



## MINUTES

### 1. Welcome & Introduction

#### 1.1. **Reminder on Confidentiality and Competition Law.**

Participants were reminded on their obligation to comply with confidentiality and Competition Law provisions.

#### 1.2. **Tour de table and apologies.**

The list of participants is available in Annex 1.

#### 1.3. **Approval of the agenda.**

The Agenda (Annex 1) was approved. The slides presented via webconference during the conference call are available in Annex 2.

#### 1.4. **Status of actions agreed at and approval of the minutes of the last meeting (26 April 2013). Cf. slide 4 of Annex 2.**

Most actions on-going and for discussion/update today. One action relative to the type of solubility information that should be provided for an insoluble material is pending. The minutes were approved.

### 2. Feed-back from Dutch Competent Authorities

The meeting with RIVM has been confirmed to take place on 20 September. The members of the PMC delegation were approved. It was agreed to invite RIVM to consider the addition of a number of Agenda items to the Agenda for the meeting (AP1). As regards the item regarding CoCam it appeared that EBRC has experience in compiling datasets for other metal sectors and that CoCam may be adapted to another type of programme in a couple of years. PMC may hence need to re-consider how to approach the programme depending on the format it has after Substance Evaluation.

A meeting to prepare the PMC representatives for the 20 Sep meeting with RIVM will take place on 4 Sep from 9:00 till 10:30, before the 4 Sep Ag WG meeting. Eurométaux representatives will participate in this preparatory meeting. The Ag WG will naturally be updated on the outcome of this preparatory meeting and invited to comment on the key messages and background documents of relevance (e.g. PMC decision on one dossier, PNEC derivation report, etc.) suggested by the participants of the preparatory meeting (AP2).

As regards the outcome of the 20 Sep meeting, PMC Secretariat will issue notes of the meeting shortly after by e-mail, and a verbal update for discussion will also be made at the 23 Oct Ag WG meeting (AP3).

### 3. “Dossier content” box proposal

One of the reasons it has not always be clear for external parties that the 2010 Ag Registration Dossier did not include nanoAg was the absence of reference to this in the Dossier itself (only made in an *ad hoc* PMC document). This is probably one of the reasons explaining the listing of Ag on the CoRAP list related to grounds for concern associated to nanoforms of Ag.

The COM seems to have identified the need to generate a specific field where the scope of the dossier needs to be reported, and PMC has committed to including this in all Dossiers from now on. The form of this ‘dossier scope’ will either follow the recommendations of the COM (if available in time for Dossier update finalisation) or follow the recommendations by EBRC and WCA (cf. slide 10 of Anne 2) (AP4).

### 4. Project plan towards Evaluation (including adjusted roles and responsibilities)

A draft project plan/to do list containing a first set of individual tasks required to prepare for the Substance Evaluation of the Ag Dossier by The NL was circulated before the conference call for preliminary comments. This document should contain all actions of all actors so it can be used as an action tracker during the Dossier update preparation, and subsequently as check-list before the Dossier is finalized and submitted. It is therefore intended for internal use and should not be circulated externally.



Preliminary comments on the draft To Do List (Annex 4) include:

- Agreement with the proposed Ag WG meeting dates: 4 Sep, 23 Oct, and 3 Dec
- Agreement that priority should be on Ag metal Dossier update, followed very closely by Ag compounds Dossier update
- Actions relative to policy developments around nanomaterials should be included
- Actions relative to characterization data generation should be included
- Actions on lead/individual registrants should be included

It was agreed that PMC Secretariat would circulate updated versions of the To Do List with a brief description of the changes made to the Ag WG when available. These versions will also be stored onto the PMC Ag Database (AP5).

#### 5. Review of Ag Dossier before update submission?

Though PMC company experts are regularly looking at the Ag Dossier under preparation and spotting items to be corrected, re-discussed, improved, etc., following a recommendation from ECHA it was proposed to organize a parallel review by someone less involved in the daily work of the Ag project, and a more neutral or critical eye.

When brainstorming on the idea of a review, the following questions were discussed and answers provided (AP6):

- Is a review useful? Yes
- Should it be formal or informal? Preferably informal to allow it to happen in the available timeframe
- When should the review start? Sufficient time before the Dossier update submission timeframe, i.e. potentially on an interim version of the Ag Dossier in Oct 2013
- Should it be reviewed by one or more readers? Ideally more than one
- Who should review the Dossier?
  - Internally it was suggested for company experts to continue their review while BASF (new Member of PMC, not involved in Ag project before) and the new PMC Manager (starting on 2 Sep, REACH knowledgeable but not necessarily knowledgeable on metal-specific issues) have a thorough reading of the Dossier and revert with your questions and comments
  - Externally it was suggested to request Eurométaux (V. Verougstraete and H. Waeterschoot) as well as other consultants like ARCHE to review the Dossier. Furthermore, it was recommended to look for additional possibilities.

#### 6. Circulation of WCA report to Silver Institute members for information

The Ag WG agreed to share the WCA report with the members of the Silver Institute in principle, under a number of the conditions (AP7).

#### 7. Minimum substance identification & characterization data requirements for individual registrants

##### 7.1. Review of PMC characterisation recommendations

The latest version of the PMC recommendation on characterization is available in Annex 3. The Ag WG agreed with the changes made to the document (cf. slide 19 of Annex 2).

##### 7.2. Targeted compliance checks on Substance Identification on Dossiers subject to Evaluation in 2013

Participants were reminded on ECHA's intention to screen both individual and joint/lead registration dossiers of substances subject to Substance Evaluation soon, with a focus on substance identity and characterization.

All Ag metal registrants should be generating and preparing to include the relevant characterization information (as per PMC recommendation, unless this is already in their dossier) in their Dossier, as well as regularly checking their REACH-IT mailbox for ECHA Article 36 letters requesting more information (AP8).

#### 8. AgCl and Ag compounds in general: update of section 1 & 2 in joint dossier

The Ag WG agreed that it would be useful to describe the general profiles of forms (purity- and size-related) of the substance covered by a given Dossier in all PMC Dossiers, starting with the Ag



and Ag compounds ones.

In the Ag metal one in particular, a reference should be made to the Doré dossier for all those impure metallic forms of Ag metal which are used as intermediates.

As regards AgCl, the Ag WG confirmed that AgCl can be normally found in impure form when it is used as an on-site intermediate (cf. slide 24 of Annex 2). Since this impure form is only used as an intermediate < 10 t/a its classification can be reported in the joint dossier (properly associated to the relevant composition) but does not need to be included in the AgCl hazard assessment.

It was agreed for all Ag and Ag compounds registrants to look again at the sizes and purities they manufacture and import so as to update sections 1.2 and 2 of the relevant files with the applicable profiles (AP9).

#### 9. 4th ATP to CLP: impact on Ag project classification and labelling requirements

Following review by EBRC and WCA and discussion with the Ag WG, the 4<sup>th</sup> ATP to CLP does not impact on the classification and labelling requirements of any of the Ag substances in scope.

#### 10. Other tasks

- **Standard phrases for ES of inorganic substances:** it was agreed to support the request for Eurométaux to launch such a project, as part of the review of Chesar (due in ~ 1 year), or as a separate *ad hoc* project.
- **Generation of short ES for Ag substances:** it was agreed to check whether these short ES have/can be generated before launching any type of translation work. **Post-meeting note:** *the short ES have been produced and circulated to the relevant registrants on 22 Aug 2012.*
- **Translation of ES/SDS:** it was agreed to organise the translation of the short ES once these are available, in the number of languages decided by the Ag WG at its next meeting. (AP10)
- **Transport classification in PMC inventories:** it was agreed that this would be useful exercise that should be launched ASAP (AP11).

#### 11. AOB, next meetings and closing remarks

##### 11.1. Alert on significant changes to IUCLID 5 file to facilitate review.

It was suggested to alert Ag WG participants when significant changes are made to the IUCLID 5 file so as to allow company experts to focus on these changes when (more or less) regularly reviewing the file (AP12).

##### 11.2. Other AOB

- **C. Braibant has been nominated as Chairperson of the Eurométaux Nano TF.** This TF mainly functions as a network in which mainly only the experience on the ZnO (Christine Spirlet) and Ag cases are used as a basis to participate in and respond to a number of EU initiatives on nanos.
- **COM reviewing recommended definition of nanomaterial.** The aim is to make it less broad. It was suggested to request that the definition should more explicitly apply to nanomaterials that are intentionally manufactured but no clear definition of where this intention starts and stops is available at the moment.
- **Public consultation on REACH annexes.** The aim is to collect views on which clarifications/nano-specific information requirements should be added to the REACH annexes. The response to the consultation will be prepared jointly with Eurométaux, and the Zn association. It was recommended for as many companies as possible to respond to the consultation (Annex 5), whether or not they are involved in nanomaterials (AP13).

##### 11.3. Next meetings

Cf. slide 13 of Annex 2 and cover page of Ag Sub Ev To Do List.

#### Annexes:

1. Agenda and list of participants
2. Slides presented at the conference call
3. 10 Jul 2013 version of PMC recommendation on characterisation
4. Updated version of Ag Sub Ev Master To Do List (including actions of 17 & 18 Jul Ag WG cc)
5. .pdf version of public consultation relative to REACH annexes and nanomaterials



**Table 1.** Actions agreed at the 18 July 2013 Ag WG + Nano TF joint conference call

	What?	Who?	When?
1.	<p>Revert to RIVM requesting that the following Agenda items are included in the Agenda for the meeting:</p> <ul style="list-style-type: none"> <li>• Timeline, logistics, communication, and roles and responsibilities in preparing for and during Substance Evaluation (RIVM)</li> <li>• Organisation of RIVM services re REACH, Water, OECD activities, and identification of potential bridges across services (RIVM)</li> <li>• Clarification on the grounds for concern on Ag (RIVM)</li> <li>• Ag Dossier update under preparation and Ag research work in progress (PMC)</li> <li>• Interest in joint contribution to OECD CoCam programme after Substance Evaluation? (PMC)</li> </ul>	PMC Secretariat	Done on 19 Jul 2013
2.	<p>a) Propose key messages/positions and relevant background documents for circulation to RIVM</p> <p>b) Approve key messages/positions and relevant background documents for circulation to RIVM proposed by PMC representatives participating in 20 Sep meeting with RIVM</p>	Participants of preparatory meeting Ag WG	4 Sep 2013 9:00 4 Sep 2013 10:30
3.	Update Ag WG on outcome of 20 Sep meeting with RIVM	PMC Secretariat	By mail w/c 23 Sep 2013 At 23 Oct 2013 mtg
4.	<p>a) Include clear dossier scope in all PMC dossiers, starting with Ag metal Dossier, based on COM recommendation or one or more of the following approaches:</p> <ul style="list-style-type: none"> <li>• The CSR: top of the document, between front page and part A</li> <li>• The UCLID 5 file: by adding a section under "Type of Substance" in section 1.1 Identification</li> <li>• The dossier header in step 7 of dossier creation: in free text box "Dossier submission remark", under Dossier name given by user</li> </ul> <p>b) Add this task to Ag Substance Evaluation To Do List</p> <p>c) Send extract of Cu Dossiers' CSR illustrating approach to describing the scope of a risk assessment/Dossier</p>	EBRC & WCA  PMC Secretariat D. Cholakova	Propose wording for approval at 3 Dec 2013 Ag WG mtg  Done on 19 Jul 2013 ASAP
5.	<p>a) Update To Do List integrating all suggestions made and re-circulate to Ag WG for comment</p> <p>b) Provide comments on Updated To Do List to PMC Secretariat</p> <p>c) Prepare final draft To Do List and circulate to Ag WG for approval at 4 Sep 2013 meeting</p> <p>d) Circulate updated versions of the To Do List with description of changes made to Ag WG + upload onto Ag database</p>	PMC Secretariat Ag WG  PMC Secretariat PMC Secretariat	19 Jul 2013 26 Aug 2013 28 Aug 2013 On the 10 <sup>th</sup> of every month and before Ag WG mtgs
6.	<p>a) Elaborate a formal proposal for the Ag Dossier review including all options discussed at the 18 Jul cc and circulate to Ag WG</p> <p>b) Discuss and decide on best way forward for review</p> <p>c) Contact recommended reviewers and launch Ag Dossier review logistics</p> <p>d) Report on outcome of Ag Dossier review and agree on final adjustments to the Dossier</p>	PMC Secretariat  Ag WG  PMC Secretariat PMC Secretariat or reviewer(s)	26 Aug 2013  4 Sep 2013 Ag WG mtg Sep-Oct 2013 3 Dec 2013 Ag WG mtg



Chairperson: R. Garrett (Ames Goldsmith)  
Secretariat: C. Braibant (EPMF)

18 July 2013, 10:30 CET  
Pin code: 36389671#

	What?	Who?	When?
7.	a) Add following items to report before circulation to Silver Institute: <ul style="list-style-type: none"> <li>• “Confidential, do not cite” as watermark on all pages</li> <li>• Disclaimer indicating that the document contains opinions that do not necessarily reflect the opinion of the PMC Members</li> <li>• Disclaimer indicating that the document has been reviewed for possible TSCA 8e) notification content and that nothing was found to be of reportable nature</li> </ul> b) Confirm agreement to share the WCA report with the Silver Institute c) Circulate updated report to Silver Institute	WCA  DuPont  PMC Secretariat	31 Jul 2013  31 Jul 2013 1 Aug 2013
8.	a) Generate and include characterisation information in individual Ag metal registration dossiers, and monitor REACH-IT mailbox for ECHA requests for more information on substance identity b) Forward characterisation information to PMC Secretariat c) Aggregate characterisation information and include in joint dossier sections on physico-chemical properties	Ag registrants  Ag registrants EBRC	Aug-Sep 2013  Oct 2013 Oct 2013
9.	a) Report impure form of AgCl (only used as an intermediate < 10 t/a) in sections 1.2 and 2 of AgCl joint dossier (no need to be included in the AgCl hazard assessment) b) Look again at the sizes and purities of Ag and Ag compounds that are manufactured and imported and inform PMC Secretariat accordingly so the typical profiles can be included in the relevant dossiers	EBRC  Ag and Ag compounds registrants	Oct 2013  Oct 2013
10.	a) PMC should support the request for Eurométaux to launch a project on standard phrases for ES of inorganic substances, as part of the review of Chesar (due in ~ 1 year), or as a separate <i>ad hoc</i> project b) Decide on languages in which Ag short ES should be translated at PMC level c) Organise translation of the short ES once these are available, in the number of languages decided by the Ag WG at its next meeting	PMC Secretariat  Ag WG  PMC Secretariat	EM 23 Sep 2013 ES mtg  4 Sep 2013 Ag WG mtg Nov-Dec 2013
11.	Derive transport classification for all PMC substances and add to PMC inventories	PMC Secretariat	ASAP
12.	Prepare response to public consultation on REACH annexes and circulate to Ag WG for discussion/approval at 4 Sep 2013 Ag WG meeting	PMC Secretariat	28 Aug 2013