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1. Context / background

PMC will prepare the Registration Dossier for silver metal. In preparing this Dossier, a substance identification and sameness discussion needs to take place. When addressing substance identification and sameness, nanoforms of silver appear to be different and to require a separate registration.

According to the OECD working definition of nanomaterials, nano-objects are materials which are confined in one, two, or three dimensions at the nanoscale (approximately 1 – 100 nm); typical examples are nanoplates, nanorods and nanoparticles. Nanoparticles such as nanosilver are nano-objects with three dimensions at the nanoscale. Nanosilver can further form aggregates, which are called nanostructured materials (materials that have an internal structure at the nanoscale).

Nanosilver is one of the 14 manufactured nanomaterials that are in scope of the OECD Sponsorship Programme for the Testing of Manufactured Nanomaterials.

Nanosilver is also one of the four case studies that have been selected by the REACH Implementation Project on Nanomaterials (RIP-oN1) group composed of ECHA, EU COM, NGOs and industry representatives. This group is responsible for developing specific advice on how to establish substance identity of nanomaterials by (as far as nanosilver is concerned):

- obtaining information about the existing forms of silver on the EU market and their main physico-chemical properties;
- mapping the existing and ongoing characterisation work on nanosilver; and
- analysing the outcomes of the above tasks in order to propose adjustments to the existing guidance on substance identification.

In the absence of a dedicated REACH guidance on nanomaterials, and the need to finalise the silver Registration Dossier before December 2010, PMC requires to develop a provisional position.

2. Provisional position

The PMC will not include nanosilver in the Registration Dossier of silver metal nor will it prepare a Registration Dossier for nanosilver.

Existing expertise within the membership of the PMC and its external consultancy research organisations indicate that nanosilver should be registered separately because:

- i. Nanosilver is deliberately engineered and manufactured to behave in a different way to other forms of silver. Nanosilver is clearly different from ionic silver as regards



granulometry or particle size, and surface charge, which are the main physical parameters that are engineered. Difference between silver and nanosilver for other physico-chemical properties cannot be confirmed yet as such information for nanosilver is usually not available or read-across directly from silver

- ii. From an (eco-)toxicological point of view measured data on nanosilver clearly shows that nanosilver is different from silver metal or bioavailable silver salts, for which the (eco-)toxicological effect seem to be driven by the silver ion (only)
- iii. According to section 4.5.1 of the ECHA guidance on data-sharing “[...] *in cases where all data [on one substance] is clearly not suitable for the other substance these substances can be regarded as different [...]*”
- iv. ECHA guidance on nanomaterials registration under REACH will not be available in time for the 2010 silver registration deadline
- v. The testing guidelines for nanomaterials are currently being developed under the OECD sponsorship programme and developing data on nanosilver using agreed protocols will therefore not be possible before the 2010 registration deadline
- vi. The absence of data on nanosilver and of tested protocols to produce the required information would not allow to properly cover this form in the Registration Dossier to be submitted in 2010

3. Way forward

All pre-registrants of silver, whether in nanoform or not, are currently part of the same pre-Substance Information Exchange Forum (pre-SIEF). Once this position and the proposed silver ID Card are accepted by the PMC Members, the description of silver will be provided to the silver pre-SIEF. Pre-registrants registering “a” silver that does not match the ID card description proposed by PMC will be invited to organise separately. Data-sharing and cooperation will naturally be promoted between pre-registrants, where and as meaningful.

PMC may be required to adjust this position and update the silver Registration Dossier after it has been submitted, in light of the outcomes of the ECHA and OECD ongoing initiatives.