

Precious Metals and Rhenium Consortium Silver Work Group & Nano Task Force Admin Conference call

18 July 2013, 10:30am-11:30pm CET

[1]

1. Welcome and introduction

Rob Garrett

[2]

Welcome and introduction

- Confidentiality and Competition Law
- Tour de table & Apologies
- Approval of the agenda
- Status of actions agreed at and approval of minutes of the last conference call (26 April 2013 Nano WG) (*C. Braibant*)

[3]

Actions agreed at the 26 April 2013 Nano WG conference call

	What?	Who?	Status
1.	Confirm what solubility information should be provided for an insoluble material: H2O solubility, T/D, and/or bio-elution?	CB	Pending
2.	Update on exchanges with NIA	CB	Nothing to report
3.	Identification of potentially relevant studies from RAS Materials	EBRC & WCA	Done
4.	Record agreed way forward for all data gaps identified in table 5.3 of WCA report	WCA	Done
5.	Update on status of NTP study	EBRC	Reminder sent to NTP
6.	Update on feed-back from RIVM	CB	Done today
7.	Update on SAS Substance Evaluation	CB	No new info
8.	Update on PMC proposal to include a dossier content box	CB	Done today
9.	Presentation of Ag Evaluation Plan for discussion	CB	Done today

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Actions agreed at the 26 April 2013 Nano WG conference call

	What?	Who?	Status
10.	Update on on-going testing	KR & WCA	Done on 17 Jul
11.	Update on additional research options	KR & WCA	Done on 17 Jul
12.	Update on status of CSIRO nanoAg dataset	KR & WCA	Done on 17 Jul
13.	Update on comments on WCA report	KR & WCA	Done on 17 Jul
14.	Pros and cons of using JRC nanoAg material as sample source	WCA	Done on 17 Jul
15.	Draft workplace ES and/or recommendation on additional measurements or monitoring needs	EBRC	Discussed on 17 Jul
16.	Update on waste ES	KR	Done on 17 Jul

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2. Feed-back from Dutch Competent Authorities

[6]

Mail received on 25 June 2013

From: Peter van Iersel on behalf of bureau-reach@rivm.nl
Sent: mardi 25 juin 2013 17:02
To: Klaus Rothenbacher
Cc: Betty Hakkert; Caroline Braibant; bureau-reach; d.cholakova@aurubis.com; Eric Bleeker; Peter Simpson; Petra van Kesteren; Rüdiger V. Battersby; Susan Wijnhoven; Maarten Nederveen
Subject: RE: Evaluation of Silver (CAS 7440-22-4)

Dear Mr Rothenbacher,

We will invite you for the informal meeting at RIVM on 20 September from 13.00 to 16.00 hr, RIVM Bilthoven

RIVM Participants from our side are:
Dr. Betty Hakkert, human toxicologist and coordinator Substance Evaluation Bureau REACH
Dr. Petra van Kesteren, human toxicologist, VSP
Dr. Eric Bleeker, eco toxicologist, VSP
Dr. Susan Wijnhoven, human toxicologist, VSP
Dr. TheoTraas, eco toxicologist and coordinator Substance Evaluation Bureau REACH
Ing. Maarten Nederveen, secretary Substance Evaluation Bureau REACH

Begin September we will contact you for more details on location and agenda.

Hoping tot have informed you sufficiently.

Best regards,

Peter van Iersel

Bureau REACH
Expertise Centre for Substances (RIVM/SEC)
RIVM
The Netherlands

PMC to propose following Agenda items?

- Organisation of RIVM unit re REACH, Water, OECD activities and identification of bridges across services
- Ag Dossier update under preparation and Ag research work in progress
- Communication between 20 Sep and start of Substance Evaluation
- Contribution to OECD's Cooperative Chemicals Assessment Meeting (CoCAM) after Substance Evaluation

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Preparation for 20 Sep 2013...

1. Participants:

- Peter Simpson, WCA environment, UK (consultant to PMC, ecotox.)
- Dr. Rodger Battersby, EBRC (consultant to PMC, mammalian tox.)
- Daniela Cholakova, Aurubis (LR)
- Caroline Braibant, PMC (PMC secretary general)
- Dr. Klaus Rothenbacher, PMC (PMC science manager)

2. Pre-meeting on 4 Sep 2013 to:

- With EM representatives
- Agree on key messages
- Identify possible topics for Agenda (if allowed)
- Determine material that should be sent to RIVM in advance

3. Communicate back to RIVM in preparation of 20 Sep 2013 meeting

[8]

3. “Dossier content” box proposal

[9]

Clarification on dossier scope needed

- One of reasons explaining listing of Ag on CoRAP list is absence of explicit description of dossier scope, i.e. the 2010 version of the dossier did not appear to be a ‘bulk only’ dossier
- PMC anticipating the need to develop a proposal for a dossier scope to be included in:
 - The CSR: top of the document, between front page and part A
 - The UCLID 5 file: by adding a section under “Type of Substance” in section 1.1 Identification
 - The dossier header in step 7 of dossier creation: in free text box “Dossier submission remark”, under Dossier name given by user
 - Other?
- Meanwhile, COM has picked up this suggestion and considering how to do so (cf. public consultations relating to REACH annexes on nanomaterials, Question 21a *et al.*)

[10]

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

[11]

Cf. To do list circulated in advance of the meeting

- Aim:
 - Until 2 Dec 2013: To do list/action tracker
 - As from 3 Dec 2013: check-list before submission of dossier update
- Internal document, confidential, not for large distribution outside Ag WG, TAP and Management Committee of PMC
- Brief presentation by CB today:
 - Pre-Dossier update versus post-Dossier update tasks
 - PMC versus Consultants work (colour-code)
 - Three meetings between Sep and Dec before Dossier update submission
 - Includes communication/administrative and technical/scientific tasks
 - First column will indicate status of action
- Comments on the document today + by e-mail by deadline to be agreed by all

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Some questions already...

- Three meeting dates/milestones proposed, ok?
 - 4 Sep: prepare meeting with RIVM
 - 23 Oct: progress all key deliverables and IUCLID 5 + confirm future research needs for presentation to Assembly on 4 Dec
 - 3 Dec: finalisation all key deliverables and IUCLID 5 + preparation for Dossier update submission
- Ag metal and Ag compounds:
 - All in Dec 2013? Or,
 - Ag metal in Dec 2013 and remaining in Jan 2014?
- Other?

[13]

5. 'Peer' review of Ag Dossier
before update submission? If
yes, who?

[14]

(Peer) review...?

- No doubt dossier is of high quality!
 - Review is ECHA's informal recommendation to maximise chances of success of Substance Evaluation
 - Aim is to have an extra pair of eyes looking at dossier and spotting items we may be missing (by being so closely involved) so they can be improved in the next update
 - For discussion by the team
1. Yes or No?
 2. Formal or informal?
 3. When?
 4. By one or more readers?
 5. By whom?
 - Internal:
 - Company Member
 - New EPMF colleague
 - Other
 - External
 - Eurométaux
 - Wim Van Tilborg
 - ETAP
 - Other consultant
 - Academia (e.g. Eric Smolders, KUL)
 - Member State
 - Other

[15]

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

[16]

- Silver Institute fighting similar battle in US
- Silver Institute experts have been consulted by WCA a number of times – group work
- Elements of work done by WCA are of interest to Silver Institute Nano Task Force
- OK for Silver Institute experts to circulate WCA report to their members?
- Anonymity, confidentiality, work in progress, etc... Proper disclaimer to be added to report before circulation

[17]

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

[18]

7.1. Review of PMC characterisation recommendations

Following additions made to earlier version:

- Under step 3 - *NOTE: DLS only is not appropriate or sufficient as it is heavily weighted towards detection of larger agglomerates; the intensity of the DLS signal varies in proportion to the sixth power of the diameter of the particle (Domingoes et al. 2009).*
 - Contribution from Silver Institute
- At the end of the document
 - “...and reported to the entity preparing the joint registration dossier so the individual registrants’ information can be reported in an aggregated manner in the joint dossier and provide an indication of the boundaries of applicability/coverage of the scope of the dossier.”
 - “The information resulting from the above measurements are aimed at identifying and characterising a material, not at inferring on the hazard or risk that the substance may pose.”
- Latest version dated 10 July 2013

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7.2. Targeted compliance checks on SID on Dossiers subject to Evaluation in 2013

- One of learning lessons of first round of Substance Evaluations:
 - ECHA to perform compliance checks before Evaluation commences
- Usual weakness so far in dossiers is around substance identification:
 - Compliance checks will be targeting this aspect in dossiers
- Ag on CoRAP + general SID weakness =

Compliance checks on individual Ag registrations anticipated!
Start generating SID information ASAP!

[20]

8. AgCl and Ag compounds in general:
update of section 1 & 2 in joint dossier
to reflect purity profiles: pure, impure
specific, impure general

[21]

Pure and less pure...? Bulk and nano...?

- Ag and AgNO₃ dossier contains more than one size and/or composition profile in section 1.2 (with associated classifications under section 2)
- This needs to be done for all Ag dossiers, which should typically contain (combinations of) the following profiles (for transparency or because of varying classifications):
 - Size:
 - Massive
 - Powder > 100 nm
 - Nanoform
 - Purity:
 - Pure > 99,9%
 - Typical impure with specific classification profile
 - Impure < 99,9%

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Ag example

Section 1.2 of Ag IUCLID 5 Dossier contains:

- Massive pure Ag: not classified
- Massive impure Ag: classified according to impurities
- Powder pure Ag: classified for ENV
- Powder impure Ag: classified for ENV + classification of impurities

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Typical impure AgCl with specific classification

Composition:

- 93-97 % of AgCl (medium 96%)
- 0-5% of H₂AuCl₄ (medium 3 %)
- 0-0.5 % of H₂PtCl₆ (medium 0.2%)
- 0-1.5% of H₂Pd Cl₄ (medium 0.8 %)

Applicable CLP classification:

- Skin corr 1B
- Eye dam/irrit 1
- Resp/Skin Sens 1A
- ENV Acute 1 and Chronic 1

Question to the WG:

- Is this a:
 1. Typical profile that should be included in the dossier
 2. Profile out of other possible ones, which would be covered by a generic impure composition/classification entry

[24]

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

[25]

- EBRC and WCA have been requested to check what impact the 4th ATP to CLP would have on Ag and Ag compounds
- Only relevant change is:
 - *Substances or mixtures classified as corrosive to metals but not corrosive to skin and/or eyes which are in the finished state as packaged for consumer use do not require on the label the hazard pictogram GHS05 (the corrosivity pictogram).*
- Questions to the group:
 - Is the condition “*which are in the finished state as packaged for consumer use*” relevant for AgCl?
 - Is inner packaging with ≤ 10 mL content (Section 1.5.2.) relevant for Ag and Ag compounds in general?

[26]

10. Translation of ES/SDS?

[27]

Next tasks...

Eurométaux project:

- Deriving standard phrases in various EU languages

PMC:

- Translating ES/SDS in various EU languages?
- Deriving transport classification and add to PMC inventories?

[28]

11. AOB, next meetings and closing remarks

Rob Garrett

[29]

AOB

- CB nominated as chair of Eurométaux Nano Task Force
- Commission reviewing definition of nanomaterial
 - Comments:
 - Deadline: 15 July 2013
 - Received/conveyed: definition should be specified as pertaining to those nanomaterials that are 'intentionally engineered'
 - Data:
 - Deadline mid-Sep 2013
 - Constituent (primary) particle size distribution by particle numbers
- Public consultation relating to REACH annexes on nanomaterials
 - Deadline: 13 September 2013
 - Approach: as many responses as possible
 - EPMF's response will take on board all PMC Member companies' responses
 - Eurométaux' response will take on board all EM Members' responses (including EPMF)
 - Proposed way forward:
 - A) PMC completes a questionnaire and circulates for comment, or
 - B) Companies complete questionnaire and PMC completes one with answers received, and then circulates for comment

[30]