



European Precious Metals  
Federation

European Precious Metals Federation

# Silver advocacy workshop

**Report**

8 October 2019 | Brussels, Belgium

# Introduction

- An internal advocacy workshop between members of the EPMF Silver Work Group was held in Brussels on 8 October 2019 to agree the overarching advocacy strategy for the current CLH proposal from KEMI.
- The objectives of the meeting were:
  - Share and exchange views on the consequences of the classification proposal
  - Align messages
  - Agree the overall strategy and advocacy plan
- This document provides an outline strategy and action plan as the basis for a presentation to the DU workshop to be held on 7 November 2019



# Attendees

- Katrien ARIJS, Consultant for EPMF (Arche, Belgium)
- Francisco BOO, Metalor (Switzerland)
- Arno Buthe, Heraeus (Germany)
- France CAPON, EPMF (Belgium)
- Eliot DEAG, Johnson Matthey (United-Kingdom)
- Julien DE CRUZ, Rud Petersen (Belgium)
- Sylvaine DUARRI D'HAENE, Umicore (Belgium)
- Herbert FUCHS, Heraeus (Germany)
- Rob GARRETT, Ames Goldsmith (United-Kingdom) – *via Skype*
- Simon LAI, Varinor (Switzerland) – *via Skype*
- Michael HUBER, C. Hafner (Germany)
- Marie-Laure LEDRICH, Traxys (Luxemburg) – *via Skype*
- Olga LEMKE, BASF (Germany)
- Johanna LEPMETZ, Rud Petersen (Belgium)
- Jelle MERTENS, EPMF (Belgium)
- Nissanka RAJAPAKSE, Johnson Matthey (United-Kingdom)
- Marc SIMON, Traxys (Luxemburg) – *via Skype*
- James STEVENS, Rud Petersen (Belgium)
- Michael THIEL, BASF (Germany)
- Mika TOIVOLA, Boliden (Finland)
- Steven VERBERCKMOES, Umicore (Belgium)
- Paul YLIOJA, Johnson Matthey (United-Kingdom)





# Situation Analysis

**What are we facing?**

# Silver and silver nitrate CLH: Process and timing

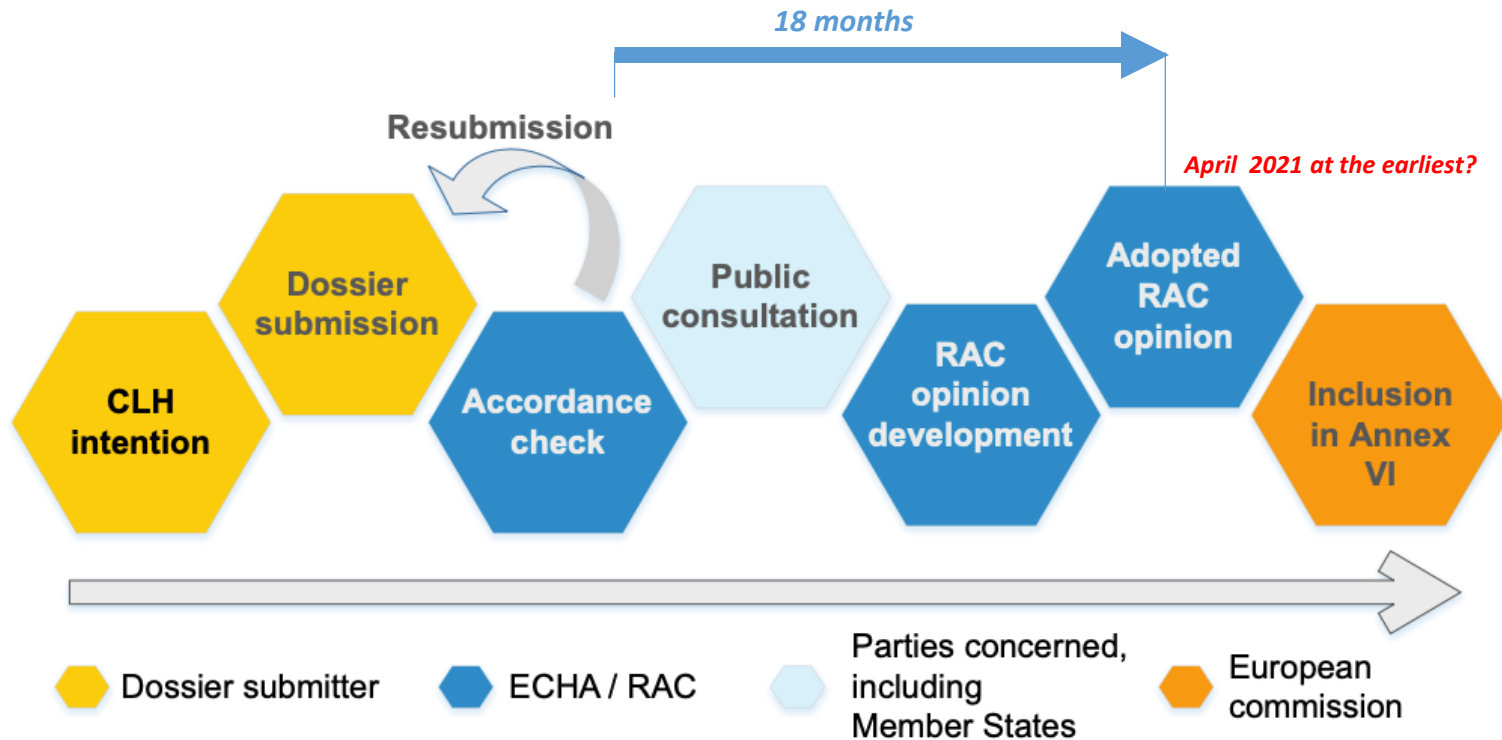


Figure from <https://echa.europa.eu/regulations/clp/harmonised-classification-and-labelling>

► **RAC opinion CLH before EOGRTS test results available?**  
(EOGRTS test results should be available before inclusion in ATP)

# KEMI Proposal & EPMF Comments

Kemi CLH proposal	EPMF Classification	Comments based on current weight-of-evidence
Skin Sens. 1	-	<ul style="list-style-type: none"> <li>• Human evidence very low despite long term industrial experience and consumer uses</li> <li>• Animal studies with other Ag substances: clear negative outcome</li> </ul> <p>➔ No basis for classification</p>
Muta. 2	-	<ul style="list-style-type: none"> <li>• No direct human evidence</li> <li>• Outcomes from <i>in vivo</i> and <i>in vitro</i> studies with several Ag substances do not provide cohesive picture of genotoxicity, with many study outcomes being negative or equivocal</li> </ul> <p>➔ Weight-of-evidence: no firm basis for classification</p>
<b>Repr. 1B</b>	-	Cf. next slides
Aq. Acute 1	Aq. Acute 1	
Aq. Chronic 1	Aq. Chronic 1	



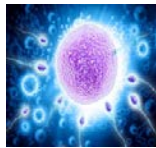
# Science defence reprotox (1/2)



**Ag<sup>+</sup> as toxicant:** available studies performed on ≠ Ag substances, some containing potential confounding toxicologically relevant moieties ► relevance to Ag<sup>+</sup> not always clear ► **EOGRTS** with simple Ag<sup>+</sup> substance (AgAc)



**Developmental effects:** new data (Sprando et al., 2017) suggests Ag<sup>+</sup> is developmental toxicant ► may be reliable study but several deficiencies ► **EOGRTS** superior design allowing robust evaluation of reproductive outcomes

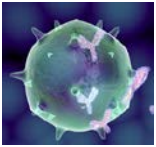


**Fertility effects:** weight-of-evidence for Ag<sup>+</sup> equivocal: indicators from most available studies unremarkable, Sprando reported effect at high dose only ► **EOGRTS** superior design (incl. 10 weeks pre-mating exposure)



**Potential for indirect effects:** multiple animal studies demonstrating Ag<sup>+</sup>/Ag effects on gut biome (dysbiosis) ► secondary reproductive effects? ► biome investigations will be examined as part of **EOGRTS** ancillary studies

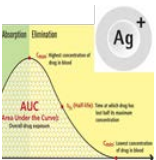
## Science defence reprotox (2/2)



**Developmental immunotoxicity (DIT):** recent study (Babu et al., 2016) suggests possibility of DIT in rat model ► several limitations in protocol but industry consider it prudent to investigate further ► **EOGRTS** incl. DIT cohort



**Developmental neurotoxicity (DNT):** limited indications of DNT have been described in some studies ► do not meet evidential triggers for DNT concerns but industry (and ECHA / MSCAs) consider it prudent to investigate further ► **EOGRTS** incl. DNT cohort



**Ag toxicokinetics (TK):** dataset Ag TK fragmentary and often conflicting ► data for secure read-across lacking ► EPMF planning comparative TK study and integration of TK parameter assessments in **EOGRTS**

# The audience

	Role	Observations
KEMI (SE agency)	Dossier submitter	<ul style="list-style-type: none"> <li>• Under pressure from Commission to complete BPR review by 2024</li> <li>• Under pressure domestically to deliver on chemicals</li> <li>• Desire to collaborate with industry on science</li> <li>• HH for silver, but also driven by focus on environment in water (EQS)</li> <li>• Worrying about data on C,M – R means cut off criteria met under BPR</li> </ul>
DG ENV	Responsible for CLH	<ul style="list-style-type: none"> <li>• Worrying about weak cases after recent issues on other substances</li> <li>• Seeking alignment and consistency with between chemicals legislation</li> <li>• Worrying about impact of precedent of delaying process to await new science</li> </ul>
DG GROW	Responsible for CLH	<ul style="list-style-type: none"> <li>• Not engaging</li> <li>• Not feeling competent</li> </ul>
DG SANTE	Responsible for biocides	<ul style="list-style-type: none"> <li>• Tired of BPR programme and feels under pressure to complete from NGOs and others</li> <li>• Niche part of the chemicals regulatory universe that is not understood by REACH/CLH and others</li> </ul>

# The audience

	Role	Observations
ECHA	Manager of opinion process	<ul style="list-style-type: none"> <li>• Embarrassed about delays in process for Testing Proposals</li> <li>• Suffering from similar silos between BPC/BPR and RAC/CLH</li> <li>• Overwhelmed with work at RAC</li> </ul>
Commission (political level)	Final decision-maker	<ul style="list-style-type: none"> <li>• Focused on European Green Deal and new political programme of Commission</li> <li>• Increasingly aware of linkages between different policies and impacts</li> <li>• New actors in Cabinets</li> </ul>
Other MSs	Influence on opinion through ECHA bodies, input to Comm on draft and scrutiny on final decision	<ul style="list-style-type: none"> <li>• Some interest following TP outreach, but many remain unaware of impact</li> <li>• No media/NGO activity or pressure on silver to speak of (FOE report on nano in 2009)</li> <li>• Focused on their own files at technical level</li> <li>• Lacking in administrative capacity in many cases</li> </ul>
EP	Pressure group on process and provide scrutiny on final decision	<ul style="list-style-type: none"> <li>• Not yet aware of issue</li> <li>• No NGO or third party activity</li> <li>• Not yet champions of silver</li> <li>• Focused on the political priorities for next five years</li> </ul>



# Our socio-economic case

- A socio-economic impact study is about to start, which will provide the basis to underline in advocacy why the science should be listened to and regulators need to get the decision on CLH right. It is important to note that the RAC will not look at socio-economic factors and the only public consultation may be at this stage
- The CLH could increase costs, create uncertainty and disrupt investment plans
- A number of applications have already been identified that may be either critical (essential for now or future policy objectives):
  - Micro-electronics
  - Renewable energy (PV panels)
  - Electric battery charging connectors
  - Aerospace
  - Soldering (replacement for lead and cadmium)
  - Surface treatment (replacement for lead and cadmium)
  - Medical devices
  - Catalysts
  - Jewellery
  - Industrial measurement
  - Industrial measurement applications
  - Musical instruments (emotional attachment) – flute
  - Investments
- The workshop is an opportunity to explore how to leverage such uses



## Key concerns

- Time pressure of study - potential for delays in a complex and unpredictable EOGRTS
- Uncertainty of science – we won't be sure until study is done what result will be
- Having a clear road map – need for all parties to be aligned on advocacy goals, strategy, messages and actions
- Comms around impact of classification – if we can live with the result (i.e. it's about cost) why not be precautionary, therefore need to show critical impact



## In summary

- **Time is the key issue:** the process is being driven largely by the pressure of BPR and its implementation timelines (2024) and the interplay between the deadline for a RAC opinion (18 months after public consultation starts) and our own EOGRTS.
- **Silver and its compounds are not currently political:** there would appear to be no 'agenda' that is driving this work and no broader public debate that would affect the hearing that silver receives
- **The weakness of the science is recognized:** Conversely there is an acceptance that the current science is not robust enough and a decision based on current science could lead to an incorrect/disproportionate outcome. However, we're clear that we don't know for certain the outcome of the EOGRTS and need to prepare for the worst as well as the best.
- **Dossier needs to be put in a positive political context:** Using the economic footprint of the industry value chain as well as contribution of silver applications to the political agenda of incoming Commission could elevate the importance of the science.
- **Solutions will need to balance competing interests:** Any solution that allows science to be properly considered will need to satisfy different actors and their motivations.





# Advocacy plan

**What we intend to do about it**

# Our strategy

## Advocacy goals

1. Ensure a classification based on robust science that is fully understood by regulators
2. Delay process to allow RAC to take into account new science generated (April 2021 initial results)



# Audience change

	Today	Tomorrow
KEMI	<p>We feel under pressure to deliver by 2024</p> <p>We think based on current information our proposal is the right one</p>	<p>We feel happy that the pressure has come off</p> <p>We think that the new information we have received changes the basis for our original proposal</p>
Member States	<p>We feel that we've too much on our plate to look at another CLH dossier</p> <p>We think that the science currently available is what a decision should be based upon</p>	<p>We feel worried about the impact on our country of getting this wrong</p> <p>We think the Commission needs to find a solution to allow new science to be taken into account</p>
Commission Services (DG ENV)	<p>We feel concerned that getting this wrong could mean a whole series of problems for the future</p> <p>We think there's no option but to follow the current process</p>	<p>We feel under pressure to find a solution from our political masters</p> <p>We think that we can find a way to solve this that doesn't set a precedent for all other industries</p>
Commission political level	<p>We feel unaware of any issue relating to silver that impacts our agenda</p> <p>We think that the chemicals regulators are on top of things</p>	<p>We feel worried that chemicals decisions are affecting our political agenda and silver is an example</p> <p>We think our services should be able to find a solution that safeguards health and enables the European Green Deal</p>



## Messages (top line)

- As new actors in this process, we're committed to working with regulators to understand the science behind silver and human health. As long ago as 2015 we identified a gap in the data and proposed to fill it, with a testing proposal finally accepted last year by ECHA.
- The results of this new science will be available in early 2021, allowing regulators to make a decision based on the facts.
- Any harmonized classification will have an impact on investment in key applications from micro-electronics to renewables and electric battery charging that will help achieve the political priorities set out in the new Commission's European Green Deal.
- Given this we are asking for the time needed to allow the RAC to properly consider all relevant data before any regulatory decision on silver is made. While this may delay the BPR evaluation process by a few months, it's important for the vast majority of uses (which are outside of BPR) that we get this right.
- In the meantime, as a responsible industry we're examining our own occupational exposure levels, actively communicating to the value chain so it can prepare for change and our members are communicating with their customers.



## Asks/Solutions (for further elaboration and discussion)

Option	Desirability	Likelihood
ECHA/Commission to informally agree to delay start of public consultation to ensure new science can be examined by RAC	High	Medium
ECHA/Commission informs RAC of new science pending and RAC states it cannot issue an opinion until new science is received	High	Low
RAC issues provisional opinion based on current science but leaves open question mark over relevant endpoints, providing Commission with ability to refer back when new science is received	Medium	Nil
Commission delays entry into ATP and refers back to RAC for new opinion upon receipt of new science	Low	Medium
Commission sits on ATP and does nothing, allowing BPR to move ahead but having no effect on other processes	Low	Low

## Materials/Assets

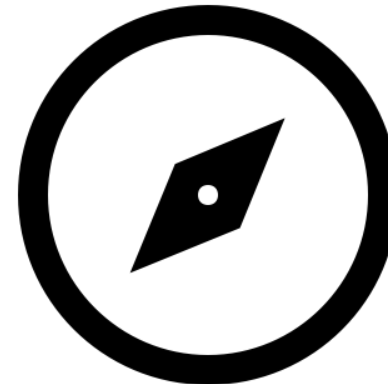
- Message document
- Q&A
- Factsheet
- Base advocacy presentation
- Summary of socio-economic study
- Visual of silver applications and relationship with political objectives of EU



# Our strategy

## Advocacy strategies

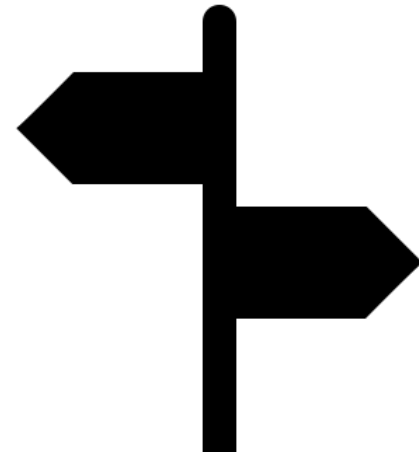
- 1. Leverage concerns about quality of science and alignment between processes.** Raise doubts in minds of decision-makers about the validity of basing a decision on the current information by pointing to shortcomings in science base and showing how the new science will answer these questions.
- 2. Activate value chain to underline wider impact.** Underline the effects across the economy so as to ensure that the regulators take the time to look at the science properly.
- 3. Elevate issue to political level through association with broader policy priorities of incoming institutions.** Make the decision to be creative about solutions about something that political actors care about – the goals they are seeking to achieve in the next five years outside of chemicals management.



# Our strategy

## Process milestones

1. **Beginning of public consultation (point of no return)**
2. **RAC opinion adoption**
3. ***Commission draft delegated act proposed***
4. ***Publication in Official Journal***



# Milestone: Beginning of public consultation

**Success: Commission and ECHA agree to delay public consultation start**

**Timing: now to end Q1 2020?**

## Leverage scientific concerns

### Play to DG ENV concerns

- Chemicals Watch article about workshop
- Meeting with DG ENV to update on revised timeline of studies

### Place on public record state of science

- Independent article on science around silver for placement in peer review journal

### Re-engage with interested MSCAs from TP phase to encourage to submit to public consultation

- Reach out to PL, IT, FIN, DE

### Activate third country regulators to submit to public consultation

- Outreach to CH, NO, India, NZ, RSA, US, OECD

## Activate value chain

### Ensure on same page

- Host DU workshop

### Establish coordination mechanism

- Regular update calls scheduled

### Promote broad participation in public consultation

- Prepare template for public consultation responses

### Prepare for joint outreach to MSs in next phase

- Map political and economic footprint – create joint DU/Silver teams
- Prepare materials pack for advocacy use by all actors (Strat on page, Messages, Q&A, Standard Deck, Summary of SEA)

## Elevate to political level

### Take the pressure off BPR

- Find policy dissonance/application that is under threat of interest to DG SANTE
- Outreach to DG SANTE hierarchy

### Underline benefits of silver

- Create visual representation of contribution of silver to VdL/European Green Deal political agenda
- Outreach programme to incoming cabinets around critical applications/positive policy agenda
- Outreach to MEPs as part of MetalsWithAmbition weeks



# Milestone: RAC adoption

**Success: Reference in RAC to one of our potential solutions**

**Timing: Q1 2020 – end Q2 2021 (earliest)**

## Leverage scientific concerns

### Scientific symposium

- Symposium on first public results
- Trade media outreach

### Seek EFSA/ECHA alignment

- Outreach to EFSA on interaction with food opinion

## Activate value chain

### Ensure coordination mechanism

- Regular update calls/news updates/information sharing
- Quarterly f2f meeting of coordination group

### Undertake joint outreach to MSCAs to apply indirect influence on RAC and prep for regulatory/political stage

- Coordinated roadshow of meetings in key Member States

### Prepare communications for negative opinion/crisis

- Crisis comms prep
- Messages and comms assets
- DU communications plan for members

## Elevate to political level

### Underline benefits of silver

- LinkedIn series from FC highlighting benefits of silver applications
- Participate in EM benefits ad campaign

### Launch socio-economic study

- Event around study (July)
- Paid social using socio-economic data using visuals using initial results (Jan onwards)

### Outreach to Perm Reps

- Programme of discussion with Brussels reps in areas where policy affected

### MEP champion programme to ensure allies in scrutiny phase

- Follow up with initial EP contacts/site visits/combined silver/DU events



# Gateway decision

Upon the adoption of the RAC opinion (mid-2021), a decision will need to be taken by the industry as to future activities. This decision will depend on the positive/negative outcome of the RAC and its reception by DG ENV.

