REACH Substance Evaluation of Silver
- justification of read-across from ionic silver to nanosilver.

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INTRODUCTION & OBJECTIVES

- **Nanomaterials:** engineered for their specific phys-chem and biological characteristics » reactivity and/or behaviour can differ from the bulk form of the same material.
- **REACH Registration dossier for silver also covers silver nanoforms:** available reliable data on ecotoxicity of nanosilver has been compared to the available key data for ionic silver » overwhelming body of evidence is that the primary mechanism of toxicity of nanosilver is caused by dissolution of silver ions, and that soluble silver salts exert greater toxicity than nanosilver particles over comparable time periods » **basis for read-across** from ionic silver to silver nanoforms.
- As part of the **REACH Substance Evaluation for silver**, further justification of the read-across from ionic silver to silver nanoforms was required:

1. Information on **aquatic and soil ecotoxicity** of the smallest silver nanoform with the highest specific surface area registered under REACH as compared to ionic silver
2. Information on the **fate** of nanosilver in soil only in case any of the ecotoxicity tests show higher toxicity for nanosilver as compared to ionic silver
3. Information on the **uses** for each individual nanoform registered under REACH

MATERIALS AND METHODS

- Silver nanoform (**Ag-NP**): aqueous suspension (Heraeus, 37% Ag), mean primary particle size = 8.4 nm, volume specific surface area = 714 m^2/cm^3.
- Silver nitrate (**$AgNO_3$**, Heraeus, 63.5% Ag, purity > 99.9%) was used as reference compound for ionic silver.
- **Ecotoxicity testing programme** comparing effects of Ag-NP with $AgNO_3$:
  - Toxicity to the alga *Pseudokirchneriella subcapitata* (OECD TG No. 201)
  - Long-term toxicity to *Daphnia magna* (OECD TG No. 211)
  - Toxicity to soil microorganisms (OECD TG No. 216) in 3 soils representative for the EU
- Three silver fractions measured (IPC-MS): **total silver, 'conventional' dissolved silver** (0.45 µm membrane filtered) and **'truly' dissolved silver** (3 kDa centrifuge filtered).
- **Dissolution behaviour** of Ag-NP: determined in the specific test media used (following OECD TG No. 29), with measurements of the three silver fractions.
- Data collection on the uses of all nanosilver forms registered under REACH via questionnaires sent to nanosilver registrants and downstream users.

RESULTS

- **Ecotoxicity testing programme:**

Toxicity to the alga *Pseudokirchneriella subcapitata*	**Ag-NP was less toxic than $AgNO_3$**
Long-term toxicity to *Daphnia magna*	**Ag-NP was less toxic than $AgNO_3$**
Toxicity to soil microorganisms	**Ag-NP was equally or less toxic than $AgNO_3$**

- The Ag-NP **dissolution behaviour** partially explained why Ag-NP was equally or less toxic than $AgNO_3$.
- Data collection on the uses of the silver nanoforms covered by the REACH registration dossier:
  - Only 2 forms of nanosilver and low tonnage (< 10 t/a).
  - Only used at industrial sites in sintering processes for production of electronics.

CONCLUSIONS

- The ecotoxicity testing showed that nanosilver was equally or less toxic than ionic silver. Further fate testing in soil was not required.
- The silver nanoforms covered by the REACH registration dossier represent a limited tonnage and are only used at industrial sites for production of electronics. During this use, nanosilver is transformed to 'bulk' silver with a limited release potential to the environment.
- **The data confirm that the read-across of ecotoxicity data from ionic silver to nanosilver is conservative and scientifically justified.**

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