**eMSCA Substance Evaluation for Silver**
**Informal suggestions on the draft decision on Silver for discussion with eMSCA**

*Blue text refers to RIVM responses*

**Participants to the call**

- Theo Traas (RIVM)
- Eric Bleeker (RIVM)
- Willie Peijnenburg (RIVM)
- Katrien Arijs (EPMF)
- Graham Merrington (WCA)

## 1. Identification of nanosilver registrants

As mentioned during our previous call already, we have so far only been able to identify a few of the 10 individual Registrants registering nanosilver. Would you be able to clarify how those 10 nanosilver Registrants were identified? The Draft Decision states "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." Does this mean that any company that indicated either the generic group 5 or 6 in section 1.2 is considered a Registrant of nanosilver, regardless of any additional company-specific information they included in section 1.2 or section 1.4?

*RIVM confirmed that these registrants were identified via section 1.2, i.e. any company that indicated either the generic group 5 or 6 in section 1.2 is considered a Registrant of nanosilver, regardless of any additional company-specific information they included in section 1.2 or section 1.4*

## 2. Specified pH / temperature for testing

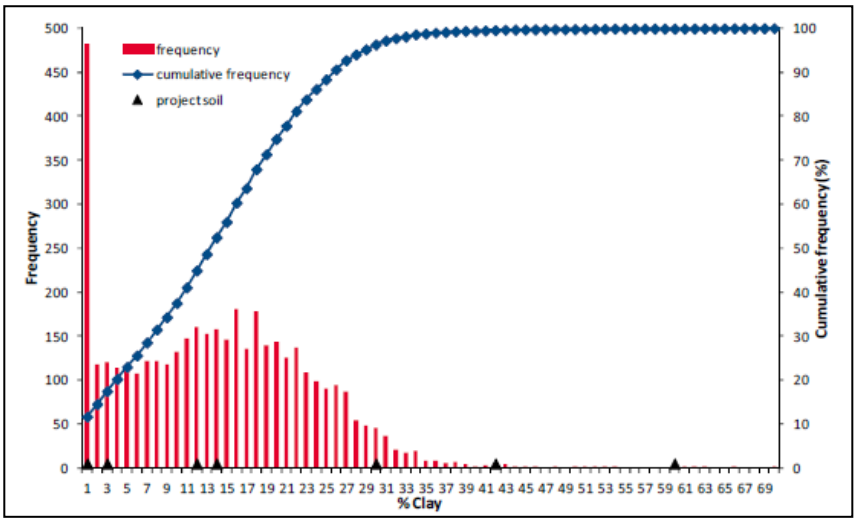
For the testing requested in the Draft Decision where pH and temperatures are specified, do we need to maintain the specified pH and temperatures throughout all tests or can we work within the usual limits of these tests (e.g. starting pH is close to specified value but no adjustment/buffering undertaken during the actual test)?

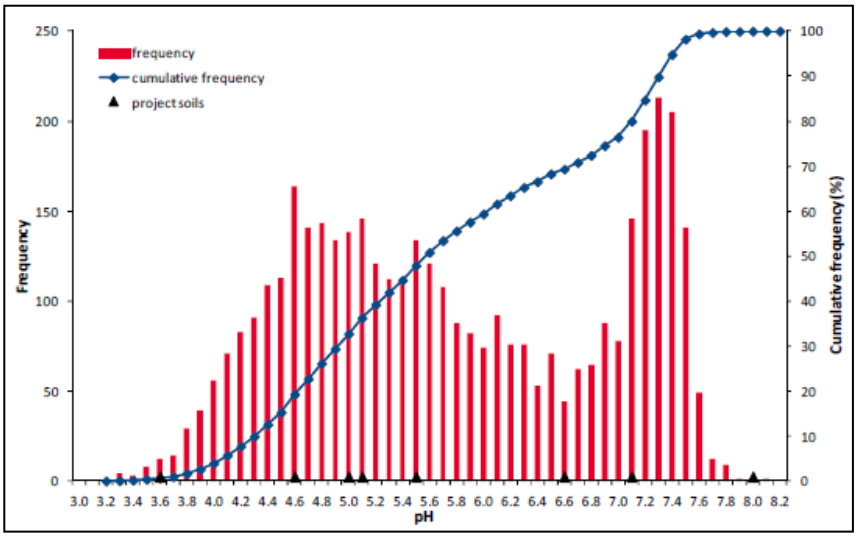
*RIVM stated that where the pH / temperature is specified, it is very important to keep these as stable as possible. Reference to the OECD guidance is made, but RIVM thinks that pH variation should be lower than 1 pH unit. What is needed foremost for the testing, is that pH and temperature are tracked throughout the tests. Then PMC will need to address case by case where adjustments are needed. E.g. for algae tests it may be needed, for other tests it may not be needed.*

## 3. Soil selection for testing

On page 4 of the draft decision, fourth paragraph (and further on pages 16 and 17) it is stated that “The three soils to be selected need to cover – as wide as possible – a range of soil properties expected to affect the fate of nanosilver in soil; especially pH, clay content and organic matter content are expected to be of major relevance in this respect.” We would suggest that three soils are selected from those that were used for the previous “Evaluation of toxicity and bioavailability of silver in soils” undertaken by CSIRO and given in the CSR. This would mean that full characterisation of the soils has already been undertaken and that practical experimental knowledge, such as the behaviour of silver salts post spiking and dosing concentrations, is already known saving a great deal of time and allowing linking/comparing the new program outcome with the existing data sets of the silver registration file.

Frequency distributions of selected physicochemical properties of European soils, as taken from the GEMAS soils database (n = 5000) are shown in Figure 1. GEMAS was developed to map and define the European background of long series of metals, physicochemical properties of European soils as well as parameters that influence the bioavailability. It forms thereby the best available reference to define and select such soil types/conditions. The soils used in the CSIRO project are marked as black triangles on the x-axis and cover a wide range of the salient properties likely to influence the behaviour of silver. We recommend that three soils are selected from these, as shown in Table 1, for example perhaps Bordeaux, Millicent and Balaklava as they cover a wide range of physicochemical properties, specifically pH, clay content and organic matter content.



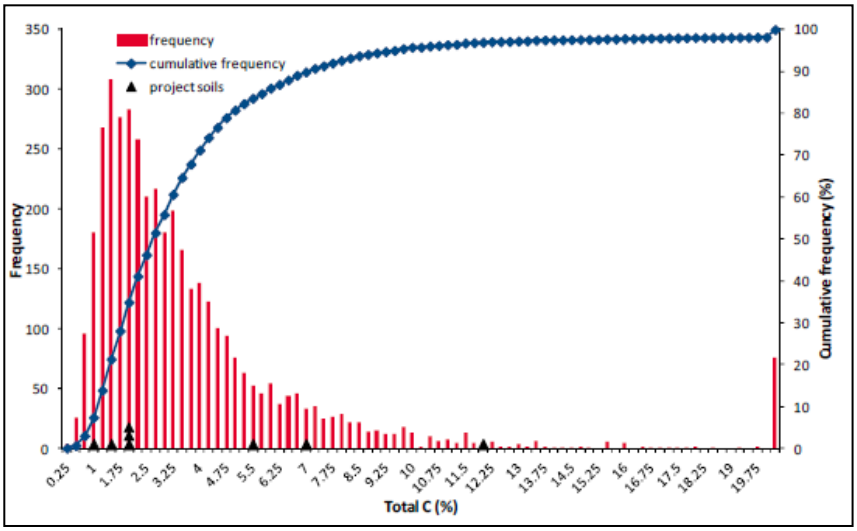



**Figure 1. Frequency distributions of European soil properties, as given in the GEMAS soils database and the soils used in the CSIRO project.**

**Table 1. The physicochemical properties of the soils used for the CSIRO Project detailed in the CSR**

| SOIL | pH ($CaCl_2$) | pH (WATER) | ORGANIC CARBON (%) | CATION EXCHANGE CAPACITY ($cmol^+/kg$) | PARTICLE SIZE DISTRIBUTION (%) | | |
|---|---|---|---|---|---|---|---|
| | | | | | CLAY | SILT | SAND |
| Houthalen | 3.6 | 4.9 | 1.5 | 5.3 | 1.4 | 1.7 | 93 |
| Bordeaux | 4.6 | 5.6 | 1.9 | 6.4 | 2.5 | 1.6 | 93 |
| Charleston | 5.1 | 6.6 | 6.9 | 12 | 14 | 12 | 63 |
| Port Kenny* | 8.0 | 8.8 | 1.8 | 13 | 12 | 4.2 | 21 |
| Millicent | 6.6 | 6.9 | 12 | 42 | na | na | na |
| Kingaroy | 5.5 | 6.1 | 0.9 | 13 | 60 | 17 | 19 |
| Inman Valley | 5.0 | 6.0 | 5.3 | 25 | 42 | 22 | 26 |
| Balaklava | 7.1 | 8.5 | 1.9 | 27 | 30 | 20 | 47 |

na, indicates that the data is not available as analyses are still being conducted
* note that particle size distribution for Port Kenny is equal to 37.2% due to the high concentration of $CaCO_3$ that is present in this soil (60%)

*RIVM states that they will not make a specific decision on which soils to use now but that they are open to suggestions from PMC, and invite PMC to include this in their official comments. RIVM agrees that it clearly makes sense to use soils PMC already has information about. What is missing here and what is specifically asked for in the draft decision is the use of the LUFA 2.2 soil, which has the advantage that several studies are already available on it in the literature.*

*Furthermore, RIVM points out that according to above table, the clay content (which is an important parameter) was not measured in the Millicent soil, which is one of the soils PMC suggests to use. WCA replies that this information is available in one of the annexes to the Ag CSR (19% clay). PMC will include the suggestions on which soils to use in their comments, adding the LUFA soil and the missing information on the Millicent soil.*

**4. Fate in soil and aging**

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 as for most metals, 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 and nickel) 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.

When soil ecotoxicity testing for metals is undertaken, soluble metal salts are used to spike a soil and the test then undertaken after perhaps 1-2 days equilibration. However, this type of metal exposure is unlikely to happen in the field and so researchers have assessed the importance of aging (and leaching) in soils post spiking to more reasonably reflect what will happen in the field.

The process of aging the soils results in a decrease in the labile pool of metal ions as they become incorporated into the solid phase of the soils. An aging period for experimental soils is important as it allows the metal ions to equilibrate in the soil to reach a point that is more representative of field soils. This has been demonstrated as a difference between spiked soils in pots tested after one month (often using plants) and then retested in the same soils after 12 months. The difference between the ECx values for a metal for the same species are generally always more than a factor of 1 indicating that the toxicity has decreased over the aging period.

For silver the ECx values for plant growth tests in soils spiked with silver nitrate after 1 month and then again in the same soils after 12 months were different by factors of between 1.3 and 22. Therefore, after aging the silver was less toxic than before the soil was aged. The ECx values before aging were on average 2.4 times lower than those after aging. It is important to provide enough time to account for the aging process of silver in the soils, i.e. 12 months.

Furthermore, the extent of aging is dependent upon, in-part, soil physicochemical characteristics. The CSIRO project on the Evaluation of toxicity and bioavailability of silver in soils given in the CSR provides a relationship that was developed using multiple linear regression to estimate the aging factor if soil properties are know:

$$log_{10}AF = 0.78 + (0.46 \times log_{10}CEC) + (-0.50 \times log_{10}OC) + (-0.92 \times log_{10}pH)(R^2 = 0.92)$$

Where:

CEC = effective cation exchange capacity
OC = organic carbon
pH = pH in water.

This relationship could reasonably be considered to mean that the soil specific aging factors could robustly be predicted for soils without the need to incubate soils for 12 months. Yet, this relationship is developed for silver nitrate and not nanosilver particles. While it could be assumed to hold for nanosilver particles one of the key areas indentified in the Draft Decision requiring greater information is in relation to potential behaviour and fate differences between ionic silver soil exposures and nanosilver particle exposures.

Therefore, if an insight is to be gained into the behaviour, fate and ecotoxicity of nanosilver particles, it is necessary to not assume that the aging relationship for ionic silver potentially holds for nanosilver too. As such it would seem necessary to age the soils with nanosilver exposure for at least 12 months, as was done for ionic silver. Therefore, this will influence greatly the timelines given for the experimentation and return of information. A minimum of 18 months would be required to undertake the terrestrial component of the research experimentation alone.

*RIVM agrees that aging would be useful, but is not sure at this point on the exact period. RIVM states they asked for a soil fate test of 28 days, and the micro-organism test they ask for is also 28 days, so we can make the connection. If PMC wants to put in aging, they should put it in their official comments, together with an argumentation on why 12 months is needed.*