Precious Metals & Rhenium Consortium
Silver Work Group meeting

BRUSSELS, 19 MAY 2015, 10:30-16:00

1. Welcome and introduction

1.1 Confidentiality and competition law

DO	DON'T
Application of competition law	
Art. 101 and 102 TFEU may be applicable to the conclusion of any preliminary agreement and activities of any preliminary phase.	Don't assume that conflicts with competition law are excluded simply by the fact that the Agreement complies with the provisions of the REACH Regulation.
Consultation in Matters of Competition Law	
Consult an in-house legal expert or the compliance officer of your company or an external lawyer whenever there are uncertainties respecting compliance with competition law. Stop all meetings/discussions which are not in compliance with these Compliance Guidelines until a legal expert has been involved.	Don't assume that these Compliance Guidelines deal with all competition law issues exhaustively. Basically, compliance with Art. 101 and 102 TFEU can be determined only on the basis of market impact in each individual case. These Compliance Guidelines may therefore be regarded only as a means of providing general conduct recommendations.
Activities in any preliminary phase and at any other stage of operation of the Consortium	
Restrict cooperation within the scope of the preliminary phase to the initially defined goals and purposes of the cooperation.	Pursuant to Art. 101 and 102 TFEU, activities which have the object of the effect of preventing, restricting and/or distorting competition are prohibited within the scope of this Agreement, including: - Coming to agreement, including arrangements or collusions, about prices, markets and customers (see Art. 101 paragraph 1 a)-e) TFEU); - Joint boycotting of other companies; - The unjustified unequal treatment of trade partners; - The abusive exploitation of a dominating market position.
Exchange of Confidential Information	
Involve a Trustee for the exchange of Confidential Information.	The exchange of information concerning market behaviour and having the object or the effect of preventing, restricting and/or distorting competition is inadmissible; in particular, this relates to : - Production capacities; - Productions or sales volumes; - Import volumes; - Market shares; - Price policy; - Distribution and marketing terms; - Marketing strategies; - Information regarding the relationship with suppliers.
Documentation on Cooperation	
Keep minutes of all meetings which detail the subject of the meeting. In case of uncertainty, have the contents of the minutes reviewed by an external legal expert prior to sending them to all parties of the Agreement. Stop all meetings which are not in compliance with these Guidelines until a legal expert has been involved.	

1.2 Tour de table and apologies

List of Participants

- Bodo Berkner (Ferro, Germany)
- Roland Brasch (Heraeus, Germany)
- Nathalie Dom (Umicore, Belgium)
- Jan Drzymalla (Aurubis, Germany)
- Rob Garrett (Ames Goldsmith, United Kingdom)
- Daniel Glowacki (KGHM, Poland)
- Michael Huber (C. Hafner, Germany)
- Mari Jarvikivi (Norilsk Nickel, Finland)
- Dean Leverett (WCA, United Kingdom)
- Becky Marks (WCA, United Kingdom) - *by phone*
- Graham Merrington (WCA, United Kingdom) - *by phone*
- Marie-Amélie Paul (DuPont, Belgium)
- Adam Peters (WCA, United Kingdom) - *by phone*
- Nissanka Rajapakse (Johnson Matthey, United Kingdom)
- Mike Shepherd (Vale, United Kingdom) - *by phone*
- Hege Stubberud (Glencore, Norway) – *by phone*
- Michael Thiel (BASF, Germany)
- Carole Wilson (Vale, United Kingdom) - *by phone*

Secretariat

- Katrien Arijs (EPMF, Belgium)
- France Capon (EPMF, Belgium)
- Klaus Rothenbacher (EPMF, Belgium)

Apologies

- Angela Alderman (Johnson Matthey, United Kingdom)
- Massimo Blattner (Valcambi, Switzerland)
- Edwin Broekaert (Umicore, Belgium)
- Paul Frost (Glencore, United Kingdom)
- Agnieszka Piechota (KGHM, Poland)
- Mark Raffray (Johnson Matthey, United Kingdom)
- Mika Toivola (Boliden, Finland)

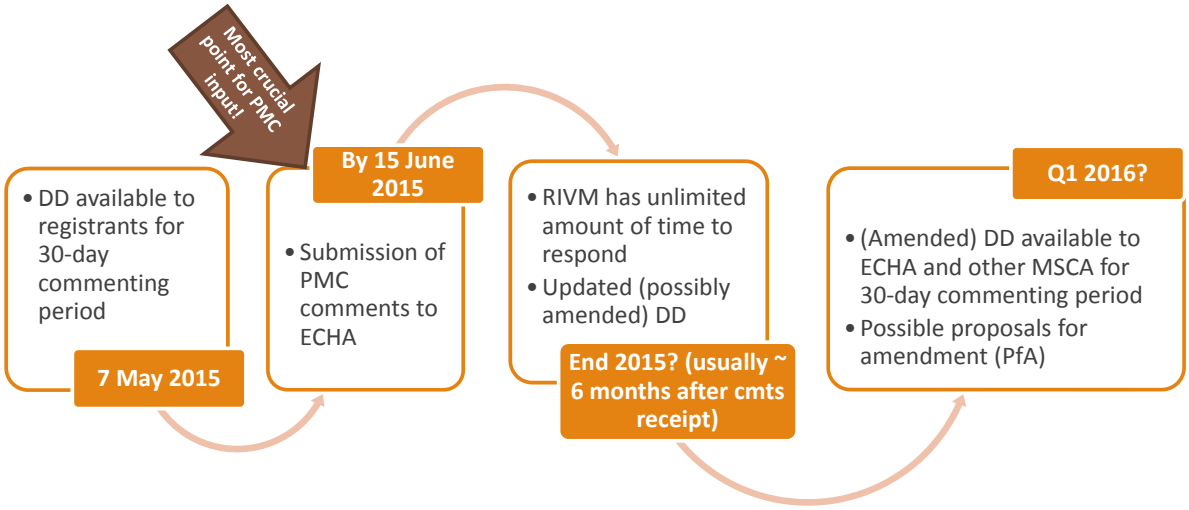
1.3 Approval of the agenda

1. Welcome and introduction
2. Evaluation by Dutch MSCA
   - 2.1 Update on process/timeline
   - 2.2 Draft Decision: information required on nanosilver and comments/concerns
     - 2.2.1 General comments/concerns
     - 2.2.2 Physico-chemical properties
     - 2.2.3 Fate in soil
     - 2.2.4 Ecotoxicity
     - 2.2.5 Uses
   - 2.3 Next steps
3. Effects assessment
   - 3.1 Nautilus test and agreement on way forward
   - 3.2 Status of NTP study
4. CLH proposal silver zinc zeolite
   - 4.1 Update on process/timeline
   - 4.2 Feedback from meeting PMC / EU Silver Task Force
   - 4.3 Preparation for 45-day commenting period and next steps
   - 4.4 Potential interactions between Substance Evaluation and CLH
5. A.O.B., next meetings/calls and closing remarks

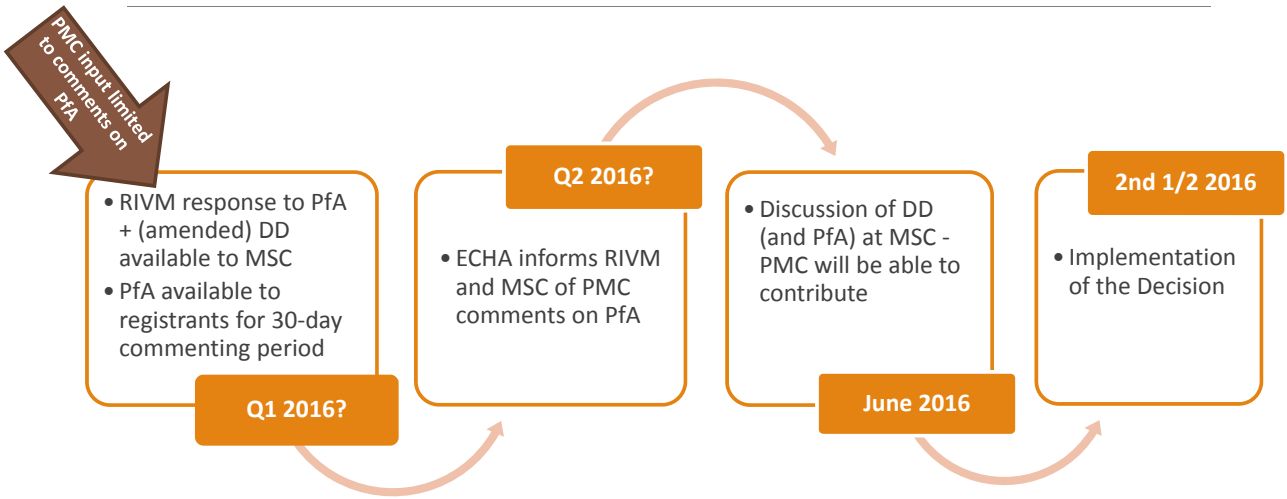
2. Evaluation by Dutch MSCA

2.1 Update on process / timeline (1)

- Ag SEv started in 2014, by NL (RIVM)
- Based on registrations and other relevant and available information



Update on process / timeline (2)



- Updated registration to be submitted within **12 months** from the date of the final decision
- This decision does not imply that the info provided by the Registrant(s) in the registration(s) is in compliance with the REACH requirements
  ➔ Still possibility of compliance checks on the dossier(s) or new SEv process!

2.2 Draft Decision: information required on nanoAg (1)

- **Initial grounds for concern**: Nanoparticles/ Ecotoxicity of different forms of the substance; Environmental fate; Exposure/Wide dispersive use; aggregated tonnage
- Scope of SEv limited to the properties of and information on **nanoforms of Ag**: only those Registrants whose registration covers nanoforms of Ag shall provide the information requested in the DD
  - In absence of explicit and suitable information in all available individual registration dossiers that they **do/do not** cover nanoforms of Ag, ECHA is not in a position to determine whether and which individual registration dossier actually covers any specific nanoform of the substance
  - In case where a Registrant actually manufactures or imports nanoforms of Ag as defined in the Commission Recommendation (…), failure to report sufficient information on **each grade** of a substance in the registration dossier, including nanoforms, may result in these grades not being covered by this registration.
  - All Registrants of Ag shall therefore determine whether their individual registration dossier cover forms of nanoAg in order to establish certainty as to which manufacturer or importer will have to provide the information requested in the DD.

Draft Decision: information required on nanoAg (2)

The eMSCA considered that further **information was required** to clarify the initial concerns:

1. Phys-chem properties of nanoAg
2. Fate in soil
3. Ecotoxicity studies
4. Uses

Registrant(s) invited to provide comments within 30 days of the receipt of the DD.

2.2.1 General comments/concerns

Overall, the DD is reasonable and in line with what was expected.

1. **Timing**: only 12 months to perform testing and update the registration file -> PMC suggests to contest the time needed to conduct the request (ask for extension from 12 to 24 months) – needs to be well motivated!
    - Evidence that testing labs need more time (capacity issue given 2018 REACH deadline)
    - Soil testing: method development needed, need for extensive equilibrium times for soils
2. **Grade/form**: unclear why sometimes the wording 'grade' is used and why sometimes 'form' -> PMC suggests to ask RIVM for clarification

2.2.2 Phys-chem properties (1)

Information on the following phys-chem properties of **each individual form of nanosilver** that is manufactured, imported and/or placed on the market, using the indicated test method(s):

Cf. next slide

Phys-chem properties (2)

	Parameter	Method
A	The granulometry, incl. primary particle size and shape, aggregate/agglomerate size, and particle size distribution (number-based)	• For powders: Transmission Electron Microscopy (TEM) combined with Energy Dispersive X-ray (EDX), and Laser Diffraction • For suspensions: TEM combined with Dynamic Light Scattering
B	The specific surface area (by volume)	• For powders: BET (ISO 9277:2010) • For suspensions: calculation based on theoretical model
C	The surface treating agent(s)	• Chemical identity (IUPAC name, CAS and EC numbers) • Type of reaction with the Ag surface and relative coverage of the Ag surface (as this info is part of the SID, it should be added in IUCLID 1.2 and 1.4)
D	The dissolution rate 	OECD GD 29, taking note of OECD Guidance on Nanomaterials testing (ENV/JM/MONO(2012)40, in particular sections III, IV, V-A - V-C). • Test medium: Elendt M7 medium as described in OECD 211 (*Daphnia* Test), **<u>with adaptations</u>** ($Na_2EDTA{\cdot}2(H_2O)$ should not be added and Cl salts should be replaced by NO_3 salts) • pH: 7.5, temperature: 20 °C • The composition of the test medium should be fully reported
E	The density	OECD 109 (Density of liquids and solids)
F	The point of zero charge	Micro-electrophoresis or electrophoretic light scattering to be performed at fixed low salt concentration and at fixed particle concentration, as described above for dissolution rate

Phys-chem properties (3)

Only the Registrant(s) of the substance know the details of each of its forms necessary for their characterisation. Based on this knowledge, they **may consider that a test method requested by ECHA is not suitable in order to characterise each form of the substance**.

Nevertheless, it is the exclusive responsibility of the Registrant(s)

1) to ensure that eMS and ECHA are in a position to identify precisely each form of the substance registered and
2) to verify the reasons for the use of another test method instead of a method explicitly required in the present decision.

Phys-chem properties (4)

56 Registrants, only 10 registered nanoAg

- only 2 provided data on the PSD that enables a proper comparison with the EU recommendation on the definition of nanomaterial, although not clear how representative these PSD data are for the registered form(s)
- 2 do not provide data on PSD of their nanoAg forms at all
- In all cases regarding impurities and additives, the general text of the J-CSR is copied in. Info on specific surface modifications is therefore not available

PMC is only aware of 5 nanoAg registrants!

Any non-reported nanoform/grade during this SE decision follow-up, may be considered as a new substance meaning that a **full registration** may be required. **It is therefore critical that all registrants/ORs/importers submit the information requested for their forms/grades.**

Phys-chem properties (5)

PMC concerns:

1. PMC does not have information on the total number of Ag nanoforms
    - Proposal implicitly requires **all legal entities** to **test all their different forms/grades** of nanoAg
    - Comparison to SiO_2 SEv case: > 400 forms ➔ grouping allowed for phys-chem properties (grouping based on production process and surface area)
    - Lack of information in the Ag Registration files on the number of potential nanoforms may have led ECHA to conclude that the number of nanoforms is limited
    - View of Ag registrants?

Phys-chem properties (6)

PMC concerns - continued

2. Registrants are responsible for phys-chem testing but 'LR shall ensure that each form of the substance is taken into account for all data included in sections 2-11 of the technical dossier as per REACH requirements' ➔ PMC Sec needs to be aware of all Ag nanoforms included in dossiers
    - Option 1: Each registrant performs own phys-chem testing and informs PMC Sec ➔ risk of high variability in results
    - Option 2: PMC Sec coordinates phys-chem testing (cf. PGM blacks) ➔ higher workload for PMC Sec but lower variability in results

Phys-chem properties (7)

PMC concerns - continued

3. T/D testing: deviation standard protocol (adaptations to dissolution medium)
    - T/D medium becomes more "worst case" ➔ may lead to higher M-factor
    - Results not comparable with results other metals ➔ important precedence for all metals!
    - Challenges the OECD-MAD (Mutual Acceptance of Data) status of the future Ag data set ➔ would limit the use of the data/conclusions of this data set for other jurisdictions than the EU
    - While some "adaptations" may be relevant (NO_3 salt instead of Cl to prevent precipitation = OK from a MAD viewpoint), others are challengeable (eliminating the EDTA salt).
4. Suggestion to express T/D results in release per surface to be comparable with other metals

Phys-chem properties (8)

Suggested PMC comments:

1. Proposal for grouping to provide information on phys-chem properties?
   - Depends on nr of Ag nanoforms…
   - Should be sufficiently justified
2. No deviation from standard protocol T/D testing (OECD 29) as designed for comparing the intrinsic toxicity of the ion with the available fraction in the TDp on an equal basis for all metals
   - The medium was established after long discussion and should not be changed at this stage to make the protocol more worst case than determined by the OECD 29
3. T/D results to be expressed in release per surface

2.2.3 Fate in soil (1)

- Nanosilver particles in soil pore water and soil solid fraction
- Transformation products of nanosilver determined in clay, organic matter and remaining inorganic fraction
- Perform a mass balance for the redistribution of silver in the soil from the nanosilver particles using 3 types of soils and three nanosilver forms. Ionic silver to also be tested and used as a comparison.

- ❑ This is not routine testing, but research…….
- ❑ Time needed to identify organisation and methods to undertake work
- ❑ Long lead in required - iteration with Dutch needed on the methodology
- ❑ Initial discussions on-going with CSIRO and Mike McLaughlin's group

2.2.4 Ecotoxicity (1)

- New comparative ecotoxicity studies required for 3 nanosilver forms:
  - 72-hour Inhibition of algal growth (OECD 201)
  - 21-day *Daphnia magna* reproduction (OECD 211)
  - Toxicity to soil micro-organisms (OECD 216) – 3 soils
- Nanomaterials to be tested:
  - Surface modification with positive charge (z-potential >20mV)
  - Surface modification remains intact and hampers release of Ag ions
  - No surface modification
- All should be representative of those manufactured and of similar size and shape (within a 10nm range)

Ecotoxicity (2)

- Supporting requirements for ecotoxicity tests:
- Dissolution rates (T/D testing) required for the 3 nanomaterials in test media
  - Only for algal media as *Daphnia* media should have been addressed already?
- The concentrations of, and ratio between, nanosilver and ionic silver should be monitored in exposures
  - Potentially using filtration or a chelator
  - Full characterisation of nanosilver in test media also required?

Ecotoxicity (3)

- Supporting requirements for ecotoxicity tests:

- A 'control' using silver nitrate is to be included
  - Identical analytical procedures to be applied as in nanosilver tests to assess potential for 'formation' of nanoparticles
  - Assume this requirement refers to a '4th test' using silver nitrate to allow derivation of full toxicity endpoints?

- Test media for algal and *Daphnia* tests should not include EDTA and should replace chloride salts with nitrate salts
  - Lack of EDTA in algal tests may affect control growth owing in ability of algal to take up Fe; may be optimal to use a media in which molar concentration of EDTA is balanced with Fe, minimising excess EDTA and potential for chelation of Ag
  - Presence of chloride salts promotes precipitation of silver, hence replacement with nitrate salts; potential to affect algal growth/ *Daphnia* reproduction?

Ecotoxicity (4)

- Immediate next steps:

- Dialogue with laboratories with relevant capabilities to assess:
  - Potential modifications to testing requirements for discussion with RIVM and/or formal response to DD
  - Potential costs for testing programme
  - Potential timelines for completion of testing programme (or various elements thereof)

- Detailed assessment of the justifications provided by RIVM for requesting additional ecotoxicity testing
  - Conclusions to be provided in formal response to DD

2.2.5 Uses (1)

Information on the uses of each individual form of nanosilver that is manufactured, imported and/or placed on the market

- As the environmental fate may also depend on the specific route of entry into the environment, information on which form(s) enter the environment via which route is essential.
- Based on the provided information, a selection of relevant exposure scenarios and relevant (surface modified) nanosilver forms can be made. To ensure safe use of nanosilver, it may be necessary to provide exposure estimations in a follow up of the present decision.

➔ No PMC comments on this request

2.3 Next steps

	What?	Who?	Timeline
1.	Drafting of comments on DD	PMC / WCA	By 2 June 2015
2.	Approval of comments on DD	Ag registrants	By 8 June 2015
3.	Submission of comments to ECHA	Designated contact person	By 15 June 2015
4.	Based on the DD and agreed comments, development of an advocacy strategy with MSCAs	PMC	Second ½ 2015
5.	Start implementation of the decision which is not challenged (data gathering on uses + characterisation work)	PMC / registrants	Second ½ 2015
6.	Finalisation of the Decision	RIVM / ECHA	2016
7.	Participation to the MSC hearing	PMC	June 2016
8.	Implementation of the final decision	PMC	2016 and beyond

3. Effects assessment

3.1 Nautilus test (1)

Ringwood et al. (2010)

- Comparative assessment of nano and ionic Ag in embryos of Eastern oyster
- Suggested nano forms significantly more toxic than ionic forms
- All other evidence suggests that nano forms less (or equivalently) toxic than ionic forms
- There are a number of deficiencies in the Ringwood study which deem the results unreliable (K=3)

Previously agreed to attempt to reproduce this study to address deficiencies and ensure robust nano-particle characterisation

- Study contracted to a partnership of Nautilus (ecotox) and Nanocomposix (nano characterisation) in California, USA
- The study has been seriously delayed owing to issues with lack of supply and difficulty spawning Eastern oyster in western US
- Related Pacific oyster also trialled but similar difficulties encountered
- Reluctance to switch labs owing to high quality nano characterisation offered by Nanocomposix

Nautilus test (2)

wca met with Nautilus at SETAC-NA in Vancouver last November to plan next steps

- Nautilus proposed using local mussels as a substitute for oysters as they routinely use this organism and can assure spawning
- Test is identical using mussels (endpoints the same) and this will still provide a reliable comparison of bivalve-specific effects
- wca requested that Nautilus undertake a literature search to compare sensitivity of mussels and oysters to silver and other metals: results demonstrated that mussels consistently more sensitive to metals than oysters, so the assessment should represent worst-case

Ag WG decided to wait for the DD and then re-evaluate how to proceed

- RIVM did not comment on the oyster test

Marine SSD

- Quotes for marine testing obtained > 1 year ago; new quotes would be needed
- Regular literature searches conducted - 47 reliable studies found, including some marine species
- Suggestion to review data gap for marine species and determine if testing still required
- Ag WG decided to wait for comments on Evaluation before proceeding

3.2 Status of NTP study

- US NTP have conducted a highly relevant sub-chronic (90-d) oral tox study in rats with nanoAg (3 sizes) and Ag acetate in direct comparison.
- Endpoint study record with the (preliminary) available findings is included in the dossier and the study is mentioned in the discussion on repeated dose toxicity.
- It is anticipated that this study will significantly complete and strengthen the database and confirm a number of results which have already been published by other authors.
- NTP study director contacted several times: **final results/report not yet available** – manuscript currently undergoing internal review.
- New information from EU Silver Task Force – *cf. agenda point 4.2*

4. CLH proposal silver zinc zeolite

Background

	Ag REACH	Ag BPR
Scope	PMC Ag project includes eight substances/Dossiers: 1. Silver 2. Disilver oxide 3. Silver nitrate 4. Disilver sulphate 5. Disilver carbonate 6. Silver chloride 7. Silver bromide 8. Silver iodide	STF single core active substance dossier supporting eight substances: 1. Silver 2. Silver (reaction mass with SiO2 – nano?) 3. Silver chloride (reaction mass with TiO2) 4. Silver nitrate 5. Silver sodium hydrogen zirconium phosphate 6. Silver phosphate glass **7. Silver zinc zeolite** 8. Silver copper zeolite
Under review by	RIVM, Dutch CA	KEMI, Swedish CA
CLH	Not a requirement (only as a possible conclusion from the Substance Evaluation itself)	Requirement

Proposed future entry in Annex VI of CLP Regulation	Carc. 2; H351 Repr. 1B; H360D STOT RE 2; H373 Skin Irrit. 2; H315 Eye Dam. 1; H318 Aquatic Chronic 1; H410
Regulatory programme	BPD

Effects attributed to Ag ion –> need to avoid domino effect on REACH Ag dossiers!

Biocides vs CLP

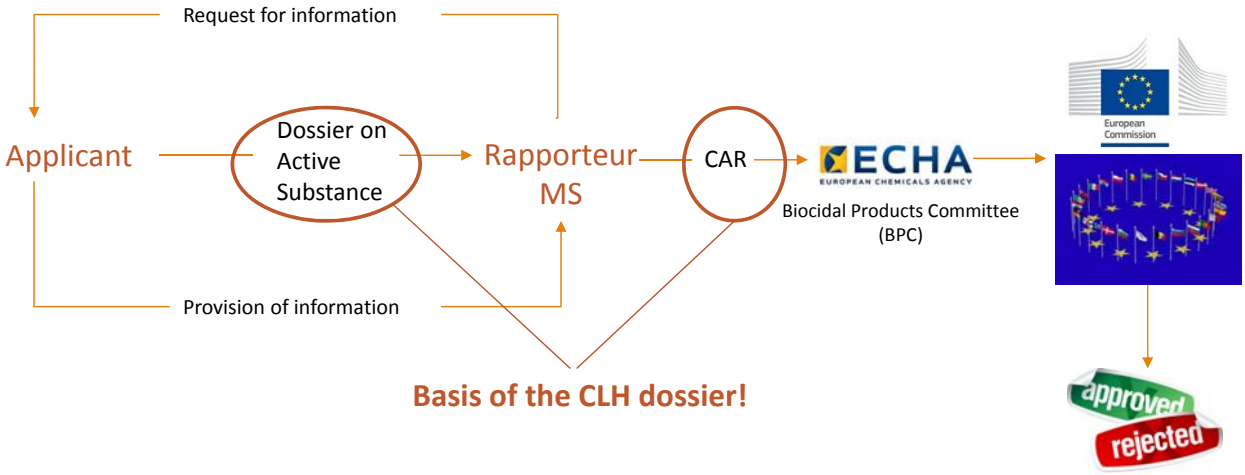
Harmonisation of classification and labelling under CLP (article 36, CLP)

A substance that is an **active substance** (e.g. silver zinc zeolite) in the meaning of Directive 91/414/EEC or Directive 98/8/EC shall normally be subject to harmonised classification and labelling under CLP and to evaluation under BPR (Biocidal Products Regulation)

- CLH dossier: to be submitted to ECHA by the CA in the same MS than the RMS (Rapporteur Member State) preparing under biocides the DAR (Draft Assessment Report) or CAR (Competent Authority Report) for the active substance
- A specific justification that action is required at EU level is NOT needed
- CLH dossiers should address ALL hazard classes (except if an entry already exists in Annex VI to CLP)
- Even if the conclusion of the assessment is NO classification, a CLH dossier must be submitted. If RAC concludes that no classification is warranted, an opinion will be adopted BUT no entry into Annex VI.

How is the CLH dossier prepared?

Under BPR, approval of active substance:



Alignment CLH process under CLP and active substance approval under BPR

- Roles of BPC and RAC: clearly defined
- Relationship between the approval of active substances in BPR and the harmonized classification and labelling process under CLP
  - E.g.: approval of the active substances and the identification of candidates for substitution are based also on the classification according to CLP criteria
  - E.g.: exclusion criteria described under BPR like CMR cat. 1A and 1B

  ⇒ Demonstrate the need for clear alignment!
- New active substances under BPR (article 7): CLH dossier must be submitted in advance of submission of CAR (2-3 months before)

4.1 Update on process / timeline

- Meeting with Ag TF on 2 April to discuss preparation for public consultation / synchronisation of efforts:
  - End of March, Ag TF had a tripartite meeting with ECHA/KEMI
  - ECHA stated that the commenting period for the SZZ CLH would likely start soon (i.e. around 10 April)
  - Dossier will go to public commenting first, then go to the RAC in Q1 2016

- Eurométaux information:
  - ECHA and RAC received from KEMI the SZZ CLH dossier end of April
  - Accordance check now ongoing (~ 6 weeks)
  - Unlikely that the public consultation starts before summer 2015

4.2 Feedback from meeting PMC / EU Silver Task Force (1)

Timing:

- SZZ: cf. previous slide
- Silver nitrate, silver chloride (reaction mass with TiO2) and silver sodium hydrogen zirconium phosphate (SSHZP): draft human health section for the CAR issued Jan 2015; full CAR expected end 2015
- Other Ag biocides: timing currently unknown

Process:

- Although essential, the CLH is not decided based on both the BPR and the REACH dossier (e.g. KEMI is not using the REACH dossier for the Ag nitrate CLH).
- KEMI sent a copy of the SZZ CAR to RIVM. The consultation period on the SZZ CLH may be a good opportunity for The Netherlands (RIVM/ctgb) to comment. Ag TF suggested PMC to contact RIVM on this.
- UK and France (ANSES) disagreed with the SZZ classification (no support for carc. classification) and with the read across approach.
- Ag TF shared the non-confidential CAR of SZZ and the RCOM.

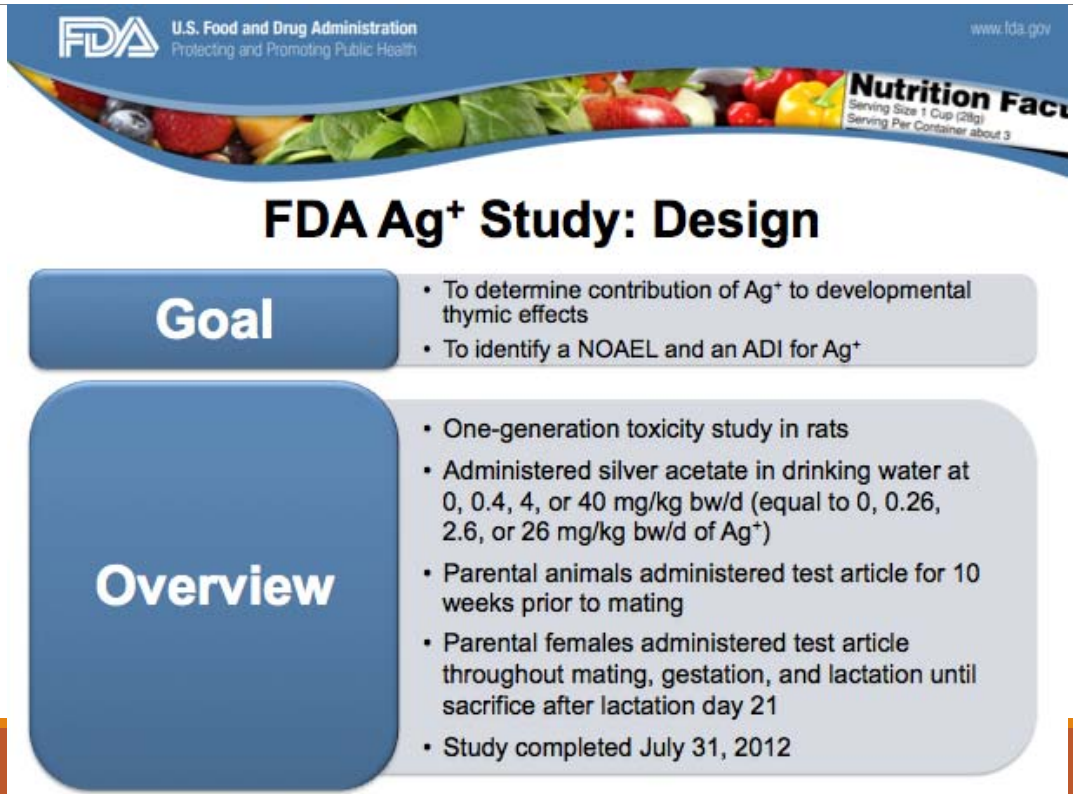
Feedback from meeting PMC / EU Silver Task Force (2)

Comments on SZZ CLH:

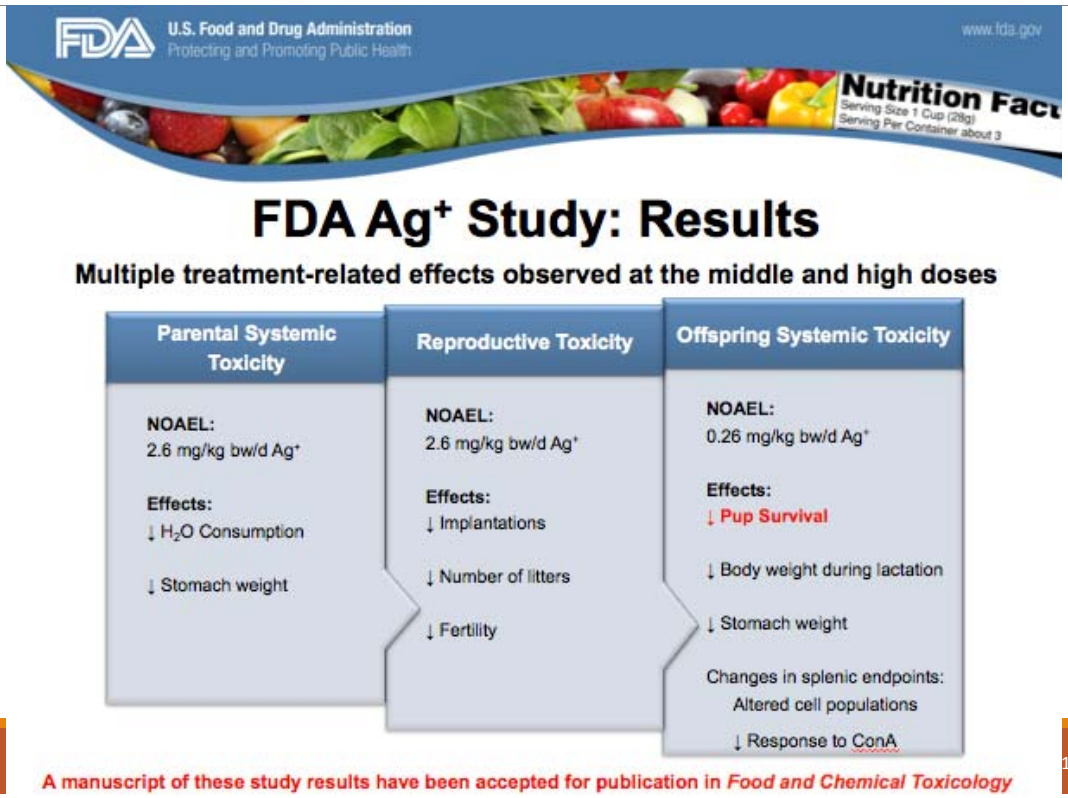
- Ag TF mentioned one-generation toxicity study in rats with ionic silver performed by the US FDA - Division of Food Contact Notifications (DFCN) – *cf. next slides*
  - ✧ Study finished but results are still to be published.
  - ✧ Study found some effects (at mid and high doses), which could be interpreted either way (no access to the raw data to understand the interpretation and comment on these findings).
  - ✧ Observed effects could be secondary effects via change in Cu homeostasis.

Ag REACH dossier: update current waiver with reference to the study?

Feedback from meeting PMC / EU Silver Task Force (3)



Feedback from meeting PMC / EU Silver Task Force (4)



Feedback from meeting PMC / EU Silver Task Force (5)

Synchronisation of efforts:

- PMC and Ag TF agreed it would be useful to work together on an advocacy plan. Suggestion to ask MS to submit comments during the consultation period
- Ag TF and PMC agreed to re-evaluate sharing of testing costs when possible for future testing

Literature searches:

- Under the BPR, there is no requirement to keep the dossiers up to date with the latest available data -> Ag TF currently perform literature searches ad hoc and the costs are minimal, so they have no strong interest to share costs with PMC

4.3 Preparation for 45-day commenting period & next steps

EBRC action plan & proposal

Endpoint	Classification proposal	Comments/concern for Ag	Recommended action
Developm. tox	Repr. 1B	• Key endpoint, of high concern for Ag. • Several studies on this endpoint available. Classification proposal based on reduced viability in foetuses/pups. • Based on series of papers (Shavlovski), KEMI postulates a mechanism for effects on offspring.	EBRC will evaluate and produce an expert statement on available studies/papers. Both direct and indirect effects will be discussed, incl. indirect effects of zeolites on homeostasis (zeolites are used in medicine for detoxification). The previous comments from the Ag Task Force did not include anything on the effects of zeolite.
Carcinogenicity	Carc. 2	Classification is based on study with SZZ, which has been discussed extensively by Ag TF.	EBRC will not add anything to the discussion by ESTF, but will focus their expert comments on whether effects seen in SZZ studies can be attributed to the zeolites, so Ag is not affected.
STOT RE	STOT RE 2	Classification is based on kidney effects observed in a two-generation study with SZZ.	EBRC will put this study into context and check if effects can be attributed to the zeolites and/or to Ag.

Endpoint	Classification proposal	Comments/concern for Ag	Recommended action
Fertility	-	• Not specifically addressed by KEMI (focus on developmental effects) but formal data gap. A waiver is currently included in the Ag dossier, with reference to a sequential testing strategy (unpublished 90-d study). • 2-gen studies are available on 2 Ag biocides (SZZ and SSZHP).	• EBRC will review 2-gen studies and produce an expert comment on these as to whether the findings are of concern with regards to Ag effects on fertility. • PMC Sec requested copy of manuscript on 1-generation study with Ag acetate -> if available, EBRC will review this as well

- EBRC will provide comments by 22 June
- Proposal to have meeting with EBRC and Ag TF end of June to discuss / align comments

4.4 Potential interactions between SEv and CLH

- **Impact KEMI on SEv**: The justification document for the selection of Ag for CoRAP inclusion only mentions **eco**toxicity under the initial grounds for concern and no additional concerns than those listed in the CoRAP were identified -> Assumption that RIVM will dismiss comments from KEMI on human health toxicity on these grounds.
- **Impact RIVM on CLH**: The consultation period on the SZZ CLH may be a good opportunity for The Netherlands (RIVM/ctgb) to comment. Ag TF suggested PMC to contact RIVM on this.

5. AOB, next meetings/calls and closing remarks

AOB, next meetings/calls and closing remarks

- AOB?
- Next Ag WG meeting:
  - 15 October 9:00-12:00