



EPMF Silver workshop - Report

The Silver downstream users workshop hosted by EPMF took place on 7 November 2019 in Brussels. It gathered more than 80 participants including manufacturers and downstream users of silver in EU supply chains as well as representatives from European, national associations, and consultancies. Representatives of the European Silver Taskforce (responsible for the silver biocides dossiers) were also present.

1. Situation analysis

The introductory speech was given by Clémence Siret from SAFT. She highlighted the impact that the Category 1B Reprotoxicity classification proposal from Kemi for silver and silver compounds already has on the silver business, citing as an example impact on batteries used for defence and in connectors for fast charging of electric cars.

a. Regulatory state of play and the EOGRTS study

France Capon, the Secretary General for EPMF, gave an overview of the regulatory state of play for silver and silver compounds. She emphasised specifically three processes running in parallel but not in full alignment as a cause of immediate concern:

- The evaluation of silver and silver compounds under the Review Programme of the Biocidal Products Regulation;
- The harmonized classification proposal of silver nitrate and silver metal as (between others) Category 1B Reprotoxicity submitted by Kemi, the Swedish Chemicals Agency in the context of the Biocides review;
- The ongoing EOGRTs study performed by EPMF under the REACH Regulation (results expected mid-2021).

Katrien Arijns from EPMF outlined the science defence of EPMF regarding the Swedish proposal for the different endpoints with a specific highlight on reprotoxicity. She highlighted the deficiencies of the current science in this field:

- The substances that have been tested are difficult to relate to effects of silver ion
- Studies showing effects on reproduction & fertility do not form a consolidated picture
- Available studies do not provide replies to our DIT and DNT questions
- Toxicokinetics results are often contradictory and fragmented

She outlined the benefits of waiting for the outcome of the EOGRTs and ancillary studies before making a final decision on silver and silver compounds classification:

- The test substance (Ag Ac) will be representative of the silver ion
- It considers the possibility of secondary reproductive effects
- Answers questions on DIT and DNT
- Toxicokinetics will be investigated to allow robust read-across

France Capon made clear however that the results of the EORGTS study could either way contradict or confirm Kemi's findings. It is therefore important at this stage to stress that the sector's message to



the regulator **is not that silver and silver compounds are not classified but rather to urge them to wait for the results of the EOGRTS study to take a decision based on robust science.**

One participant inquired whether an argument could be made that silver presented secondary developmental toxicity effects and whether endocrine disruption should be investigated. Katrien Arijs explained that ECHA Guidance states that in order to be classified (as reprotoxicity cat 1B or cat 2), reprotoxicity effects should be observed in the absence of other toxic effects, or if occurring together with other toxic effects the adverse effect on reproduction should be considered not to be a secondary non-specific consequence of the other toxic effects. This means that, if there are indications that the reproductive effects are secondary effects and not direct effects, this could help lower the reprotoxicity classification. Concerning endocrine disruption, a literature study is currently being performed by the European Silver Taskforce in the context of the BPR Review Programme.

One participant inquired whether the EOGRTS that was performed on silver acetate should not be performed on silver metal instead. Katrien Arijs clarified that read-across is usually done from the most bioavailable form (i.e. the worst case form) to other forms and therefore testing is usually performed on the most soluble form. She added that in any event, a toxicokinetics study is ongoing to refine and validate the read-across approach and the way of extrapolating from the more to the less soluble form.

b. Regulatory impacts of the Category 1B classification proposal

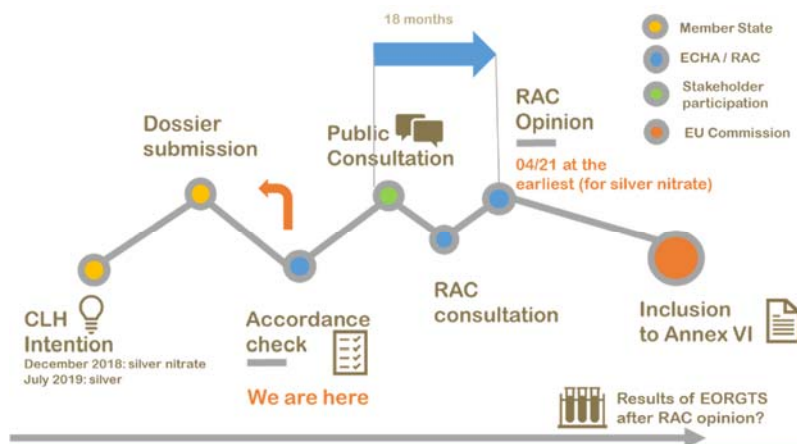
France Capon highlighted the regulatory impact of the proposed classification. It is worth to note that a classification as reprotoxicity cat. 1B qualifies the substance as Substance of Very High Concern (SVHC) under the REACH which would make it likely to be added to the REACH Authorisation List. The Authorisation process would bring uncertainty to the silver business triggering significant administrative and financial burden for users of silver as manufacturers. Under the Cosmetics Directive, a classification would trigger an outright ban of silver in cosmetics products. A classification would also trigger concentration limits, labelling and analysis of alternatives for use in Medical Devices. Under Workers' protection legislation, increased risk management measures would have to be put in place.

Silver would also be impacted under many more regulatory areas including but not limited to Ecolabel, Toys, General Product Safety, Construction, Waste and End of Life Vehicles.

Replying to a participant's question on the presence of silver in water streams, France Capon explained that silver was also being discussed in the context of Environmental Quality Standards under the Water Framework Directive. Timing is unclear for now and monitoring data are not showing strong concerns, but the issue must be monitored since so far, Sweden was also in the driving seat.

c. Regulatory timeline and advocacy strategy

France Capon outlined the timeline of the regulatory process for the classification proposal.





Timing is currently unclear: silver nitrate went already through the accordance check and silver metal is still ongoing. There is no formal deadline to conclude the accordance check, while the clock will start ticking when the public consultation will start. Indeed, the CLP Regulation imposes a non-extensible 18-month time period between the public consultation and the opinion of the Risk Assessment Committee (RAC) in charge of classification proposals at ECHA.

One participant inquired about the possibility to request RAC to postpone its opinion in order to wait for the development of new science. Violaine Verougstraete from Eurometaux answered that RAC cannot take this decision. However, under Article 77(3) of REACH, the Commission could request to RAC a new opinion based on the availability of new data. This could be an option if the CLH process continues and that the outcome of the EOGRTs becomes available after the RAC opinion. However, this process is heavy and difficult to trigger for the Commission.

Regarding the science defence, a participant asked if the fact that silver is used since centuries without any issues cannot be used as an argument. France Capon confirmed that we could be tempted to use such a type of arguments, but precedents showed that at the RAC level, this argument never flies.

France Capon outlined the EPMF advocacy strategy, starting by a summary of the situation:

- Time is a key issue (pressure from the BPR angle)
- Science needs work and time
- Solutions will need to balance competing interests
- Silver and compounds are not currently political
- The issue needs to be put in a positive political context

The audience of relevant stakeholders consists of:

- ECHA as the manager of the opinion giving process for classification;
- the European Commission as final decision maker;
- Member States as they directly input into the decision-making process through ECHA committees;
- The European Parliament to a lesser extent as it may exert indirect pressure throughout the regulatory process and has scrutiny power on the final decision before adoption.

The main milestones in the process are the following:

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

It is important at this stage to focus on the two first ones.

The following objectives have been set and agreed:

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)

The key messages to be used are the following:

- Getting silver CLH right It's worth a short wait
- Its major uses are too important to the EU's goals to get this classification wrong
- Neither industry nor regulators need another problematic CLH substance debate
- Europe shouldn't miss out on the benefits of silver investment for an administrative error



- It's only a wait of a matter of months – in a town where things are always delayed for years
- We're already taking measures to prepare and protect in the meantime

2. Breakout sessions

The participants were divided in 3 breakout groups to discuss the following issues:

- Group 1: What are the downstream users impacts?
- Group 2: how best collaborate?
- Group 3: How to organize the outreach?

a. Downstream users impacts – Group 1

Lisa Allen from the International Lead Association reported on the discussions in Group 1. She reported that the workshop discussion reflected the multitude and fragmentation of downstream uses of silver. In addition, it was challenging for participants to evaluate the market value and volumes of silver in the EU as there are both large imports and a large production of silver. Also, while some uses may be low volume if taken individually, they add up to large volumes, this was the case for instance for biocides uses.

Below is a breakdown of the uses of silver discussed by the breakout session participants:

- Alloying agent (2-3%) / batteries / solder
- Surface finishing / electroplating – includes satellite telecommunications (wave guide coating)
- Jewellery / watches
- Electrical / electronics / soldering in contacts and conductivity
- Chemical intermediate
- Photographic films / imaging (including data storage)
- Biocide / antibacterial for water treatment – hospitals (re: Legionnaire's disease) – energy saving as the alternative to use silver means is to use very hot water
- Pharmaceutical sector / biomedical e.g. wound dressing
- Treated articles e.g. antibacterial textiles in socks, pillows etc.
- Decorative / tableware
- Solar panels, mirrors and batteries – collectively
- Precision mirrors for safety purposes e.g. automotive
- Coins and bars – banks / investment
- Carrier metal for other precious metals in the recycling sector – Circular Economy
- Personal care products, e.g. deodorants
- Laboratory reagent, including cucumber-family gender detection
- Plant growth regulator (freshly picked flowers/harvested plants) – ethylene protection
- Explosive cladding for chemical industry reactors and vessels (millimetres thick)
- Aerospace – plated fasteners (nuts and bolts)

The group also agreed that more data are needed on volume/use. To a large extent, this data gathering exercise will be part of the effec study. The mapping of the silver universe will be needed, as the connection of it to everyday life. The silver Institute volunteered to support the effort having already a lot of information on the markets and trends available.



b. How do we work together? – Group 2

Martin Wieske from WirtschaftsVereinigung Metalle reported on the discussions in Group 2. Participants to this group discussed the following points:

- What should be the format of internal communications?
- What should be the frequency of such communications?
- Who should lead?
- How to achieve leadership?
- How to communicate internally?
- How to communicate between downstream users?

The group noted that there was a high level of concern among participants and that one way to alleviate this concern was to give structure to internal communications and prepare crisis communication in case if needed (e.g. NGOs activities). The following plan was suggested by participants:

1. Technical communication on **essential uses** of silver
2. Use the existing formats and channels of communication of associations
3. Designate **champions** to communicate on the silver classification file
4. Keep regular contact on development of the etfec Impact Assessment, using for example the following materials:
 - a. A short presentation of the IA
 - b. A one-pager on the state of play
 - c. Timelines and contacts
 - d. Q&A
5. Prepare crisis communication
6. Prepare a Webinar
7. Maintain a contacts list
8. Use a webpage with restricted access to centralize the communication

The group emphasised that stakeholders should communicate to the extent possible using existing formats and using existing events as a platform to disseminate messages on the classification.

It was also highlighted that to expand the network it is very important to identify the relevant stakeholders in the industry (not just the name of a company but the right person responsible of the issue).

The companies and associations present in the room were invited to activate their own network to support EPMF spreading the message to the relevant stakeholders.

The International Lead Association (ILA) offered its support to share experience and learning lessons since they went already through this exercise.

c. Outreach – Group 3

Juha Parkkinen from Norilsk Nickel reported on the discussions in Group 3. The group agreed that efficient outreach could take place in several stages:

Steps	Timeline
Outreach on the <i>importance</i> of the silver file (i) CEO letter outreach at political level of the Commission	Before public consultation



<ul style="list-style-type: none"> (ii) Outreach to relevant units of supply chain <ul style="list-style-type: none"> a. Chemical manufacturers b. Downstream users (iii) Outreach to Member States contacts <ul style="list-style-type: none"> a. Stakeholder mapping b. letter 	
Briefing to key MEPs on the classification issue and its link to the big political headlines like Climate change, circular economy etc. .	January 2020
Prepare position on the outcome of the PC. Outreach to Member States. Outreach to technical units of Commission DG ENV and GROW and ECHA.	After public consultation

3. Impact assessment of the potential classification of silver and silver compounds as reprotox cat. 1B – eftec

Eftec presented the state of play of its project on the impact associated with the Cat 1B proposal for silver and silver compounds.

Eftec summarises the contents and objectives of impact assessments in general and detailed the timeline of the project for the months to come. The project has been launched in October 2019 and final deliverables are expected in July 2020.

They highlighted the following periods in the project where the input of the different stakeholders will be needed:



They outlined also very clearly that the respect of the confidentiality will be very high in this project, using the following approach:



- **EPMF is the Trustee of data**
- **Sector assessment**
 - They will aggregate companies responses – No company names mentioned
 - Sector must have at least 3 survey responses to be reported (or more depending on the case)
 - Respondent data will be extrapolated/uplifted to produce sector-wide assessment
- **Rounding and use of drop downs**
 - They will round the data provided (e.g. nearest thousand tonnes)
 - Drop downs where possible will be used in questionnaire/survey to avoid having to give precise numbers
- **Interviews**
 - No company names mentioned in impact assessment
 - Companies involved will sign-off their interview report
 - Companies involved can mark what info is deemed confidential

France Capon reminded that this exercise will only be successful if companies and associations contribute actively, and especially the downstream users sectors impacted by the classification.

A participant raised the question of the adequate communication with the Downstream Users on uncertainties related to the classification discussion. EPMF is in charge of the horizontal communication related to process, science and advocacy activities while the EPMF companies are invited to have a more tailor-made communication to their customers related to the potential risks and uncertainties.

4. Conclusions and next steps

James Stevens of Rud Pedersen Public Affairs presented a summary of the advocacy plan and the next steps.

Based on discussions in the breakout sessions and on earlier contacts with EPMF, the three following pillars are of utmost importance:

- **Science:** concerns expressed today have to be leveraged to key actors of decision process on the classification proposal. EPMF has already met some of these key actors but uncertainties remain as to the outcome of the EOGRTS study.
- **Communication:** downstream users and supply chains at large have to be activated
- **Politics:** economic weight and importance of the file must be emphasised to political level who is not technical, they must get interested and motivated.

James Stevens presented the advocacy milestones agreed with EPMF and enriched by the discussions in the breakout group (as from next page).



Before the public consultation starts

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 supply chain

Ensure on same page

- Host DU workshop

Establish coordination mechanism

- Follow up call
- Regular update calls scheduled
- Online platform

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

Political level outreach

- C-suite communication/outreach
- Supply chain meetings with Units
- MS outreach

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



Before the RAC opinion

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 supply 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 EPMF 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



After the completion of the two first milestones, it will be important to take stock of the situation and analysis the situation before defining the next advocacy steps.

France Capon confirmed that this workshop is the first one of a series of communication activities. As a first follow-up, a conference call will be organised in December 2019 with all participants as well as companies that were not present at the workshop.

It is important to increase our network at downstream user levels and involve more companies and associations, but also national federations in the advocacy exercise. EPMF needs the brains, resources and expertise of all the downstream users sectors to act collectively in a resource efficient way.

A communication material package (Q&A, presentation etc.) will be developed in the next weeks.

France Capon closed the meeting thanking the audience for their active participation and confirming that the presentation, as the list of participants following the GDPR rules will be available.

List of acronyms

BPR: Biocidal Products Regulation

CLH: Harmonised Classification and Labelling process

CLP: Classification Labelling and Packaging Regulation

DG: Directorates-Generals (within the EU Commission)

DG ENV: Directorate-General Environment (within the EU Commission)

DU: Downstream Users

ECHA: European Chemicals Agency

EFSA: European Food Safety Authority

EM: Eurométaux

EORGTS: Extended One-Generation Reproductive Toxicity Study

EP: European Parliament

EU: European Union

MS: Member State

MSCA: Member States Competent Authorities

RAC: Risk Assessment Committee

REACH: Registration, Evaluation, Authorisation and Restrictions of Chemicals

SEA: Socio-Economics Analysis

SVHC: Substance of Very High Concerns

TP: Testing Proposal