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Precious Metals & Rhenium Consortium

# Meeting EU Silver Task Force – PMC

5 July 2018 | Brussels, Belgium



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## 1. Welcome and introduction

## Confidentiality reminder

*Terms of the non-disclosure agreement signed in December 2013 by PMC and STF apply.*

## Tour de table

- |                   |                     |                |
|-------------------|---------------------|----------------|
| • Katrien Arijns  | Consultant for PMC  | Belgium        |
| • Andrew Goodyear | Consultant for ESTF | United Kingdom |
| • Jelle Mertens   | PMC                 | Belgium        |
| • Ian Watt        | ESTF                | United Kingdom |



## Agenda

1. Welcome and Introduction
2. Update on respective regulatory processes (*PMC and STF*)
3. Update on ED Expert Group process and outcomes (*STF*)
4. Status of PMC REACH testing proposal (*PMC*)
5. Other available or proposed toxicology/ecotoxicology testing (*PMC and STF*)
6. Potential for data sharing (*PMC and STF*)
7. CLH proposals for the SCAS (*PMC and STF*)
8. PNECs under REACH/BPR (*PMC and STF*)
9. Any other business (*PMC and STF*)



## 2. Update on respective regulatory processes

PMC and ESTF

ESTF - PMC meeting 5 July 2018

Pg5

### Scope of REACH Ag Dossier and Ag Biocide Dossier

	Ag REACH	Ag BPR
Scope	<b>PMC</b> Ag project includes 8 substances/Dossiers: 1. Silver (incl. nano) 2. Disilver oxide 3. Silver nitrate 4. Disilver sulphate 5. Disilver carbonate 6. Silver chloride 7. Silver bromide 8. Silver iodide	<b>ESTF</b> single core active substance dossier supporting 8 substances: 1. Silver <b>nano?</b> 2. Silver (reaction mass with SiO <sub>2</sub> ) (nano) 3. Silver chloride 4. Silver chloride (reaction mass with TiO <sub>2</sub> ) 5. Silver nitrate 6. Silver sodium hydrogen zirconium phosphate 7. Silver phosphate glass 8. Silver zeolite 9. Silver zinc zeolite 10. Silver copper zeolite
Under review by	RIVM, Dutch CA (SEv) ECHA (DEv)	KEMI, Swedish CA
CLH	Not a requirement (only as a possible conclusion from the SEv itself)	Requirement

Silver REACH dossier covers 3 forms:

- Massive (> 1 mm)
- Powder (100 nm – 1 mm)
- Nano (< 100 nm)



## Review by Member States

### REACH Evaluation

#### Substance Evaluation by NL:

- Ag on **CoRAP** list – **SEv** started in 2014, final decision received July 2016, results submitted July 2017, waiting for conclusion
- Grounds for **concern**: Nanoparticles/Toxicity of different forms of the substance, Exposure/Wide dispersive use, Consumer use, Aggregated tonnage
- Scope limited to **nanosilver** and **ENV**
- eMSCA not convinced about read-across approach and considered that further info was required to clarify initial concerns:
  - 1) Comparison of **ecotox** of smallest Ag nanoform ('nanoAg') registered and ionic Ag + phys-chem characterisation of tested form
  - 2) Quantitative info on **fate** of nanoAg in soil only in case info in Request 1 indicates toxicity nanoAg > ionic Ag in at least one of the toxicity tests
  - 3) Info on **uses** of each individual nanoform registered

#### Dossier Evaluation by ECHA:

- See agenda point 4

### Biocides Evaluation by SE

- Dossier evaluation started July 2007 and April 2008 – information submitted was considered sufficient to conduct evaluation
- RMS prepares Competent Authority Report (CAR) – substance evaluation report – for each silver substance
- First CAR – silver zinc zeolite – issued May 2012  
Draft CARs for silver zeolite, silver copper zeolite, silver, silver sodium hydrogen zirconium phosphate issued June 2017



## REACH Ag Substance Evaluation by NL (1)

### Ecotoxicity testing

- Comparison of toxicity of smallest nanoAg form registered and ionic silver (as AgNO<sub>3</sub>)



- **Algae** growth inhibition test (OECD 201):

➤ AgNO<sub>3</sub> more toxic than nanoAg



- **Daphnia magna** reproduction test (OECD 211):

➤ AgNO<sub>3</sub> more toxic than nanoAg



- **Soil microorganisms** nitrification test (OECD 216):

➤ In 1 soil, AgNO<sub>3</sub> more toxic than nanoAg

➤ In 2 other soils no significant difference

SEv  
Request 1

### Phys-chem characterisation

- 2 Ag nanoforms registered under REACH: granulometry, specific surface area, surface treating agents, density, point of zero charge
- T/D testing only on smallest Ag nanoform



## REACH Ag Substance Evaluation by NL (2)

### Information on uses

- Only 2 forms of nanoAg currently registered under REACH, < 3 t/a
- One industrial use and 2 ES for nanosilver included in the dossier:
  - 1) Manufacture of nanosilver
  - 2) Use of nanoAg at industrial site in sintering processes for production of electronics
- No nanoAg present in the end product (transformed to 'bulk' silver layer)
- Limited release to environment

SEv  
Request 3

All results testing / data collection included in Ag dossier and submitted by LR and 2 co-registrants by **13 July 2017**

eMSCA has 12 months to evaluate new information

Possible conclusion	eMSCA action
1 No further data needed	Submission of 'conclusion doc' to ECHA
2 Further info needed to address concern	New Draft Decision (incl. soil fate testing?)

## Ag and Water Framework Directive (WFD) (1)



- "Directive 2000/60/EC of the European Parliament and of the Council establishing a framework for the Community action in the field of water policy" or **EU Water Framework Directive (WFD)**: entered into force in 2000
- Sets out **Environmental Quality Standards (EQS)** concerning the presence in surface waters of certain pollutants and substances or groups of substances identified as priority owing to risks they pose to or via the aquatic environment ('**priority substances**')
  - EQS for PS must be respected to achieve good chemical status
- Management activities should aim to achieve the goals of the WFD within geographical areas or **river basin districts (RBDs)**. For each RBD, a river basin planning process must be set up: first milestone of this planning process is the initial **river basin management plan (RBMP)**
- Regular **review of the Priority Substances (PS) List** under the WFD

## Ag and Water Framework Directive (WFD) (2)

- **Monitoring based exercise** JRC (2016): Ag mentioned in short list of substances under further consideration for EQS derivation (STE score > 1.8)
- First draft **EQS dossier** by JRC: freshwater EQS of 10 ng/L proposed versus REACH PNEC of 40 ng/L
- March 2017 EC proposed **process** for shortlisted substances:
  - Prioritisation exercise postponed (same time as overall WFD review)
  - Shortlisted substances: confirmation of **PNEC** in **substance-specific sub-groups** → re-run STE-score & conclude on shortlisting
  - Ag: MS invited to send further **monitoring data**
  - Output of review PS list and use of work: **EQSs harmonised at EU-level** → MS encouraged to take into account shortlisted substances for 3<sup>rd</sup> RBMP
  - Output of review PS list may include identification of substances for which analysis shows potential risk at EU level, but for which insufficient monitoring data to conclude → considered for inclusion in **WL**


## Ag and Water Framework Directive (WFD) (3)

-  **WL report** JRC (Feb 2018):  
silver not proposed for WL

- **Further monitoring data Ag**

- JRC calculated **new STE score < 1.8** (using PNEC of 10 ng/L)
- STE score > 1.8 was criterion for shortlisting
  - Oct 2017 WG Chem meeting: COM replied that it is important to **wait until outcome of work on Ag EQS** to conclude whether Ag poses a significant risk at EU level

## Ag and WFD: WG Chemicals Ag sub-group discussions

- **Participants:** SE (lead), DK, DE, FR, LV, EM & PMC
- **Aim:** agree on EQS (for all matrices that could be of relevance, incl. sediment) → dossier to be presented to SCHEER
- **Starting point:** JRC report + available studies from REACH, RIVM Ag ERL report, BPR, open literature
- **Current status:**
  - **Freshwater** EQS: initially insufficient data for SSD → additional tests performed by PMC (see agenda point 8)  
 *Important note: PNEC will not be < 10 ng/L → even low PNEC does not result in STE score > 1.8 with latest monitoring data...*
  - **Marine** organisms less sensitive → separate datasets for marine and freshwater organisms appropriate
  - **Sediment** EQS: not yet discussed



## Update on the evaluation of silver substances under the Biocides Regulation (528/2012)

Meeting of EPMF and EU BPR Silver Task Force  
Brussels, 5 July 2018

## Regulatory Process - status of assessment reports

Silver Substance (SCAS)	Assessment Report	BPC Opinion
Silver zinc zeolite (SZZ)	May 2012	October 2018
Silver copper zeolite (SCZ)	June 2017	October 2018
Silver zeolite (SZ)	June 2017	October 2018
Silver zirconium phosphate (SSHZP)	June 2017	October 2018
Silver nitrate*	End 2018	October 2019
Silver (metallic)*	End 2018	October 2019
Silver chloride/titanium dioxide**	End 2018	October 2019
Silver phosphate glass**	End 2018	October 2019
Silver chloride ***	End 2020	October 2021
Silver/silicon dioxide (nano) ***	End 2020	October 2021

\* Update from Sweden (May 2018)  
 \*\* According to BPC schedule (May 2018)  
 \*\*\* Estimate

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## 3. Update on ED Expert Group process and outcomes

ESTF



## Update on ED process and outcomes



### Entry points from the biocides process to ED EG

Entry point 1: during evaluation

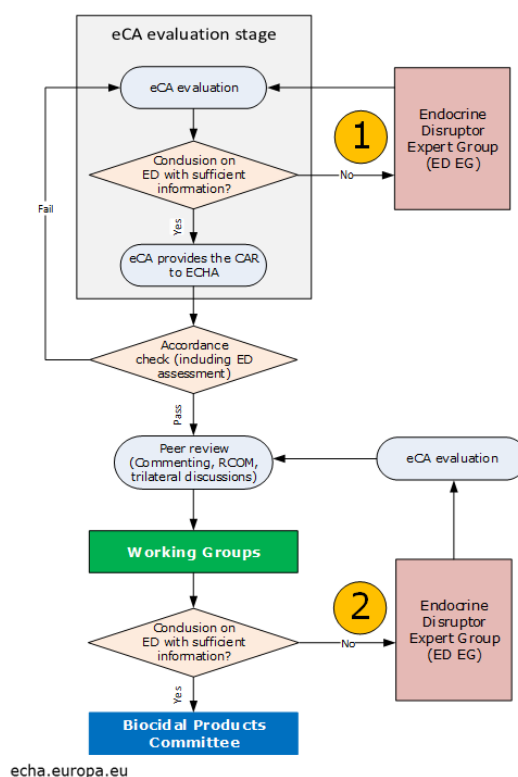
- Preferred option

Entry point 2: during peer review

- If the WG cannot conclude
- Not the preferred option

Entry point 1 is preferred to avoid evaluations being stuck partially peer-reviewed for potentially extended time periods

ED EG provides informal, non-binding scientific advice to the eCAs



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## Update on ED process and outcomes (SZZ updated CAR 29 June 2018)

- ED effects considered due to new Regulation (EU) 2017/2100 on ED criteria
- Spring 2018, eCA assessed data available. eCA stated that SZZ shows some indications of effects on endocrine organs – **although this was contrary to earlier indications**
- The ED EG was consulted in April 2018 to advise on the potential need for additional information with respect to human health and if so, the type of information needed
- No firm conclusion was reached but the majority seemed to consider the available data sufficient and not to favour requesting further data – **read across for other SCAS?**
- Considering also that the CAR for SZZ was submitted before the BPR was in force, no further data on endocrine disruption is requested by the eCA – **similar treatment for other SCAS?**
- With respect to effects on the environment, eCA carried out an assessment in June 2018. **Although there are no indications of endocrine activity, the available information does not allow to dismiss silver as an endocrine disruptor in non-target organisms, but does not allow for stating endocrine effects either**
- **No further action for SZZ, but further work for other SCAS - literature survey for environmental ED effects**

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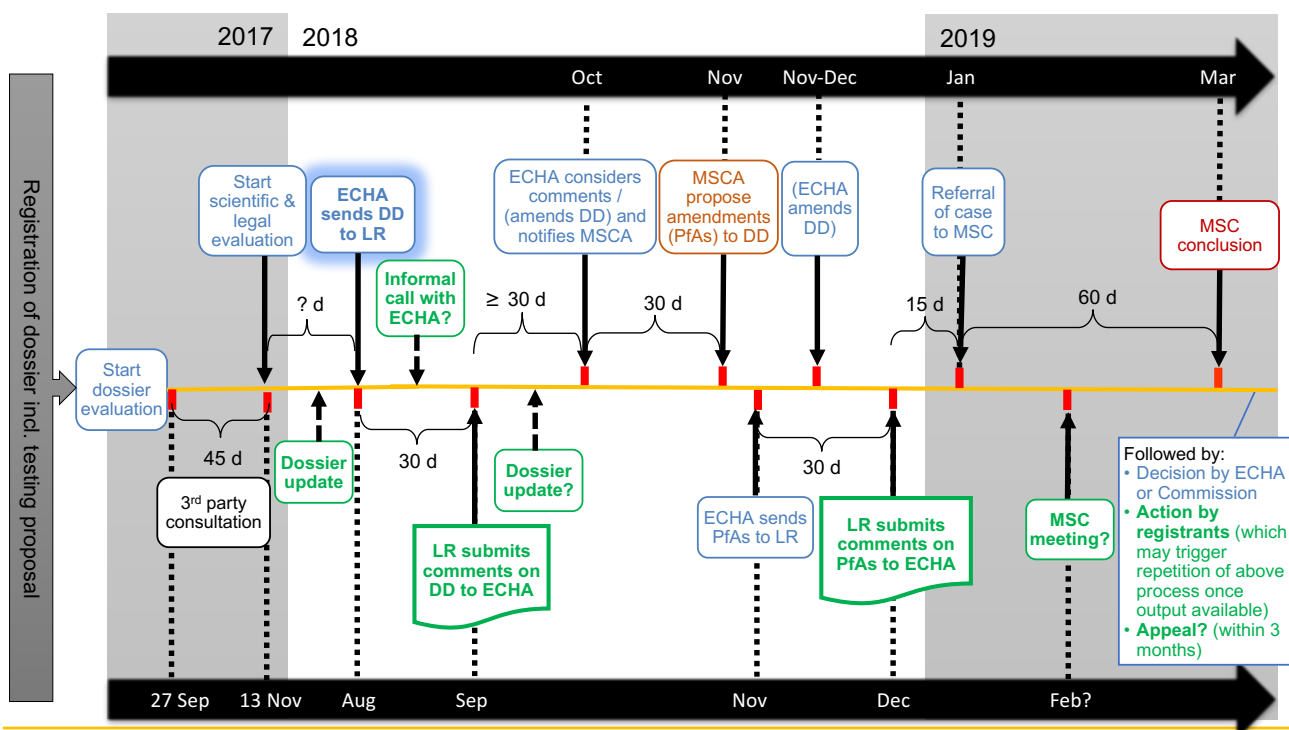


## 4. Status of PMC REACH testing proposal

PMC

### Status EOGRTS TP

DD = Draft Decision  
LR = Lead Registrant  
PfAs = Proposal for Amendments



## Current situation silver reprotox (1)

- Ongoing discussions under BPR on **classification of SCAS**
  - SZZ: Repr cat. 1B proposed, cat. 2 agreed; RAC mainly attribute effects to Ag<sup>+</sup>
  - SZ, SCZ and SSZHP: Repr cat. 2 proposed
- **Data gap** on reprotox → PMC submitted original **TP for EOGRTS** in 2015
- Since 2015: further research published suggesting Ag is reprotox
  - maybe even **Repr cat. 1B?**
  - several weaknesses in recent silver research → data gap still remains, but **update of TP** was necessary
- **TP updated** early April:
  - Addition of recent studies to the TP / registration dossier
  - Addition of developmental immunotoxicity (DIT) cohort to the EOGRTS design
  - Need for enabling studies on the mode of action (MoA) prior to the EOGRTS final dose-setting and study start
  - Revision of dose-setting
- Even if TP accepted: outcome of EOGRTS is highly unpredictable and **risk of classification as Repr cat. 1B** still exists

## Current situation silver reprotox (2)

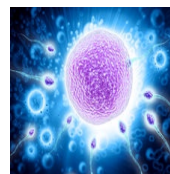
Reproductive toxicant	Criteria	Remarks
Category 1A	<ul style="list-style-type: none"> <li>• Known <u>human</u> reproductive toxicant (development and/or fertility)</li> </ul>	<ul style="list-style-type: none"> <li>• Few substances classified to this level.</li> <li>• Metals: Pb/Pb cmpds</li> </ul>
Category 1B	<ul style="list-style-type: none"> <li>• Mainly based on <u>animal</u> studies</li> <li>• Strong presumption relevance to humans</li> <li>• Evidence must be clear (dev./fert.)</li> <li>• Not secondary i.e. non-specific consequence (including 2° due to marked maternal toxicity, stress etc.)</li> </ul>	<ul style="list-style-type: none"> <li>• <b>SVHC implications!</b></li> <li>• Metals: Cmpds of Co, Cr6+, Ni; metallic Hg</li> </ul>
Category 2	<ul style="list-style-type: none"> <li>• Evidence not sufficiently convincing to assign Cat. 1</li> <li>• Typically only <u>animal</u> data</li> <li>• Same caveat: should not be a non-specific consequence of other toxicity</li> </ul>	<ul style="list-style-type: none"> <li>• Due to REACH testing increasingly common classification (eventually &gt;1000 substances?)</li> </ul>

## Current situation silver reprotox (3)



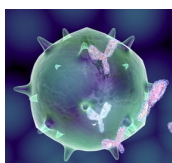
### Developmental

- Main battleground (*MR view*)
- Pre- & post-natal effects
- Uncertainty: indirect effects, MoA



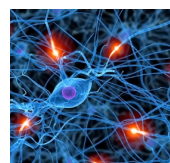
### Fertility

- Limited evidence (*Sprando study*)
- SCAS data (2-gen) no effect



### Developmental immunotoxicity

- Babu study
- Indicative not firm evidence
- Weaknesses in study approach



### Developmental neurotoxicity

- DNT Ag partial/complex picture
- PMC understood risks to TP
- Ag-Cu axis impact?

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## Current situation silver reprotox (4)

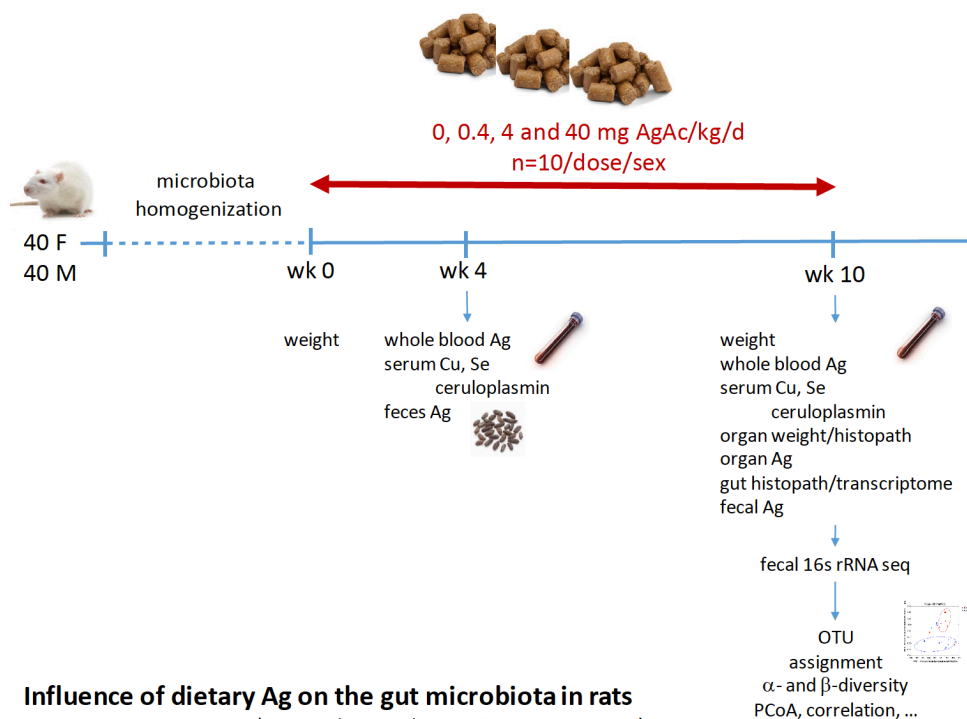
- Repr cat. 1B classification now at bigger risk
- Some weaknesses in Sprando/Babu studies already identified in defence of EOGRTS TP + expert advice gathered
- **MoA** still unclear but might include:
  - Effects on **Cu homeostasis**
  - Indirect effects via **gut microbiome** (maternal / fetal)
  - More speculative possibilities (e.g. generalised stress responses related to indirect reprotox, Ag+ depletion of Se): less likely to be accepted by regulators as true confounders / would take even more experimental effort to build defense case
- **Indirect microbiome effect** (+ data gap at low Ag doses): strongest leverage point for PMC for questioning the outcomes in SCAS / Sprando studies

## Enabling study effects Ag on gut microbiome (1)

- **Main objective:** investigate effects of Ag on (parental) gut microbiome of rats at low dose levels (equivalent to those used in Sprando et al.), and in exposure settings that are relevant/directly comparable to planned EOGRTS → strengthen PMC hypothesis that the silver MoA for reproductive effects includes **indirect effects** via the gut microbiome
- Study would help in EOGRTS design and could provide argumentation to
  - 1) further **defend our TP** and
  - 2) **avoid classification** → point stands even if TP is eventually denied! (i.e. study has fallback value even if not directly useful for EOGRTS design)



## Enabling study effects Ag on gut microbiome (2)





## 5. Other available or proposed toxicology/ecotoxicology testing

PMC and ESTF

### Available or proposed tox / ecotox testing

- **PMC:** see ECHA dissemination site, in addition:
  - **Tox:** enabling tests Ag effects on gut microbiome (see agenda point 4)
  - **Ecotox:** freshwater tests to strengthen SSD, sediment test? (see agenda point 8)

## New tests available for toxicology/ecotoxicology (STF)

### Ecotoxicology

- Soil microflora (N and C) OECD 216/217 - final, NOEC = 0.28 mg/kg wet weight
- Seedling emergence OECD 208 - final, NOEC = 10.43 mg/kg
- Earthworm reproduction OECD 222 - final, NOEC = 10.43 mg/kg
- Chironomus spiked sediment OECD 218 - final, NOEC = 4.33 mg/kg dry weight
- Lumbriculus spiked sediment OECD 225 - final, NOEC = 0.441 mg/kg dry weight
- Lumbriculus natural sediment OECD 225 - final, controls not guideline compliant

### Toxicology

- In-vitro skin corrosion - final, range finder for 28 day study
- 28 day oral (gavage) study in the rat - final, bridging study to other SCAS
- Silver zinc zeolite: Rat Alkaline Comet Assay - final, negative for genotoxicity
- Silver zinc zeolite: In vitro dermal penetration - final, negligible absorption (ca 0.05%)

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## 6. Potential for data sharing

PMC and ESTF

## Potential for data sharing

- **PMC:** will become part of EPMF



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## 7. CLH proposals for the SCAS

**PMC and ESTF**

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## CLH proposals for SCAS

- **Silver zinc zeolite**  
RAC decision 2015  
Repro 2, Skin Irrit. 2, Eye Dam. 1, Aquatic Acute 1, Aquatic Chronic 1
- **Silver zeolite**  
CLH dossier submitted July 2017 – public commenting not yet announced  
Repro 2, Aquatic Acute 1, Aquatic Chronic 1 (read across to silver zinc zeolite)
- **Silver copper zeolite**  
CLH dossier submitted July 2017 – public commenting not yet announced  
Repro 2, Aquatic Acute 1, Aquatic Chronic 1 (read across to silver zinc zeolite)
- **Silver sodium hydrogen zirconium phosphate**  
Aquatic Acute 1, Aquatic Chronic 1
- **Silver nitrate**  
eCA indicates possible Repro 1B classification  
Potential data gap for C and M effects  
28 day data indicate tests at higher concentrations possible without corrosive effects
- **Other SCAS**  
Unknown at present, but conservative proposals are likely

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## Status CLH proposals silver active substances (SCAS) (1)

- 3 further CLH proposals submitted by Kemi (Sweden) for SCAS under the BPR
- **Silver zeolite (SZ)** and **Silver copper zeolite (SCZ)**:
  - **Repr 2 classification**: no substance-specific data available but classification based on studies with SZZ, AgCl (Shavlovski paper) and AgAc (Price & George 2002 study and 2017 study from Sprando et al.) → conservative approach using same classification as SZZ (given structural similarity with SZZ and similarity of effects observed with other Ag salts that do not contain Zn)
  - **Env classification**: Aq. acute 1 and Aq. chronic 1: similar approach to SZZ
- **Silver sodium zirconium hydrogen phosphate (SSZHP)**:
  - **No Repr classification**: 2-gen study with SSZHP available that 'did not result in effects meeting criteria for classification'
  - **Env classification**: Aq. acute 1 and Aq. chronic 1: similar approach to SZZ
- Awaiting 60 d public consultation

## Status CLH proposals silver active substances (SCAS) (2)

- **Human health classifications:** comments on **Repr** classification SZ and SCZ:
    - Mostly based on same papers/studies as SZZ Repr classification → **re-iterate earlier PMC comments** focusing on the toxicity of the zeolite moiety and the indirect influence of the Cu homeostasis disruption
    - Add commentary on **Sprando et al.** study:
      - Kemi's misconception that argyria is adverse effect
      - View of study's severity outcome
      - Deficits in relation to EOGRTS
      - Study (still) does not inform on mode of action → important data gap
    - Taking into account established position on SZZ (Repr 2) and more recent Ag data: no strong arguments against CLH Repr proposals BUT existing studies do not cover the mode of action → covered by **EOGRTS** Testing Proposal
  - **Environmental classifications:** **re-iterate earlier PMC comments**
- ➔ PMC comments will be drafted once public consultation has started



## Status CLH proposals silver active substances (SCAS) (3)

- Further info from ESTF on timing CLH proposals SCAS?
- Cooperation for public consultation?





## 8. PNECs under REACH/BPR

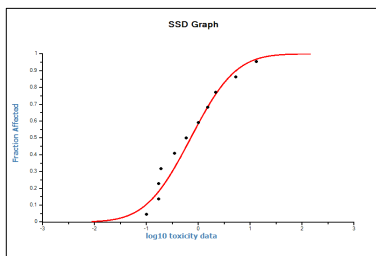
PMC and ESTF

### Comparison PNECs under REACH/BPR

Environmental Compartment	STF PNEC	STF basis	EPMF PNEC	EPMF basis
Freshwater	0.008 µg/L (dissolved Ag)	Organism: Fish ( <i>O. mykiss</i> ), endpoint: growth of larvae, NOEC = 0.08 µg Ag/L (dissolved Ag), AF of 10	0.04 µg/L (<0.45 µm fraction)	SSD with AF of 3
Saltwater	<i>Not applicable?</i>		0.86 µg/L (<0.45 µm fraction)	Most sensitive NOEC with AF of 10
Sediment	44.1 µg/kg dry weight 9.58 µg/kg wet weight (total silver)	Organism: Oligochaete ( <i>L. variegatus</i> ), endpoint: growth, NOEC = 441 µg/kg dry weight, AF of 10, correction factor dry to wet sediment matter: 4.6	438 mg/kg dry weight	Most sensitive NOEC with AF of 10
Agricultural Soil	5.6 µg/kg wet weight (total silver)	Organism: Soil microbial community, endpoint: microbial carbon respiration, NOEC = 0.28 mg/kg (nominal silver in wet soil), AF of 50, no normalisation to organic matter	1.24 mg/kg ww	Eco-region approach, bioavailability normalised SSD with an AF of 3
STP	0.009 mg/L (estimated total silver)	Organism: Activated sludge microbial community, endpoint: Respiration rate EC50 = 0.9 mg/L estimated based on measured concentration, AF of 100	0.025 mg/L	Most sensitive NOEC with AF of 1

## Revision silver PNEC/EQS freshwater by Sweden

- **SE** initially proposed **deterministic derivation** as not enough tax groups for SSD
  - Lowest reliable EC<sub>10</sub>: 0.10 µg/L for *P. subcapitata* (Schlich et al., 2017)
  - AF of 10 → **EQS of 10 ng/L**
- **SSD** also conducted to compare outcome with deterministic derivation (7 tax groups)



HC5 results			
HC5 type	Value	log10(Value)	Description
LL HC5	0,009	-2,062	lower estimate of the HC5
HC5	0,050	-1,300	median estimate of the HC5
UL HC5	0,129	-0,855	upper estimate of the HC5
sprHC5	16,098	1,207	spread of the HC5 estimate

Median HC5: 0.05 µg.L<sup>-1</sup>

AF of 5 → **EQS of 10 ng/L**

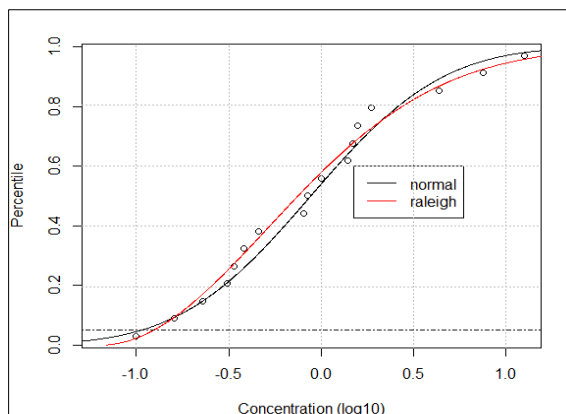
- **Note:** recent Swedish **national EQS consultation** referring to BPR value
  - “In order to harmonize with the assessments in biocidal legislation, we assume the same values (PNEC) that were used for risk assessments of silver”
  - “The risk assessment report in the biocidal legislation for silver has not yet been published, but the values regarding environmental risks are decided and available through the Chemicals Inspectorate as acting rapporteur country.”
  - “The PNEC value decided for biocides is proposed to be introduced as annual average for the limnic environment after a minor adjustment from 0.008 to 0.01 µg/l after further examination of the dossier.”

## Revision silver PNEC/EQS freshwater by PMC (1)

- **PMC** also (re-)assessed data: new studies + previous studies REACH CSR / RIVM
  - **Data selection criteria:**
    - in line with EQS guidance and MERAG criteria
    - only tox values based on measured dissolved Ag concentrations (<0.45µm)
    - in case different tox values at different hardness reported for same species: only value from test with lowest hardness retained for the SSD
  - Some data previously considered for PNEC not valid (nominal values)
  - Not enough tax groups for SSD
  - Agreement with SE on most studies considered reliable but:
    - SE sometimes Min approach instead of Geomean
    - NOEC/EC<sub>10</sub> derivation sometimes slightly different
    - SE rejected some papers PMC accepted
  - PMC performed additional ecotox tests to strengthen **SSD** dataset
    - Higher plant (*Lemna minor*)
    - Rotifer (*Brachionus calyciflorus*)
    - Cyanobacteria (*Anabaena flos-aquae*)

## Revision silver PNEC/EQS freshwater by PMC (2)

- **Updated SSD** (incl. provisional test results): 17 test species in 8 taxonomic groups



min (µg/L)	0.100
max (µg/L)	12.54
HC <sub>5</sub> (µg/L) - BestFit	0.124(0.07-0.23)

AF 3

EQS = 41.3 ng/L

- **Note:**

1. Updated SSD not yet discussed within sub-group (but agreement on majority of studies in SSD dataset)
2. Low DOC and low hardness in tests of SSD dataset (high protectiveness of suggested EQS)

## Silver PNEC/EQS sediment (1)

- **Sweden:**

- No sediment EQS proposed yet
- Look at REACH + BPR data

- **JRC report:**

AA-QS<sub>freshwater, sed</sub> : 1.2 mg/kg dw for *Hyalella azteca* (10 d / NOEC 12 mg/kg dw)

- Overview sediment PNECs:

Stakeholder	PNEC <sub>sed</sub>	Comments
UK EA	1.2 mg/kg dw	Based on 10d test with <i>H. azteca</i> and AF of 10
PMC	438 mg/kg dw	Based on 10d test with <i>H. azteca</i> and AF of 10 + PNEC normalized to a sediment with a 5% OC content
ESTF	9.58 µg/kg ww	Based on 28d test with <i>Lumbriculus variegatus</i> and AF of 10; calculated as PNEC <sub>suspended solids</sub>

## Silver PNEC/EQS sediment (2)

### • UK EA PNEC<sub>sed</sub>:

- Based on 10d test with *H. azteca* (Call et al., 2006):
  - AgNO<sub>3</sub> spiked into 2 natural lake sediments with low binding capacity (TOC < 1 %, AVS < 1.1 µmol/g dw)
  - flow-through test design
  - 7d equilibration
  - NOEC<sub>growth</sub> = 12 mg Ag/kg dw (nominal)
  - AF 10 → **PNEC<sub>sed</sub> = 1.2 mg Ag/kg dw**
- Comments:
  - 1) 10d = **acute** exposure → should not be used to derive long term PNEC
  - 2) Sediment concentrations not measured → **nominal** values



## Silver PNEC/EQS sediment (3)

### • PMC PNEC<sub>sed</sub>:

- Based on 10d test with *H. azteca* (Call et al., 2006)
- PNEC further normalized to a reference sediment with 5% OC
  - Response of *H. azteca* and *C. tentans* demonstrated clear relationship between OC & NOEC (normalization equation restricted to *H. azteca* data)
  - Default OC conc. EUSES (5%) used to set final PNEC → **PNEC<sub>sed</sub> (5 % OC) = 438.13 mg Ag/kg dw**
- Comments:
  - 1) 10d = **acute** exposure → should not be used to derive long term PNEC
  - 2) Sediment concentrations not measured → **nominal** values
  - 3) **OC normalization** equation based on only 3 data points:

Study	Test substance	OC content	NOEC <i>H. azteca</i>	Comments
Call et al. (2006)	AgNO <sub>3</sub>	0.29 %	12 mg Ag/kg dw	
	AgNO <sub>3</sub>	2.5 %	2150 mg Ag/kg dw	Other sediment parameters (clay / Fe / AVS conc.) also >>
Hirsch (1998)	Ag <sub>2</sub> S	1.63 %	> 753.3 mg Ag/kg dw	Ag <sub>2</sub> S very insoluble



## Silver PNEC/EQS sediment (4)

- ESTF  $PNEC_{sed}$ :

- Based on 28d test with *L. variegatus*:
  - $Ag_2SO_4$  spiked into artificial OECD sediment with no AVS and  $\pm 2\%$  OC content
  - static test design
  - 48h equilibration
  - $NOEC_{growth} = 0.332 \text{ mg Ag/kg ww}$  (0.441 mg Ag/kg dw), AF 10
  - PEC calculated for freshly deposited particulate matter → NOEC transformed to reflect freshly deposited matter (lower density & lower fraction of solids) →  
 **$PNEC_{suspended\ solids} = 9.6 \text{ } \mu\text{g Ag/kg ww}$**
- Comments:
  - 1)  **$PNEC_{suspended\ solids}$**  should not be used for comparison with truly measured Ag concentrations in sediments
  - 2) Short equilibration time (48h) → **toxicity caused via overlying water?** (4.4-12.7  $\mu\text{g Ag/L}$  at end of test) (OECD: equilibration time 48h-7d but for metals in general long equilibration times needed)
  - 3) Rajala et al., 2016: *L. variegatus* study on toxicity of nanoAg /  $AgNO_3$  in artificial and natural sediments (2 lake sediments) → Ag more toxic in artificial sediment than in natural sediments → importance of taking **bioavailability** into account



## Silver PNEC/EQS sediment (6)

- Sweden to propose ESTF  $PNEC_{sed}$ ?
- Current sediment studies not suitable for PNEC-derivation → PMC will perform well-designed sediment tests (long term, 3 species, natural sediments low in AVS/OC) if REACH sediment PNEC is challenged



## PNECs under REACH/BPR: points for discussion

1. ESTF: issues with low freshwater/sediment PNEC?
2. Process under BPR to change PNECs?

## 9. Any other business

**PMC and ESTF**





# THANK YOU

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