



Clarifications on Silver Draft Decision for informal call eMSCA

Blue text refers to RIVM responses

Participants to the call

- Theo Traas (RIVM)
- Eric Bleeker (RIVM)
- France Capon (EPMF)
- Katrien Arijs (EPMF)
- Dean Leverett (WCA)
- Graham Merrington (WCA)
- Roland Brasch (Heraeus) - *submitter of official comments to the DD*

General

1. Throughout the Draft Decision, sometimes the term “grade” is used and sometimes the term “form”. Is there a difference between both terms? Can you provide us with a definition? If both terms have different meanings, what is the justification for using one term or the other?

‘Grade’ is only used a few times in the DD because this wording was provided by ECHA. RIVM stated there is no difference between both terms and suggested that PMC officially requests one term is used throughout the DD. RIVM will then change ‘grade’ to ‘form’ in the final decision.

2. On page 9 of the Draft Decision, at the start of the last paragraph, it is stated “From the 56 individual Registrants only 10 indicated that they register the nanoform of silver by indicating either group 5 or 6 in section 1.2 of IUCLID.” For a successful update of the registration(s), identification of all nanoforms of silver is crucial, but despite extensive efforts, the PMC has so far only been able to identify a few (and only PMC members) of the 10 individual Registrants registering the nanoform of silver. Do you have any suggestions to facilitate the identification of these Registrants?

RIVM stated there is not much they can do to mediate and suggested that PMC deal with this at SIEF level and officially comment on these difficulties to check if ECHA can mediate.

(Post-call note: PMC will also check with Eurométaux what can be done to identify nanoAg registrants)

Physicochemical properties

3. The method recommended for information on granulometry is Transmission Electron Microscopy (TEM) combined with Energy Dispersive X-ray (EDX). Can you clarify why EDX is needed?

EDX is needed to confirm that the nanoparticles measured in the Particle Size Distribution are actually silver.

4. We are concerned that the requested adaptations to the dissolution medium for the determination of the dissolution rate will challenge the OECD-MAD status of the future silver data set and will not make the results useable for hazard classification. Can you clarify why you propose such a deviation? We suggest to not deviate from the OECD Guidance Document 29 given this was designed to determine the bio-availability of metals under a set of standard conditions and the medium was established after long discussions.

RIVM suggested the adaptations to the dissolution medium in order to have a clear connection between the dissolution rate and the ecotoxicity tests. In RIVM’s view, the OECD-MAD status of the data set is



not a big issue. PMC is welcome to come up with other options that make the connection between the dissolution rate and the ecotoxicity tests in their comments.

5. Can you clarify why a pH of 7.5 is suggested for the determination of the dissolution rate?

Same response as item 4.

Fate - soils

6. On page 17 of the Draft Decision, at the end of the second paragraph it is stated that “.....time is an important factor to take into account as well”, in regard to further clarifying the fate of nanosilver in soils. From the previous experimental work undertaken by CSIRO it was shown that aging of silver in soils had a considerable influence upon behaviour, fate and ecotoxicity of the added silver salt. The aging timeframe for the CSIRO work, like that for other trace element bioavailability programmes (e.g. copper, nickel, lead) was 12 months. The aging process is an important one if the findings of the information requested in the Draft Decision are to have environmental relevance. Can you clarify how you see the aging process?

RIVM stated that aging may be important and suggested that PMC officially comments on this with sufficient justification on the importance of the aging process. RIVM further stated that if there are crucial items that need adjusting in the decision, they welcome our suggestions before submission of our official comments, so we can informally discuss the best way forward / possible adjustments to be made in the final decision.

7. There is a clear challenge associated with the determination of silver and characterisation of possible silver particles in soil solutions in regard to the detection of very low levels of silver. Several methods can be used, including isotope dilution techniques, however, as this is largely a research and not routine testing programme, additional clarifications from the evaluating MSCA would be appreciated to ensure that the hypothesis being tested is the hypothesis that needs to be tested. Can you already provide further clarification on the methods to be used?

At this point, it is difficult for RIVM to provide further clarification on the method as such. The most important aspect is that the method can distinguish between nanoAg and ionic Ag. Although interaction with the eMSCA cannot be enforced, RIVM stated that they are willing to informally interact with PMC during the course of the testing planning, to ensure that the test design is appropriate and adequately addresses the concerns raised in the decision.

8. The term “scientifically justified” is used in several places in the Draft Decision in regard to methods and means to undertake the research. What form does the MSCA consider this justification to take?

RIVM stated that sound argumentation should be given on the choice and the representativeness of the soils and on the used analytical methods.

Ecotoxicity

9. Could clarification be provided in regard to the statement on page 6, 3rd bullet, “The study setup should include a control with exposure to silver nitrate to enable distinction between the toxicity of nanosilver and ionic silver.” Does this mean all the tests also need to be undertaken with silver nitrate salts?

In principle: yes, as the test conditions should be the same. If it can be shown that test conditions are the same in already performed tests, reference can be made to those.



10. It is requested that dissolution tests are required for all the silver nanomaterials to be tested in all ecotoxicity test media. Can you clarify that, assuming the exact same *Daphnia* media is used in the tests as is used for the dissolution tests under the physicochemical nanosilver testing requirements, only dissolution tests in algal media will be required?

Yes, although also T/D tests in soils will be required (again in order to ensure the connection between the testing and the physicochemical properties).

11. Can you clarify the exact degree of nanoparticle characterisation that will be required for test exposures and stock solutions in ecotoxicity tests?

The most important aspect is the distinction between ionic Ag and nanoAg. PMC needs to be able to demonstrate that the test organisms are exposed to either nanoAg or ionic Ag or a combination thereof. Although the test organisms may have an impact on the physicochemical parameters of the nanoparticles, no further physicochemical characterisation will be needed during the ecotoxicity tests.

12. Can you clarify the reasons for selecting Elendt M7 as the media for *Daphnia* (and T/D) tests? Would it be possible to use ISO 6341 medium as a substitute or are the additional micro-nutrients present in Elendt M7 considered critical here?

RIVM stated that it is possible to come up with an alternative medium but Elendt M7 was selected because this medium is fully defined and because it is considered most suitable for tests with nanoparticles (ISO 6341 medium has a much higher salt concentration).

13. We are concerned that the requested amendments to algal and *Daphnia* media for the ecotoxicity tests may compromise the ability to achieve the test validity criteria and may lead to the test organisms being more sensitive to toxicants (in a general sense). Can you clarify if other approaches to alleviate these issues (e.g. media in which the concentration of excess EDTA is minimised) would be acceptable?

Yes, that would be acceptable. The reason why EDTA was excluded from the medium, is to minimise complexation of the nanoparticles, but RIVM agreed that minimised EDTA / balanced media may be an alternative solution. RIVM suggested PMC to put their experience with balanced media in their official response.

During the call, PMC also asked for RIVM's view on the possible interactions between the Substance Evaluation and the CLH process for biocides. RIVM stated that they are aware of what KEMI is doing on the Ag biocides CLH, but that the human health issues are obviously very different from the environmental ones. RIVM tries to keep sufficient interactions with KEMI to minimise the differences between both processes and to keep the processes harmonised, but of course there will always be some differences between BPR/REACH.

PMC stated that on the CLH process, they are concerned that the discussions at RAC will not take into account all relevant information. RIVM will try to keep a sharp eye on the ongoing discussions at RAC level but they are not able to deal with CLH. RIVM suggested PMC to submit comments during the official CLH consultation period and to contact the Dutch MSCA.