



Silver Work Group Meeting – draft 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 Nov 2013)

The minutes of the last meeting were approved.

2 Evaluation by Dutch MSCA (RIVM)

2.1 Update on process/timeline

The process / timeline related to the Substance Evaluation (SEv) was discussed (cf. slides 7-8 in Annex 2). Registrants received the draft decision (DD) on 7 May and have until 15 June to submit preferably consolidated comments via the Registrants contact point. It was stressed that this commenting round is the most crucial point for PMC input, allowing comments on all aspects of the DD. Later on in the process, we can only comment on proposals for amendments (PfA) from other MSCAs.

2.2 Draft Decision: information required on nanosilver and comments/concerns

Information requirements (cf. slides 9-10 in Annex 2):

- The scope of the SEv is limited to the properties of and information on nanoforms of Ag, meaning only those Registrants whose registration covers nanoforms of Ag shall provide the information requested in the DD.
- It is up to each Ag producer to demonstrate whether or not he produces nanoAg.
- The DD states that information is required on each grade/form of nanoAg. It was noted that CEFIC is also working on the “grade” definition (**AP1**).
- The DD requests further information on nanoAg in the following areas:
 - 1) Physicochemical properties
 - 2) Fate in soil
 - 3) Ecotoxicity studies
 - 4) Uses

2.2.1 General comments/concerns

- PMC will ask for an extension of the indicated timeline to comply with the requests in the DD (currently 12 months), mainly for soil testing/aging (**AP3**). It is noted that an extension of 12 months may not be sufficient if we already need 12 months for the soil aging alone.
- PMC will ask RIVM for clarification on the terms “grade” and “form” (**AP2**).



2.2.2 Physicochemical properties

Cf. slides 12-19 in Annex 2. Comments/additions:

- PMC stated that any non-reported nanof orm during this SEv follow-up might be considered as a new substance meaning a separate registration may be required.
- The goal of RIVM will probably be to have separate dossiers for bulk and nanoAg.
- There is a review of the EC definition of “nanomaterial” ongoing, but the JRC report is still not published and no revision is expected before end 2015. Furthermore, there are no validated test methods yet for nanomaterials.

(Post meeting note: During the 4 June PMC Assembly meeting, Christine Spirlet (IZA) gave an update on OECD, ECHA and European Commission activities related to nanomaterials. The presentation is available in Annex 5.)

- Possibility for grouping (cf. slide 16):
 - In terms of the requests on physicochemical properties, the DD is comparable to the DD on SiO₂ (which was based on similar concerns and clearly formed the basis on which RIVM has conducted their SEv assessment for Ag nanof orms), but for SiO₂, grouping for physicochemical properties of nanof orms was allowed, reducing the number of tests to be conducted. The grouping proposal by registrants was however not accepted in the final decision (need for better justification for grouping).
 - The Ag DD implicitly requires all legal entities to test all their different forms of nanoAg. PMC has requested, but not received detailed information from producers that would allow grouping in our case. PMC therefore assumes the number of Ag nanof orms is limited and agrees with the DD that each individual form of nanoAg is tested for their physicochemical properties, and will not propose grouping in their comments. **AP6**
 - It was noted that RIVM will publish a report on grouping of nanomaterials soon (presented by Arcadis at SETAC Barcelona meeting).

(Post meeting note: The report is available via

http://www.rivm.nl/en/Documents_and_publications/Common_and_Present/Newsletters/2015/Cost_effective_risk_assessment_of_nanomaterials_may_be_feasible.)

- Furthermore, at the most recent ECHA NanoMaterials Working Group (NMWG) meeting, RIVM presented its draft report on “Read-across between nanof orms: Elements to consider”, which proposes a stepwise framework to document and perform read-across between nanof orms. **AP7**
- Physicochemical testing approach (cf. slide 17):
 - Ag WG agrees to option 2: PMC Sec to coordinate testing.
 - It is noted that it will still be up to each registrant to include the testing results in their own registration file. **AP8**
- There were no further comments on PMC’s suggestions regarding the T/D testing (cf. slide 18); the PMC WG agreed to stick to the standard protocol. **AP2-3**
(Post meeting note: The PMC Sec has made an analysis and discussed the proposed deviation from the standard protocol - i.e. using one of the ecotoxicity test media for the T/D testing - with a number of experts and has concluded that this makes sense from a financial and pragmatic point of view. Therefore the final comments on the T/D testing focus on the consequences of the deviation.)
- It was suggested to check with RIVM why EDX is proposed for granulometry measurement, as this will only determine the elemental composition. **AP2**

2.2.3 Fate in soil

Cf. slide 20 in Annex 2. Comments/additions:



- The information requests on fate in soils are clearly research focused (e.g. mass balance will be difficult to achieve, more time needed for method development). **AP3**
- WCA is getting quotes from 2 laboratories for the soil testing (CSIRO and Fraunhofer).
- A 12-month aging period is suggested based on previous soil work. **AP2-3**
- It is suggested to use 3 soils from the ones used for previous soil work. **AP3**
- It would be useful to check if similar tests have not already been carried out. **AP9**
- The cost for the soil testing alone is estimated to be 400 to 450 k€. It seems fair that only nanoAg registrants will pay for this, but the cost-sharing formula is to be discussed at the next PMC Assembly meeting. PMC will discuss the difficulties in identifying the nanoAg registrants with RIVM/ECHA. **AP2**

2.2.4 Ecotoxicity

Cf. slides 21-24 in Annex 2. Comments/additions:

- The number of required T/D tests will need to be clarified (only for algal media?) **AP2**
- The suitability of the suggested media will need to be discussed with RIVM (adaptations EDTA and Cl levels) (**AP2**). It is suggested to include an expert opinion on why we think the suggested media will be affecting algal growth/Daphnia reproduction.
- The DD requests to include a AgNO₃ control, but it is unclear whether this requirement refers to an additional full test (**AP2**). It is suggested that the AgNO₃ data may already be available and we may be able to challenge the need for a full test but perform the test with a single concentration instead and refer to the existing dataset.
- The cost for the aquatic ecotoxicity testing is estimated to be 250 k€, excluding T/D testing.

2.2.5 Uses

Cf. slide 25 in Annex 2. PMC does not plan to comment on the request for further information on nanoAg uses. Comments on the scope of the request:

- Information is required on substances “placed on the market”, while placing on the market does not trigger any obligations under REACH.
- The real nano producers are not covered since these are often below the 1 tpa threshold. **AP10**
- It was noted that an appeal can only be done after the final decision is issued and is a choice to be made per company (whereas advocacy is a common effort).

2.3 Next steps

Cf. slide 26 in Annex 2. Additions:

- PCM will hold an informal call with RIVM to get further clarifications on the DD (**AP2** and Annex 3.1 and 3.2).
- Submission of the comments to ECHA should preferably be done by one of the nanoAg producers but there are no volunteers so far.

(Post meeting note: Heraeus kindly agreed to submit the comments and will be the Registrants contact point.)

3 Effects assessment

3.1 Nautilus test and agreement on way forward

The Ag WG has previously decided to conduct a test with American (Eastern) Oysters at Nautilus to refute findings reported in a questionable publication by Ringwood et al. Since the contract lab is not able to conduct the test with the desired species, it was suggested to conduct the study with mussels



instead of oysters. At the March meeting, the Ag WG decided to wait for the DD and then re-evaluate how to proceed with this test. Since marine effects are not addressed by RIVM, the Ag WG agreed to put this study on hold.

Work on developing a marine SSD has not started yet. For the same reasons as above, the Ag WG decided to put the marine SSD work on hold.

AP11

3.2 Status of NTP study

Cf. slide 31 in Annex 2 and agenda point 4.2.

4 CLH proposal silver zinc zeolite

Explanation of the background of biocides versus CLP and how a CLH dossier is being prepared is provided in slides 33-36 in Annex 2.

4.1 Update on process/timeline

At the 2 April meeting with the EU Silver Task Force (ESTF), it was stated that the consultation period for the silver zinc zeolite CLH would likely start soon. However, Eurométaux informed PMC that the public consultation will probably not start before summer 2015.

(Post meeting note: The public consultation started 2 June and ends 3 August – cf. <http://echa.europa.eu/harmonised-classification-and-labelling-consultation/-/substance-rev/9302/term>)

4.2 Feedback from meeting PMC / EU Silver Task Force

Cf. slides 38-42 in Annex 2. The ESTF mentioned a one-generation toxicity study in rats with ionic silver performed by the US FDA (study finished but results not yet published). The study found some effects at mid and high doses, but these could be interpreted either way without access to the raw data. PMC requested a copy of the manuscript but has not received it yet. The Ag WG agreed to assess the need to update the current waiver in the Ag REACH dossier with a reference to this study once we have the study results. **AP14-15**

4.3 Preparation for 45-day commenting period and next steps

- EBRC is preparing comments on the toxicological hazard assessment of silver zinc zeolite (cf. slides 43-44 in Annex 2), while PMC will work together with Eurométaux regarding comments on the environmental hazard assessment. **AP16-17**
- PMC will have a meeting with ESTF and EBRC end of June to discuss / align comments and an internal PMC call will be organised before that to review the comments. **AP18-19**
- PMC will have to decide whether they want to submit a testing proposal during the consultation period. **AP20**
- It was noted that an FDA study has been published recently on the effects of Ag on rat thymus following maternal exposure, which found no effects in the F1 generation offspring (<http://www.sciencedirect.com/science/article/pii/S2214750014001620>).

4.4 Potential interactions between Substance Evaluation and CLH

Cf. slide 45 in Annex 2. It is suggested to check RIVM's intentions on the silver zinc zeolite CLH during our informal discussions with them. **AP21**

5 AOB, next meetings/calls and closing remarks

- A conference call will be organised to discuss the draft PMC comments on the SZZ CLH proposal.



- The next Ag WG meeting will be held **15 October 2015, 9:00 - 12:00 CET** at the Metals Conference Centre in Brussels.

Annexes

- Agenda & list of participants
- Slides presented at the meeting
- Notes from informal calls with RIVM to clarify DD:
 - Call 28 May 2015
 - Call 9 June 2015
- PMC comments to DD (submitted to ECHA 15 June 2015)
- Slides presented at 4 June PMC Assembly meeting by Christine Spirlet (IZA) “Nanomaterials: the state of play”

Actions

Table 1. Actions agreed at the 19 May Ag Work Group meeting in Brussels

	What?	Who?	When?
Substance Evaluation by Dutch MSCA			
1.	Contact CEFIC on the “grade” definition (Veronique Garny + Blanca Serrano)	PMC Sec	May/June 2015
2.	Set up conference call with eMSCA (RIVM) to clarify the following items of the DD: <ol style="list-style-type: none"> Difference between terms “grade” and “form” + definitions of both terms Adaptations to T/D testing protocol (medium, pH) and consequences on OECD MAD status and classification Use of EDX for measurement granulometry Importance of aging soils and selection of soils Possibility to interact with RIVM during the course of the testing planning Ecotoxicity test control (need for all tests to be undertaken with AgNO₃?) Amount of T/D tests Suitability of suggested media for ecotoxicity tests Difficulties in identifying nanoAg registrants 	PMC Sec with support WCA	Done (cf. Annex 3.1 and 3.2)
3.	Draft comments on DD: <ol style="list-style-type: none"> Extension of timeline to comply with the DD requests Methodology for T/D testing Research nature of certain requests in the DD (mainly soil testing) Importance of aging soils (12 months suggested) Use of soils used for previous experimental work + other comments depending on clarifications received from RIVM (see AP2) + statement on which producers the PMC submission is covering	PMC Sec with support WCA	Done (cf. Annex 4)
4.	Review comments on DD	Ag registrants	
5.	Submission of comments to ECHA	Registrants contact point (Heraeus)	
6.	Send communication to all Ag registrants stating that: <ul style="list-style-type: none"> PMC agrees with DD that each individual form of nanoAg is tested for their phys-chem properties One of the phys-chem tests to be conducted for each nanoform is a T/D test, costing approx. 20 k€ Failure to report sufficient information on each grade to the PMC Sec, 	PMC Sec	Done



	may result in non-compliance (grades not covered by joint registration)		
7.	Send RIVM draft report “Read-across between nanoforms: Elements to consider” (or summary if report cannot be shared)	PMC Sec	Done (cf. e-mail 26 May)
8.	Check how to report the company-specific information on the different nanoforms in IUCLID and provide guidance to registrants	PMC Sec	By end 2016
9.	Check with Ag TF and PMC members if any soil fate studies are not already available	PMC Sec	May/Jun 2015
10.	Consider advocacy with Eurométaux and CEFIC on how to push for better targeting of real nano producers / consider re-activating the PMC nano WG	PMC Sec	Q2-Q3 2015
Effects assessment			
11.	Cancel Nautilus test and testing for marine SSD	WCA	ASAP
12.	Update SSDs / PNECs	WCA	After Evaluation (2016/17?)
13.	Include data from ASRIT in next dossier update	WCA	After Evaluation (2016/17?)
14.	Continue trying to get hold of results of FDA studies (90-day NTP study + one-generation tox study)	PMC Sec	Q2-Q3 2015
15.	Assess need to update current waiver in Ag dossier with reference to FDA studies	Ag WG	After AP14
CLH proposal silver zinc zeolite			
16.	Prepare comments on the CLH proposal for silver zinc zeolite (human health part)	EBRC	By 22 Jun 2015
17.	Prepare comments on the CLH proposal for silver zinc zeolite (environmental part)	PMC with Eurométaux	Jun-Jul 2015
18.	Internal PMC call to review EBRC comments on the CLH proposal for silver zinc zeolite	Ag WG	26 Jun 2015 at 14:00
19.	Meeting with ESTF to discuss / align comments on the CLH proposal for silver zinc zeolite and to discuss advocacy	PMC Sec	30 Jun 2015
20.	Revisit need for testing proposal for reprotox testing	Ag WG	26 Jun 2015 cc
21.	Check RIVM’s intentions on the silver zinc zeolite CLH	PMC Sec	Done (cf. Annex 3.1)