POPs protocol and thus would need to be addressed by the POPs Regulation. MSC took note of the report.

In the following discussion, several related topics were addressed.

One stakeholder representative pointed out that according to the latest developments in the POP Review Committee of the Stockholm Convention the discussions on inclusion on SCCPs in the POP list were postponed two years. One MSC member judicated, that more clarity and education would be needed from ECHA's side on the authorization process both to the outside world and MSCAs. With regard to setting different application dates for different uses, it should be documented in the opinion of MSC that it was considered and was not found useful and feasible (as pointed out also by SECR). Application dates are desirable to be considered as early as possible. This should be balanced with ECHA's workload and work program and the final application dates should take the results of this analysis into account.

SECR acknowledged the remark that the complexity of the authorization process requires more effort from ECHA to make all the steps of the process as clear as possible for all parties. One of the important issues is to understand at which step of the process different considerations will take place.

Replying to one member's concern, SECR stressed that the recommendation process is not a risk-based one. Risk assessment is not carried out in the context of the prioritisation of substances to be included in Annex XIV although prioritisation criteria could be considered as proxies for some hazards and exposure.

Risk assessment and socio-economic analysis will be carried out only in the context of the applications for authorisations. Risk Assessment Committee (RAC) and Socio-economic Analysis Committee (SEAC) will consider these assessments and give their opinion to the Commission. The Commission will take into account the opinions of RAC and SEAC when considering granting the authorisation.

***c)* Preparations for the opinion on the draft recommendation of priority substances to be included in Annex XIV**

The rapporteur reported that preparations for the opinion of MSC are progressing well. The working group, at its meeting on 19 October, reviewed the work done by the individual working group members and discussed several issues, in particular if transitional arrangements should be changed in the recommendation, if different transitional arrangements should be applied for different uses of the same substance and if the proposed authorisation route should or should not be included into ECHA's recommendation. ECHA is currently not proposing any authorisation route in its recommendation.

Among other issues it was mentioned, that there was agreement in the working group on that although EU producers or importers could not be identified for arsenic pen-

taoxide but as it could replace arsenic trioxide its inclusion in Annex XIV is supported. In addition to the comments mentioned under item 5 a), also the non-prioritisation claim for the two lead pigments based on their encapsulation, which is claimed to make exposure not possible, awaits assessment of ECHA.

It was emphasised also that ECHA's final responses to the comments would be very useful before finalisation of the draft opinion of MSC. The current view of the working group and the rapporteur is that MSC should support the prioritisation of all the eight substances proposed to be prioritised by ECHA although the two arsenic compounds should have lower priority.

The Chair concluded that as next steps, MSC-S will ask for comments on draft opinion on the recommendation by 5 November and the working group will have a teleconference on 8-10 November. The final draft opinion of the MSC will be uploaded to MSC CIRCA on 19 November 2010.

Item 8 – Manual of Decisions (MoD) - Discussion on new entries for the MoD

Four topics proposed by MSC-S in a relevant meeting document were introduced to the MSC.

Some MSC members pointed out that the final exact wording will be crucial for all the proposed topics. Others raised concerns on some of the proposed issues and considered it not appropriate to include such an issue in the MoD. One new proposal was also mentioned, namely the inclusion of the conclusion in the MoD why a new identification as SVHC proposed in the public consultation can not be taken into account when there is no scientific argumentation available for it in the original Annex XV proposal (see the minutes under item 6 a) of the current meeting).

The Chair invited MSC members to submit their further (text) proposals and comments to MSC-S by 3 November 2010. Based on them and the current discussion, MSC-S will prepare the text proposals for the next MSC-meeting in December for discussion and possible adoption.

Item 9 – Report from other ECHA bodies and activities

SECR reported back from the last Management Board (MB) meeting where the Rules of Procedures (RoPs) of MSC have been approved by the MB. At the same meeting, MB also provided some observations on the Working Procedures (WP) of MSC on dossier evaluation, in particular on how discussions in MSC on dossier evaluation would be organized when stakeholders and case owners could be invited to the meetings. It has to be ensured that confidentiality claims made by the registrant are validated by ECHA before allowing stakeholders to the MSC discussions.

Another question raised by MB was if MSC would allow stakeholders to be present in the discussions where an alternative/public name instead of the exact IUPAC name can be used.

MB recommended to MSC to examine both questions and to amend the WP accordingly as appropriate.

In this regard, to give an example for the practical relevance of the above matters, SECR mentioned the current activities of ECHA to examine confidentiality claims for substances which might have to be discussed at the February MSC meeting in the context of dossier evaluation. Based also on the result of this analysis, the adjustment of the MSC working procedure on the two issues raised by MB can be made.

Item 10 – AOB

No items were proposed for any other business.

Item 11 - Adoption of conclusions and action points

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

Signed

Anna-Liisa Sundquist
Chair of the Member State Committee

II List of attendees

Members/Alternate members
ANASTASI, Audrey Anne (MT) (alternate member)
BIWER, Arno (LU) (alternate member)
COSGRAVE, Majella (IE)
DOUGHERTY, Gary (UK)
DRUGEON, Sylvie (FR) via WEBEX
DUNAUSKIENE, Lina (LT)
FINDENEGG, Helene (DE)
FLODSTRÖM, Sten (SE)
GEUSS, Erik (CZ)
HUMAR-JURIC, Tatjana (SI) (alternate member)
KORENROMP, Rene (NL)
LUDBORZS, Arnis (LV)
LULEVA, Parvoleta Angelova (BG)
MAJKA, Jerzy (PL)
MARTIN, Esther (ES)
MARTINS, Ana Lilia (PT) (alternate member)
PALEOMILITOU, Maria (CY) (alternate member)
PISTOLESE, Pietro (IT)
REIERSON, Linda (NO)
RUSNAK, Peter (SK)
STESSEL, Helmut (AT)
TALASNIEMI, Petteri (FI) (alternate member)
TÎRCHILĂ, Liliana Luminita (RO) (alternate member)
TYLE, Henrik (DK)
VANDERSTEEN, Kelly (BE)
VESKIMÄE, Enda (EE)

Representatives of the Commission
KOBE Andrei (DG ENV)
HENDRIX Katleen (DG ENTR)
Observers
ANNYS, Erwyn - CEFIC
LEENAERS, Joeri - EUROMETAUX
REINEKE, Ninja - WWF
WARNON, Jacques - CEPE/DUCC
ECHA staff
AJAO, Charmaine
BALOGH, Attila
BROERE, William
DE BRUIJN, Jack
FEDTKE, Norbert
KARHU, Elina
KARJALAINEN, Antti
KNIGHT, Derek
KORJUS, Pia
LEPPER, Peter
MALM, Jukka
MÜLLER, Birgit
NAUR, Liina
RODRIGUEZ IGLESIAS, Pilar
RUOSS, Jürgen
SUNDQUIST, Anna-Liisa
VAHTERISTO, Liisa
YLÄ-MONONEN, Leena

Experts and advisers to MSC members

ANDERSSON, Lars (SE) (expert to FLODSTRÖM, Sten)
ARTUS, Hannela (EE) (expert to VESKIMÄE, Enda)
ATTIAS, Leonello (IT) (expert to PISTOLESE, Pietro)
BALCIUNIENE, Jurgita (LT) (expert to DUNAUSKIENE, Lina)
BÖHNHARDT, Anna (DE) (expert to FINDENEGG, Helene)
COCKSHOTT Amanda (UK) (expert to DOUGHERTY, Gary)
CONWAY Louise (IE) (expert to COSGRAVE, Majella)
KOZMIKOVA, Jana (CZ) (expert to GEUSS, Erik)
LAGRIFFOUL, Arnaud (FR) (adviser to DRUGEON, Sylvie)
MICHEL, Cecil (FR) (adviser to DRUGEON, Sylvie)
PARRAGA, Helena (ES) (adviser to MARTIN, Esther)
PECZKOWSKA, Beata (PL) (expert to MAJKA, Jerzy)
PEDERSEN, Finn (DK) (expert to TYLE, Henrik)
RÁCZ, Éva (HU) (expert to DEIM, Szilvia)
RAMOS Cesaltina (PT) (expert to MARTINS, Ana Lilia)
TRAAS, Theo (NL) (expert to KORENROMP, Rene)
VAN ELSACKER Paul (BE) (expert to VANDERSTEEN, Kelly)

Apologies:
ANGELOPOULOU, Ioanna (EL)
CAMILLERI, Tristan (MT)

DEIM, Szilvia (HU)
FAJFAR, Simona (SI)
HEISKANEN, Jaana (FI)
MIHALCEA-UDREA, Mariana (RO)
PALMA, Maria do Carmo Ramalho Figueira (PT)
WELFING, Joelle (LU)

III Final agenda

Final Agenda
14th meeting of the Member State Committee

20 October 2010
ECHA Conference Centre
Annankatu 18, in Helsinki, Finland

20 October: **starts at 9:00**
20 October: **ends at 17:00**

Item 1 – Welcome and Apologies

Item 2 – Adoption of the Agenda

MSC/A/014/2010
For adoption

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

Item 4 –Draft minutes of the MSC-13

- Adoption of draft minutes of MSC-13

MSC/M/13/2010
For adoption

Item 5 –Evaluation tasks

a. Reporting back on seeking agreement in written procedure on a draft decision on a compliance check (CCH 009/2010 – Vegeflux soy)

ECHA/MSC-14/2010/001
For information

b. Status report on ongoing evaluation work

For information

c. Oral report from expert workshop 'Dealing with uncertainty of Non-test methods under REACH' held in ECHA

For information

d. Brief report from the workshop on prioritisation criteria for dossier and substance evaluation

For information

Item 6 –Identification of SVHC

a) Brief introduction of the comments received on the new Annex XV dossiers for SVHCs[1]

For information

b) Discussion on application of Article 57(f) criteria for current proposals

For information and discussion

c) Selection of dossiers for identification of SVHCs in written procedure

Room document ECHA/MSC-14/2010/004
For discussion and decision

Item 7 –Draft recommendation for inclusion of priority substances in Annex XIV

a) Oral report on the outcome of the public consultation on ECHA's Draft Recommendation and Draft Annex XIV entries for prioritised substances[2]

For information

b) Outcome of REACH Committee on the first entries of Annex XIV

For information

c) Preparations for the opinion on the draft recommendation of priority substances to be included in Annex XIV

- Discussion on the first draft opinion based on the non-updated draft recommendation

ECHA/MSC-14/2010/002
For information and discussion

Item 8 – Manual of Decisions (MoD)

- Discussion on next new entries for the MoD

ECHA/MSC-14/2010/003
For discussion & decision

Item 9 – Report from other ECHA bodies and activities

[1] 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-14.

[2] Comments received during public consultation of ECHA's draft recommendation for prioritised substances are available in MSC CIRCA under 04. Recommendation process

- Oral report from MB meeting held on 30 September-1 October on MB observations on the MSC working procedures on dossier evaluation

For information

Item 10 – Any other business

Suggestions from members

For information

Item 11 – Adoption of conclusions and action points

- Table with action points and decisions from MSC-14

For adoption

IV Main conclusions and action points

MAIN CONCLUSIONS & ACTION POINTS
MSC-14, 20 October 2010
(Adopted at the MSC-14 meeting)

CONCLUSIONS / DECISIONS / MINORITY OPINIONS	ACTIONS REQUESTED
Item 4 - Adoption of draft minutes of the MSC-13	
MSC-13 minutes were adopted following the changes made.	The adopted minutes will be uploaded on CIRCA and ECHA website in pdf format indicating clearly on the front page the meeting date when they were adopted.
Item 5 – Evaluation tasks **d) Brief report from the workshop on prioritisation criteria for dossier and substance evaluation**	
	SECR would report back to MSC in December meeting on the comments made by MS on the criteria for prioritising substances in substance evaluation process in written procedure. In the December meeting MSC will discuss the role of the MSC in the discussion of the criteria for prioritising the substances in substance evaluation. MSC-S will start preparing the work for the substance evaluation process for the February 2011 meeting so that there will be an understanding of what the Committee will do in terms of the opinion on CoRAP and also the substance evaluation process since MSC will be involved in the same way as for the dossier evaluation process in case proposal for amendments are made.
Item 6 – Identification of SVHC	
6b) Selection of dossiers for identification of SVHCs in written procedure	
MSC agreed with the proposal from MSC-S, that agreement for: The 4 cobalt compounds Chromium trioxide Methoxyethanol 2-Ethoxyethanol will be sought by written procedure depending on what the MSCA would decide on the content of the RCOMs and the SD. MSC agreed that the chromic acids will be	MSC-S to launch the written procedure for the selected substances on 15 November 2010 and to close on 25 November 2010. MSC-S would invite the substance ID experts

CONCLUSIONS / DECISIONS / MINORITY OPINIONS	ACTIONS REQUESTED
discussed and agreement would be sought in the MSC-15 meeting in December in the presence of the substance ID experts from ECHA. MSC agreed that agreement for the three isomers for the trichlorobenzene will be sought in the MSC-15 meeting.	for the December meeting for the discussion on chromic acids.
6c) Discussion on application of Article 57(f) criteria for current proposals	
MSC agreed that comments submitted in the public consultation proposing a new identification of the substance, over and above the identification listed in the Annex XV report, need to be properly justified to be taken into account by the MSC. MSC agreed that the comments received for the cobalt compounds and the chromium trioxide on adding the identification of 'equivalent level of concern' should not be seen as challenging the identification since they are not properly justified however it is still up to the submitter CA to make the final conclusion in the RCOMs and SD.	
Item 7 – Draft recommendation for inclusion of priority substances in Annex XIV	
7a) Outcome of REACH Committee on the first entries of Annex XIV	
	SECR will come up in the future with a training session on the authorisation process for MSC and other relevant bodies to further clarify the process.
7c) Preparations for the opinion on the draft recommendation of priority substances to be included in Annex XIV • **Discussion on the first draft opinion based on the non-updated draft recommendation**	
	MSC-S will invite the MSC to provide comments in writing on the draft opinion by 5 November 2010 to the Rapporteur and copying the MSC-S for information. The working group will organise a teleconference on 8-10 November to further discuss the draft opinion. MSC-S will place on CIRCA the draft opinion on 19 November 2010 for the December discussion.
8 – Manual of Decisions (MoD)	

CONCLUSIONS / DECISIONS / MINORITY OPINIONS	ACTIONS REQUESTED
• **Discussion on new entries for the MoD**	
The proposals for update of the MoD will be discussed in the December meeting.	MSC-S will invite the MSC to provide their proposals for wording for items to be included in the MoD by 3 November 2010.
12 - 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 MSC CIRCA together with the presentations delivered at the meeting, by 22 October 2010.