



Silver Work Group Meeting –minutes

AP refer to Action Points listed at the end of this document.

1 Welcome and 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 is available in Annex 1. No remarks / additions; agenda approved. The slides presented during the meeting are available in Annex 2.

1.4 Approval of the minutes of the last meeting (19 May 2015) and the last call (26 June 2015) and status of action points

The minutes of the last meeting and call were approved. The status of action items is available on slides 6-7 in Annex 2.

2 Substance Evaluation (SEv) by Dutch MSCA

2.1 Update on process/timeline

The process / timeline related to the SEv was discussed (cf. slides 9-10 in Annex 2). Comments on the draft decision (DD) were submitted via the Registrants contact point (Heraeus) by 15 June.

(Post meeting note: In the meantime, RIVM informed PMC that the discussion of the Ag DD at MSC level is foreseen for MSC-47, which will take place 25-29 April 2016. The 30-day commenting period for Registrants to comment on the proposals for amendments (PfAs) from MSCAs/ECHA will run from 27 February until 29 March 2016.)

2.2 Submission dossier update by 1 November

Following PMC's comments on the DD, we asked for the possibility to update the Ag dossier for the following reasons:

- 1) allow a better identification of the nanoAg registrants (because some registrants included the generic compositions in their registration while not applicable to them) and;
- 2) include 2 papers identified in our comments to the DD in the joint dossier.

RIVM agreed to a dossier update by 1 November. Furthermore, the PMC decided to submit a testing proposal for a reprotox study (cf. agenda point 3) so that will be submitted together with this update.

2.2.1 Update composition section

Cf. slides 12-14 in Annex 2. IUCLID section 1.2 (composition section) was updated to more accurately identify and reflect the number of nanoAg registrants. The compositions will be clearly marked as "generic" or "legal entity specific" in the LR dossier and the co-registrant dossiers should only include the legal entity specific composition(s). This means that – apart from the LR dossier – only the dossiers from nanoAg registrants will include nanoAg in section 1.2. Furthermore, if an update of the generic compositions is needed in the future, this only needs to be done in the LR dossier.



Comments/additions:

- Co-registrants cannot link their legal entity specific composition to a classification in their IUCLID dossier, as their dossier should not include IUCLID section 2 (classification) unless they opt-out from the joint classification.

(Post meeting note: While there is no obligation or specific field in the co-registrant dossier to indicate which of the generic classifications is applicable to their legal entity, co-registrants can add their classification in the 'name' and/or 'brief description' fields of their legal entity specific composition in section 1.2 if they wish.)

- In the future, it would be useful to link the nano form to its tonnage to demonstrate the proportionality of the SEv requests using aggregated tonnages. However, in the current IUCLID version, it is not possible to indicate a separate tonnage for the nano form. This may be possible in IUCLID 6. **AP1**

(Post meeting note: While there is no specific field in IUCLID to report the nano tonnage, it is possible to specify the tonnage for manufacture/use in Section 3.5. Therefore, it would be possible to add manufacture of nanoAg as a separate manufacture name in Section 3.5 and report the nano tonnage there. In this case, it is important that only the nanoAg registrants report this extra manufacture name.)

2.2.2 Inclusion data identified in DD comments

Cf. slides 15-16 in Annex 2. It is noted that we do not expect RIVM to change their position because of the 2 additional studies added, they are only added in support of our comments/WoE approach.

2.2.3 Guidance submission

Cf. slide 17 in Annex 2. The updated Ag co-registrant IUCLID file will be circulated by 20 October to be submitted by 30 October at the latest. The updated Ag Lead Registrant (LR) file will be sent later to allow additional review time for the testing proposal (cf. agenda point 3). It is noted that ALL registrants are invited to update their file to ensure consistency.

Since there is limited time to update the dossier due to the deadline imposed by RIVM, there will be no time for a full review of the updated dossier. **The WG approved the dossier updates with regard to the composition section and the inclusion of the 2 new papers as presented above. AP2-5**

2.3 Update on SEv testing

2.3.1 Phys-chem characterisation

Cf. slides 18-19 in Annex 2. The PMC Secretariat is currently collecting quotes for the phys-chem testing monitoring, and start of the testing is foreseen early 2016. It is noted that it would be useful for the PGM Rhodium nano budget to know the total costs for complete phys-chem characterisation of a single nanoform. **AP6**

2.3.2 Pilot testing *Daphnia media*

Cf. slides 20-21 in Annex 2. The acclimation period as described in the slides has started. The WG agreed to the suggested testing approach. **AP7**

3 Testing proposal extended one-generation reproductive toxicity study (EOGRTS)

Cf. slides 23-26 in Annex 2. Given there is still a data gap on Ag reproductive toxicity (which was already identified in 2008), the Ag WG agreed to submit a testing proposal (TP) for an EOGRTS together with the



upcoming dossier update. The draft document outlining the background and rationale for the TP and the suggested test design was circulated to the Ag WG on 21 September (cf. Annex 3).

Comments/points of discussion:

- It is noted that even CROs have limited experience with the EOGRTS.
- The expected costs and timing of the study depend on when the TP will be reviewed (the study start is not expected until several years away but there are no official ECHA deadlines for a TP that is submitted during a dossier update). It is probable that the TP will be accepted (with or without modifications) but the outcome of the TP consideration will also depend on the outcome of the RAC discussions on SZZ CLH.
- The WG discussed the optimal reference compound. Ag lactate was originally proposed (Ag nitrate is not possible because corrosive) but Ag acetate is also possible. Ag lactate is about 7 times more soluble than Ag acetate but Ag acetate is more commonly used. The WG agreed to use the more referenced compound, i.e. Ag acetate. **AP8**
- It is noted that more detail is needed on the justification of the read-across from the suggested test compound to Ag. **AP8**
- The WG discussed the need for the additional cohorts on developmental neurotoxicity (DNT) and immunotoxicity (DIT), which should be performed in case of particular concern. The WG agreed that the studies indicating possible effects are badly designed and there is no 'particular' concern based on 'relevant' data. The TP document will be further updated to clarify this section. **AP8**
- It is noted that there may be further possibility for us to comment during the public consultation. **AP11**
- A more definitive argumentation is needed related to the absence of necessary triggers to consider the inclusion of the F2 generation. **AP8**
- The WG agreed to perform the preliminary toxicokinetics work before the actual study (trans-placental, blood-brain, blood-CNS). The toxicokinetics work will cost approx. 60.000 €.
- Once the TP is approved, there will have to be a technical dialogue with ECHA. We have to make sure we are prepared for that.

4 CLH proposal silver zinc zeolite

4.1 Update on process/timeline

Cf. slide 29 in Annex 2.

4.2 Overview comments received during commenting period

Cf. slides 30-35 in Annex 2.

4.3 Advocacy plan

Cf. Annex 4 and slides 36-38 in Annex 2. Comments/additions:

- The silver zinc zeolite (SZZ) CLH will be discussed at the RAC meeting early December. PMC can send an expert to the meeting to defend our case and proposed Mark Raffray; the WG agreed.
(Post meeting note: The RAC Chair agreed to the participation of Mark Raffray and invited him to accompany the regular Eurométaux stakeholder observer for the SZZ classification discussion. In addition, Eurométaux will raise a number of more principle issues on the SZZ environmental classification, as there are some interpretations of the ECHA metals classification guidance that may impact metals classifications at large.)
- It is unsure if ESTF has a seat at the RAC meeting as an observer. **AP12**
(Post meeting note: It seems ESTF does not have a seat at the RAC meeting as an observer but may try to get an expert invitation.)
- WTO notification: it is noted that bringing in some non-EU countries in the discussion may help at this stage.



- A stakeholders mapping has been done and is attached to Annex 4. Downstream users will not be contacted at this stage as too early and the issue is limited to SZZ.
- According to a legal opinion obtained by ECI, the classification will only be applicable to biocides. For our substances, we are still allowed self-classification. **AP13**
- It is noted that the European Commission can follow a fast track procedure to make amendments to Annex XVII on restriction for consumer use following the proposed Repr. 1B classification, meaning Ag can be restricted for consumer use as a substance and in mixtures.
- The advocacy actions will be discussed with LBMA on Oct 17. **AP14**
- Suggestions/additions from the WG on the PMC advocacy letter:
 - Ag-based microbiocides are increasingly used in response to microbial antibiotic resistance, which is a topical governmental concern.
 - Sustainable technology applications of Ag should be emphasised, e.g. photovoltaics, Ag as replacement of Cd in brazing alloys.
 - Our scientific comments should be reinforced in the letter. **AP15-17**
- **The WG agreed with the main lines of the advocacy plan. AP18**
- It is noted that PMC has tried to set up a meeting/call with ESTF to join forces on the advocacy actions but without success. PMC companies may be members of the ESTF and the PMC Secretariat will follow up. **AP12**

5 Workplan and budget

Cf. slides 40-41 in Annex 2. Comments/additions:

- The 2016 CLH budget is realistic but not based on a worst-case scenario. It is suggested to increase this to 50.000 €. **AP20**
- EPMF has been working on Ag since 2006 and it is suggested to do a mapping of what has been done in the past by experts, as it is important to have a knowledge depository. **AP21**
- Regarding the nanoAg cost-sharing proposal, a first summary note has been sent to the PMC Cost-sharing WG and the Management Committee for review. The underlying idea is that the data on the nano and the 'bulk' forms will be part of a single dossier and a factor will be applied for nano registrants similar to the tonnage factor. The Cost-sharing WG will review the cost-sharing formula and present to the Management Committee. The proposal is to decide on the use of this nano cost-sharing formula on an ad hoc basis.

The 2016 budget was approved by the WG (with abovementioned revision to the CLH budget).

6 AOB, next meetings/calls and closing remarks

- The WG agreed to the suggestion to list the Ag uses on the EPMF website and link each use to the respective ES. **AP22**
- Following a question from a WG member, it is noted that as from 1 September 2015, companies selling Ag for biocidal applications have to be on the BPR Article 95 list. Not being on the Article 95 list implies that costumers using Ag for biocidal applications, will have to find another supplier that is on the list. Since the BPR is outside the scope and expertise of the PMC, the PMC cannot give advice on how companies should proceed but if there are PMC companies interested in submitting an application for inclusion in the Article 95 list, they can inform the PMC Secretariat and these companies can then decide if they want to proceed together independently from the PMC. **AP23**
- The PMC Secretariat updated the WG on the ongoing JRC monitoring programme, in which Ag is included, and PMC's contribution to the Eurométaux comments. Based on the first summary of the monitoring data, Ag would possibly be considered as a priority substance under the EU Water Framework Directive. The PMC Secretariat will keep following up this issue and considers re-



submitting previous comments submitted to JRC, including the UK monitoring study. **AP24**

- The next Ag WG meetings will be held 21 April and 6 October 2016 in Brussels.

Annexes

1. Agenda & list of participants
2. Slides presented at the meeting
3. Testing proposal extended one-generation reproductive toxicity study (EOGRTS) (M Raffray, Draft v1 - 11 Sep 2015)
4. PMC advocacy plan silver zinc zeolite CLH (F Capon, 21 Sep 2015)

Actions

Table 1. Actions agreed at the 15 October Ag Work Group meeting in Brussels

	What?	Who?	When?
Substance Evaluation by Dutch MSCA			
1.	Check if IUCLID 6 allows the split of tonnage by form (nano versus bulk)	PMC Sec	After release of IUCLID 6
2.	Circulate updated Ag co-registrant IUCLID file + guidance for submission	PMC Sec	By 20 Oct
3.	Circulate updated Ag Lead Registrant IUCLID file + guidance for submission	PMC Sec	By 26 Oct
4.	Submit updated Ag IUCLID file	All Ag registrants	By 30 Oct
5.	Inform RIVM about updates made to the Ag dossier	PMC Sec	30 Oct
6.	Check total costs for complete phys-chem characterisation of a single nanoform for use in the PGM Rh budget	PMC Sec	ASAP
7.	Inform Fraunhofer on the agreed testing approach for pilot testing <i>Daphnia</i> media	WCA	ASAP
Testing proposal EOGRTS			
8.	Review the EOGRTS testing proposal following the WG discussions: <ul style="list-style-type: none"> • Test compound Ag acetate instead of Ag lactate; • Refinement to the section on DIT/DNT; • A more definitive argumentation related to the absence of necessary triggers to consider the inclusion of the F2 generation. 	M. Raffray with input from M. Hosford, N. Rajapakse & S. Verberckmoes	By 19 Oct
9.	Circulate revised EOGRTS testing proposal	PMC Sec	20 Oct
10.	Review revised EOGRTS testing proposal	Ag WG	By 21 Oct
11.	Check procedure for further commenting during the TP public consultation	PMC Sec	ASAP
CLH proposal silver zinc zeolite			
12.	Check if ESTF will participate to the Dec RAC meeting and wants to join forces on further advocacy actions	PMC Sec	ASAP
13.	Ask ECI to share legal opinion regarding applicability of CLH with PMC/Ag WG	D. Cholakova	ASAP
14.	Discuss SZZ CLH advocacy actions with LBMA	PMC Sec	17 Oct
15.	Update PMC advocacy letter on SZZ CLH following the WG discussions and re-circulate to the Ag WG	PMC Sec	By 23 Oct
16.	Review PMC advocacy letter on SZZ CLH	Ag WG	By 30 Oct
17.	Send PMC advocacy letter on SZZ CLH to MS & EC (with special attention to those MS that commented during the SZZ CLH commenting period)	PMC Sec	Nov 2015
18.	Follow-up advocacy plan SZZ CLH	PMC Sec	Q4 2015 - Q1 2016
19.	Prepare RAC meeting discussion on SZZ CLH	PMC Sec with M. Raffray and EM	Nov 2015
Other			
20.	Increase 2016 CLH budget to 50.000 €	PMC Sec	ASAP



PRECIOUS METALS AND RHENIUM CONSORTIUM
SILVER WORK GROUP MEETING

CHAIRMAN: R. GARRETT (AMES, UNITED KINGDOM)
SECRETARIAT: K. ARIJS (EPMF, BELGIUM)

15 OCTOBER 2015, 9:00 – 12:00 CET
METALS CONFERENCE CENTRE – ALUMINIUM ROOM
RUE DU DUC 100 – 1150 BRUSSELS (BELGIUM)

21.	Check possibility to map Ag work done by EPMF since 2006	PMC Sec	Nov-Dec 2015
22.	List Ag uses on the EPMF website and link each use to the respective ES	PMC Sec	Q1 2016
23.	Inform the PMC Sec if interested in submitting an application for inclusion on the BPR Article 95 list for Ag	Ag WG	Q4 2015
24.	Follow-up ongoing JRC monitoring programme	PMC Sec	As needed