European Precious Metals Federation

ANNUAL REPORT **2023**

THE EUROPEAN PRECIOUS METALS FEDERATION

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WELCOME

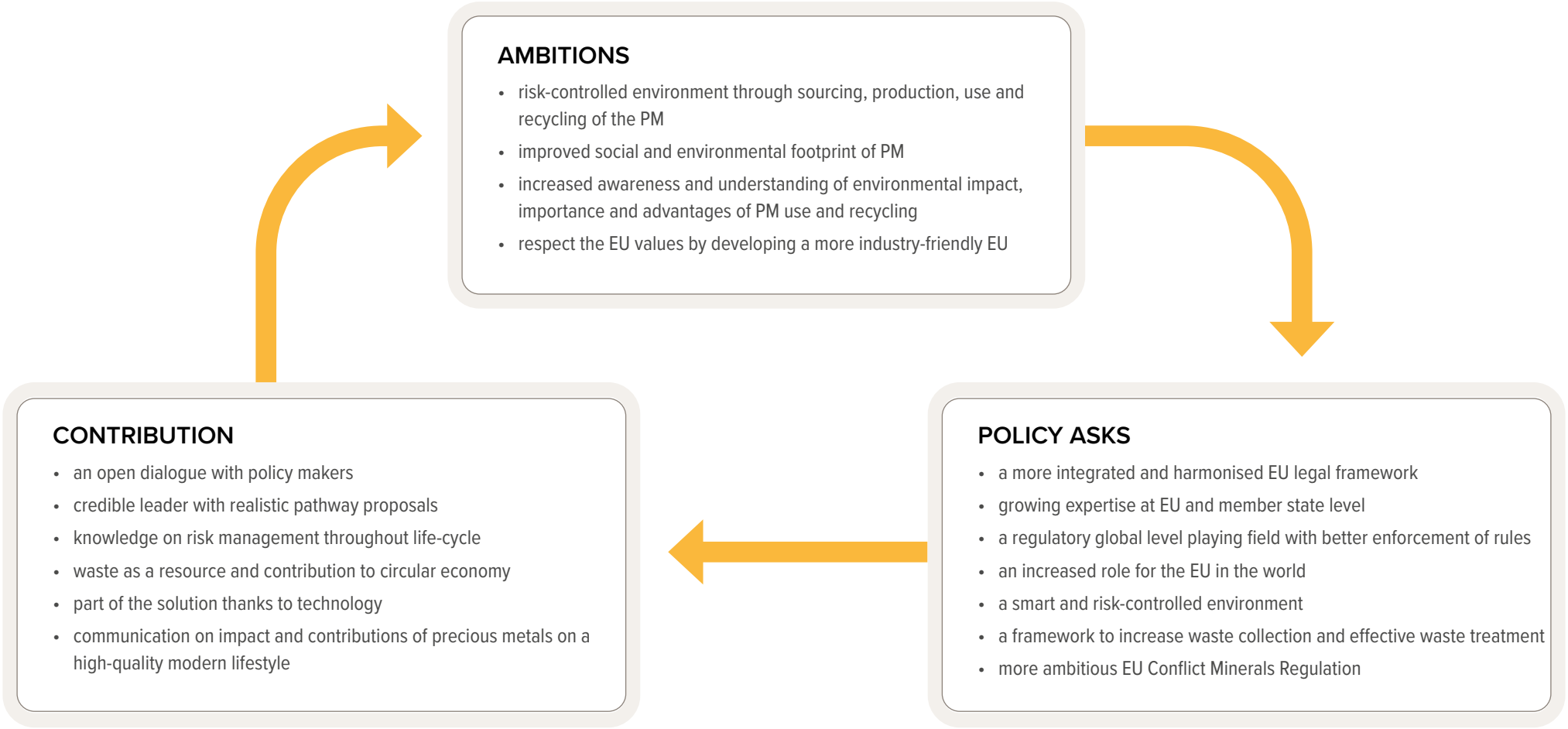
Welcome to the EPMF's Annual Report, a comprehensive journey through the achievements and milestones of 2023. To commence, we will look at our work on chemicals management and review the status of silver classification and REACH dossier updates. Are you eager to find out more about the REACH and CLP revision? Navigate further down the report. The EPMF portfolio also focuses on sustainability topics, many of them are currently in the implementation stages; find out what messages we advocated for in 2023. During the year, our outreach and communications included multiple scientific publications. 'Metals Day' in Strasbourg, a REACH revision event, is just a hint for you. Naturally, whilst reading, you will encounter facts on precious metals. Why not test your precious metals knowledge in our short quiz at the end of the report?

Enjoy the Annual Report!

The EPMF Team

THE EPMF'S MISSION

Since 2009 the EPMF has supported European companies operating in the areas of gold, silver and Platinum Group Metals (PGMs). The EPMF is keen to contribute to the ambitious EU policy agenda on a wide range of issues.



PRIORITIES AND ACTIVITIES

CHEMICALS MANAGEMENT

I. THE HARMONISED CLASSIFICATION OF SILVER METAL AND SILVER NITRATE

EU citizens own almost 60% of all the silver in the EU market via investment, silverware, and jewellery. Silver metal and silver compounds are critical for green technologies, including solar panels, wind turbines, electrodes, fast chargers for electric cars, etc.

1. The issue

In July 2019, the European Chemicals Agency (ECHA) published in the registry of Harmonised Classification and Labelling (CLH) Sweden's intention to classify silver metal (Ag) as hazardous (i) skin sensitiser cat. 1; ii) mutagenic cat. 2; iii) reprotoxic cat. 1B; iv) aquatic toxicant (acute and chronic) cat 1. This proposal has potential consequences for all uses of silver, including jewellery, silverware, electronics, solar panels, aerospace, and others. The discussions and conclusions around the classification will impact the REACH registration dossiers.

In 2023, the silver nitrate CLH proposal was accepted by ECHA, and they started the public consultation process.

2. The EPMF's contribution

In 2023, the European Chemicals Agency's Risk Assessment Committee (ECHA -RAC) published its opinion on Sweden's silver metal classification. The RAC did not consider the EPMF's position that silver metal (massive and powder) does not require a human health classification.

The Competent Authorities for REACH and CLP (CARACAL) discussed this opinion. Most Member States supported the RAC opinion except for Sweden (which defended its original proposal) and Bulgaria (which requested a review of the massive classification). At the close of 2023, the debate was still ongoing.

In parallel, the EPMF contributed to the silver nitrate ($AgNO_3$) CLH public consultation, defending the classifications shown over the page.

Endpoints	Ag			AgNO3	
	KEMI CLH proposal	**RAC** opinion nearly adopted by The Commission	**EPMF** (self)-classification	**KEMI** CLH proposal	**EPMF** (self)-classification
Physical hazards: Oxidizing solids	-	-	-	Ox. Sol. 1	Ox. Sol. 1/2
Physical hazards: Corrosive to metals	-	-	-	-	Met. Corr. 1
HH: Acute toxicity - oral	-	-	-	Acute Tox. 2	-
HH: Skin corrosion / irritation	-	-	-	Skin Corr. 1A	Skin Corr. 1A
HH: Skin sensitisation	**Skin sens. 1**	-	-	**Skin Sens. 1**	-
HH: Germ cell mutagenicity	**Muta. 2**	- **minority opinions**	-	**Muta. 2**	-
HH: Reproductive toxicity	**Repro 1B**	Repro 2 **minority opinion**	- (massive, powder) Repro 1B (nano)	**Repro 1B**	Repro 1B
HH: Specific target organ toxicity - repeated exposure	-	**STOT RE 2 (nervous system)**	-	**STOT RE 2 (nervous system)**	-
ENV: acute aquatic	Aq. Acute 1 (massive, powder, nano)	- (massive) Aq. Acute 1 (powder, nano)	- (massive) Aq. Acute 1 (powder, nano)	Aq. Acute 1 (M=1000)	Aq. Acute 1 (M=1000)
ENV: long-term aquatic	Aq. Chronic 1 (massive, powder, nano)	- (massive) Aq. Chronic 1 (powder, nano)	- (massive) Aq. Chronic 1 (powder, nano)	Aq. Chronic 1 (M=1000)	Aq. Chronic 1 (M=1000)

3. The EPMF's key messages

The EPMF acknowledges the RAC opinion regarding silver metal but disagrees with its scientific basis. The EPMF maintains that silver metal massives should not be classified for human health endpoints.

4. Next steps

The European Commission (the Commission) will publish the 22nd Adaptation to Technical Progress (ATP), which includes silver metal, based on the outcome of the CARACAL discussions. The Commission is expected to follow the RAC opinion. The silver metal classification should be implemented by the end of 2025.

The silver nitrate matter will first be placed on the ECHA RAC agenda before an opinion is issued for the European Commission to consider and discuss at CARACAL.

5. The EPMF is in dialogue with:

- The European Commission: DG ENV and DG GROWTH
- The European Chemicals Agency (ECHA)
- Member States' REACH competent authorities
- Downstream industry sectors

II. THE WATER FRAMEWORK DIRECTIVE: SILVER EQS AND THE BLM PROJECT

1. The Issue

Since 2000, the Water Framework Directive (WFD) has been Europe's main legal instrument for water protection. The WFD identifies "priority substances" (PS) as substances posing a significant risk to or via the aquatic environment. These substances must meet standards for surface waters (Environmental Quality Standards; EQS), and their emissions must be reduced or phased out accordingly. In October 2022, the Commission published its proposal to revise the list of PS and their corresponding EQS, including adding silver with a freshwater EQS of 10 ng/L. The European Parliament (the Parliament) voted on the proposal in September 2023, agreeing with the silver EQS. The EPMF is greatly affected as silver release is likely to occur in manufacturing, production, and the use of substances and articles containing silver.

2. The EPMF's contribution

The EPMF actively engaged in scientific discussions concerning the silver EQS from the early stages of the process, raising methodological concerns on the data assessment. Despite European freshwater monitoring data showing no EU-wide silver risk, it was designated a PS under the WFD. A very conservative EQS of 10 ng/L was proposed in the legislative proposal (compared to the EPMF's value of 46 ng/L). The main reason to prioritise silver is listed as the concern that it might lead to the development of antimicrobial resistance (AMR).

Following the Commission's legislative proposal, the EPMF and Eurometaux developed an advocacy strategy targeting the Commission, the Parliament and the Council of the European Union (EU Council). In autumn 2023, meetings were conducted with the Permanent Representatives of Lithuania, Romania, Italy and Sweden, as well as with the Swedish national ministry. Additional meetings are planned for 2024. These have not resulted in any amendments for silver in the EU legislative proposal. However, a notable success was achieved in Finland, where silver will not be proposed as a national harmful substance, and a national EQS will not be proposed as the selection criteria have not been met.

The EPMF also sponsored further scientific investigations undertaken in 2023:

- a new 4-year project was started with Ghent University, ARCHE Consulting and the UK Centre for Ecology and Hydrology (CEH), investigating the impact of bioavailability on silver aquatic toxicity via the development of a chronic Biotic Ligand Model (BLM). The main aim of this project is to identify critical factors in water chemistry that determine the speciation and toxicity of silver in natural waters. The project's expected outcome is a validated chronic BLM for silver, which should allow the EQS to be adjusted to the specific water chemistry. The project includes speciation and toxicity testing (algae and Daphnia) and modelling (algae, Daphnia and fish),
- further research on antimicrobial resistance (AMR) was launched under ETAP (The Environment Toxicity Advisory Panel) to assess whether metals (including silver) can contribute to or lead to the development of AMR and, if so, at what concentrations this occurs,
- further chronic sediment tests allowed the derivation of a reliable sediment PNEC (predicted no-effect concentration).

3. The EPMF's key messages

- The EPMF disagrees with the prioritisation of silver as the available EU monitoring data does not suggest an EU-wide risk. All stakeholders agreed that the prioritisation methodology should instead be applied, which this does not identify an EU-wide risk.
- The selection of silver as a PS is not based purely on risk (as mentioned in the WFD and as agreed during the prioritisation exercise) but also on a concern related to AMR, which needs further investigation.
- The EPMF believes the EQS value proposed by the Commission is overly conservative and without scientific justification.
- Adherence to the extremely low proposed EQS of 10 ng/L requires sensitive and expensive analytical methods. Several countries are expected to encounter practical problems monitoring silver at such low (and analytically challenging) concentrations.

- Developing a validated chronic BLM for silver should allow the expression of the silver EQS as bioavailable silver.

4. Next steps

The dossier has been under discussion in the EU Council since autumn 2023. Under the Spanish Presidency, an initial compromise text was formulated and circulated for review and feedback until January 2024. Following that, the Belgian Presidency assumed responsibility. Neither the Spanish nor the Belgian Presidencies have prioritised the issue. The latter has not communicated any firm dates for reaching a general approach on the dossier. However, dates may be announced at the Environment Council in June 2024.

Further meetings with the Permanent Representatives are expected until the end of June 2024. Additional advocacy efforts toward the Parliament are anticipated ahead of the trilogues and once the EU Council reaches its general approach (and the new Parliament is established). The trilogues are expected to run during the Hungarian Presidency. The final legislative text is expected to be adopted towards the end of 2024.

47
Ag
Silver

Water-born illness is a significant problem in developing nations. **Silver** helps prevent bacterial growth, such as Legionnaires' disease, caused by build-up in pipes, connections and water tanks.

5. The EPMF is in dialogue with:

- Members of the European Parliament
- The Environment Toxicity Advisory Panel (ETAP)
- Member States
- Academia

6. Timeline

III. REACH & CLP REVISIONS

Precious metals are indispensable to modern society and are fundamental in many sectors, including electronics, electrical equipment, automotive, aerospace, medicine, medical devices, jewellery and cosmetics. Therefore, the revisions of both REACH and CLP will substantially impact the precious metals industry.

1. The Issue

As announced in the European Green Deal, the Chemicals Strategy for Sustainability is the first step towards a zero-pollution and toxic-free environment. The Strategy aims to boost innovation for safe and sustainable chemicals and improve the protection of human health and the environment against hazardous chemicals. It also seeks to establish a more straightforward 'One Substance - One Assessment' (OSOA) process for chemical risk and hazard assessment. The REACH and CLP revisions are actions under the scope of the Chemicals Strategy for Sustainability.

2. The EPMF's contribution

In 2023, the EPMF continued to work on the CLP and REACH revisions in close collaboration with Eurometaux and Cefic. The primary focus of the EPMF's activities was engaging with the Commission regarding the revisions of the REACH regulations and holding discussions with key MEPs (including the rapporteur Maria Spyraki) on the CLP revision.

Unfortunately, the REACH revision has been put on hold despite significant positive progress for the metals industry. However, the CLP revision has advanced significantly, yielding favourable outcomes for the metals industry:

- **new powers for the Commission** (alongside Member States and industry) enable it to expedite the process of identifying hazardous substances and proposing the necessary CLH measures,
- the **More than One Constituent Substances** (MOCS) classification will be established using the available information on its known constituents and the substance itself. To determine whether the newly introduced powers apply to all hazard classes or only specific ones, we need to review the exact text of the document. MOCs extracted from plants or plant parts, such as essential oils, are exempted from the regulations. However, the Commission must present a scientific report on their classification as part of the agreement. If deemed necessary, this may be followed by a legislative procedure within five years of the new rules coming into effect,
- the Regulation would also apply to **online sales**, including digital marketplaces, requiring most products to include physical and potentially digital labelling,
- at the Parliament's request, the agreement **bans the use of 'green claims' for substances or mixtures classified as hazardous** - advertisements are prohibited from containing statements such as 'non-toxic', 'non-harmful', 'non-polluting', 'ecological' or any other statement inconsistent with their classification.

The trilogue was under finalisation at the end of 2023.

3. The EPMF key messages

In the context of the REACH revision, it remains for the EPMF to:

- start the chemicals risk management phase with a transparent prioritisation system to facilitate data collection and predictability,
- ensure effectiveness and target only the essential, REACH risk management should remain risk-driven and consider exposure potential in addition to hazard,
- avoid regrettable substitution by considering safer and more sustainable alternatives within a lifecycle approach,
- consider metal specificities: refine the Mixture Assessment Factor (MAF) and confirm the non-application of PBT/PMT for inorganics,
- ensure overall transparency and predictability in the various REACH processes,
- extend the low tonnage requirements proportionately while focusing on 'what matters'.

4. The EPMF is in dialogue with:

- The European Commission: DG ENV and DG GROWTH
- The European Chemicals Agency (ECHA)
- Eurometaux and Cefic

5. Next steps

The Parliament and the EU Council must formally approve the provisional agreement. The text has now been sent to the Parliament, where the measure is being adopted as the Parliament's first reading position. The plenary vote is expected to take place in April 2024.

The EU Council would then adopt the Parliament's first reading position as a legislative measure, after which it is published in the EU Official Journal. The measure would enter into force 20 days after that.

77
Ir
Iridium

Iridium is a vital raw material needed for most clean hydrogen production types. It is exceptionally scarce but irreplaceable in producing PEM (polymer electrolyte membrane) electrolysers. Demand for iridium is set to increase five-fold by 2040. However, it is in very limited supply, which may cause potential bottlenecks when realising large-scale PEM production.

IV. REACH DOSSIER UPDATES

The EPMF membership has registered approximately 100 substances under EU REACH. The dossier requirements and registration deadline for each substance depended on the registration tonnage band (from 1-10 tonnes/year for many PGMs up to >1000 tonnes/year for silver and many refinables). During the dossier preparation process or after registration, the EPMF membership identified the need to generate additional data for specific substances. This was mainly triggered by *in vitro* data that suggested a possible concern and required follow-up *in vivo* testing. However, for some substances, follow-up testing was initiated by *in vivo* testing, which indicated a need for higher tier *in vivo* testing or market changes that required an increase of tonnage band under REACH and thus compliance with additional data requirements.

Silver dossiers

Silver nitrate has been self-classified by the EPMF membership as oxidising solid category 1 for fine powders (D10≤250 µm) and oxidising solid category 2 for coarse powders (D10>250 µm). This split self-classification was based on experimental data from several powders in 2009-2010. However, it was recognised that the underlying experimental dataset was weak. Therefore, additional experimental testing was performed with six powders of varying particle size (D10 ranging from 200 to 280 µm) to extend the experimental database for this endpoint. The data have been generated and confirm that coarse particle sizes require classification as oxidising solid category 2. The EPMF split self-classification for oxidising properties of silver nitrate is justified.

Platinum Group Metals (PGMs)

The *in vitro* genetox test data with tris(nitrato-O)nitrosyl ruthenium and platinum(IV) aqua hydroxo nitrato complexes generated positive responses and triggered further *in vivo* genetox testing. Testing proposals for combined *in vivo* micronucleus and alkaline comet assays were included in their REACH dossiers and approved by ECHA. The testing for both substances has been finalised. Results are conclusively negative and do not confirm the *in vitro* concerns for genotoxicity. Thus, the genotoxicity concerns for these substances have been cleaned.

Other *in vivo* genotoxicity assays are still ongoing. Dirhodium trisulphate has a positive response in the *in vitro* AMES assay. A testing proposal for further *in vivo* genotoxicity testing was included in the dossier and approved by ECHA. The requested *in vitro* micronucleus assay was positive and suggested a predominantly clastogenic mode of action of this substance. The subsequent combined *in vivo* micronucleus and alkaline comet assay is ongoing, and the data will be submitted before mid-2024 (in line with the regulatory deadline). The combined *in vivo* micronucleus and alkaline comet assay data generated in 2020 for tetraammineplatinum dichloride demonstrated an equivocal outcome for the comet assay in kidneys. This finding triggered further *in vivo* testing to conclude the genotoxic potential of this substance. A testing proposal for a Transgenic Rodent Mutation Assay was submitted and accepted by ECHA. This assay is currently running, and data is expected during the course of 2024. The data needs to be submitted by mid-2025.

The dossier of rhodium tris(2-ethylhexanoate) has voluntarily been updated to a regular REACH Annex VII dossier (1-10 tonnes/year). Therefore, an Annex VII-compliant experimental dataset has been generated, including data for biodegradation, environmental toxicity, and mammalian toxicity. These data trigger some additional classifications for skin corrosivity and eye damage and allow the removal of the environmental hazard classification.

Most important is the harmonised classification entry for '2-ethylhexanoic acid and its salts' as a reproductive toxicant category 1B (H360D), which was officially accepted at the EU level in 2022 (Index nr. 607-230-00-6) and triggers an additional self-classification of rhodium tris(2-ethylhexanoate) as Repr1B. This self-classification has been included in the REACH registration file.

'Karstedt Concentrate' (1,3-diethenyl-1,1,3,3-tetramethyldisiloxane and its platinum(0) complexes) has been self-classified by the EPMF in 2017 as a reproductive toxicant category 2 based on the findings in a combined repeated dose toxicity and reproductive toxicity screening study. At the same time, a testing proposal for an extended one-generation reproductive toxicity study (EOGRTS) was included in the REACH dossier. After approval of the testing proposal, the testing was initiated in 2022. During the testing, a need was identified to extend the in-life phase of the second-generation pups to include sexual maturation. This extension prolonged the experimental, analytical, and reporting phases but was necessary to allow a solid interpretation of the findings. The self-classification of the substance has consequently been updated to Repr1B (H360D) following the effects of the substance on pup development. Additional aquatic toxicity data have also been generated to improve the robustness of the environmental dataset. This testing triggered an additional self-classification as Aquatic Chronic 3 (H412). Following the generation of this additional data, the risk assessment of the substance has been updated by revising the uses, use descriptors and threshold concentrations (so-called DNELs and PNECs). The dossier has been re-submitted in February 2024. To anticipate further regulatory follow-up actions related to the Reproductive toxicity 1B self-classification, the EPMF has initiated an Impact Assessment and an industry Risk Management Option Analysis. This project will cover the manufacturers and importers as well as downstream users. The data gathering was initiated in March 2024, and the final report is expected one year later.

45
Rh
Rhodium

Rhodium is found in mammography X-ray machines. Many mammography systems have an alternative rhodium filter to eliminate photons that do not contribute to the image, thereby minimising the patient's exposure to radiation.

For certain Rhodium(III) compounds, a need to update the REACH registration dossiers from Annex VII (1-10 tonnes/y) to Annex VIII (10-100 tonnes/y) has been identified. Main data gaps were identified for repeated dose toxicity and toxicity to reproduction. A testing strategy was developed to make maximum use of alternatives to vertebrate testing (e.g. read-across) and thus avoid animal testing where needed. Testing with rhodium trichloride has been finalised, and analysis and reporting are ongoing. *In vitro* genotoxicity data with rhodium trihydroxide are currently being generated. Both dossiers will be re-submitted in 2024. A dose-range finding study has been performed with rhodium trinitrate, and reporting is ongoing. For this substance, further *in vivo* testing will be required to generate reliable data for repeated dose toxicity and toxicity to reproduction. Also, environmental toxicity data will be generated in 2024 to improve the robustness of the dataset.

Lastly, the data for repeated dose toxicity and toxicity to reproduction for platinum(IV) aqua hydroxo nitrato complexes was not considered robust enough. Data is currently being generated using a combined repeated dose of toxicity and reproductive toxicity screening assay. Additional environmental toxicity data will also be generated in 2024. Later in 2024, the data will be included in the REACH dossier, including a revision of the risk assessment which will be revised.

Precious Metal Cyanides

The positive *in vitro* genetox test data with Potassium dicyanoargentate triggered further *in vivo* genetox testing. Testing proposals for a combined *in vivo* micronucleus and alkaline Comet assay were included in the REACH dossier and approved by ECHA. The testing has been finalised, the results are conclusively negative, and there is no remaining concern about genotoxicity for this substance. The REACH dossier has been updated accordingly.

Precious Metals Refinables

The Refinables are complex iUVCB intermediates (inorganics Unknown and/or Variable composition Complex reaction products or Biological materials) whose variability requires a specific assessment approach. In the past, this constituent-based assessment methodology often complicated the circumstances for years. The need to streamline/ease registration of the iUVCBs dossiers led to the inclusion of this topic in the MISA program (Metals and Inorganics Sectorial Approach, 2018-2021).

After agreeing on dossier requirements, the EPMF worked on updating all of its 18 Refinables and joined forces with the Eurometaux iUVCB platform, ensuring harmonised consistent dossiers updates and regular communication with ECHA for different iUVCB registering consortia (the European Copper Institute (ECI), International Lead Association (ILA), the Nickel Institute (NI), International Zinc Association (IZA) and EPMF).

The combined efforts of the EPMF and the Eurometaux platform resulted in a complete update of the Refinables dossiers, addressing all aspects ranging from substance description improvements (resulting in some dossier splits) to filling data gaps, updating classifications, reviewing the hazard and exposure assessment, and compliant data reporting.

The deliverables for 2023 were the the finalisation of all 18 Refinables IUCLID dossier updates and the successful submission of approximately half of them. This was a significant achievement for the EPMF after many years of discussions with ECHA, illustrating how perseverance and collaboration with the platform (and the other commodities/consortia) facilitates success.

For the remaining Refinables registrations, the split of these dossiers requires new EC identifiers. Administrative request procedures via ECHA's 'Substance Identity Adaptation – EC Change' service are ongoing. The aim is to have all Refinables dossiers in the EPMF's portfolio registered by December 2024.

V. METALS ENVIRONMENTAL EXPOSURE DATA (MEED)

MEED is a multi-metallic programme initiated under the auspices of Eurometaux in 2022. The program runs until 2025. MEED is a comprehensive program that gathers and assesses environmental exposure and toxicity data to facilitate the compliance of the metals industry with the Zero Pollution Action Plan (ZPAP) and biodiversity objectives. It includes six projects focussing on 1) an assessment of the mixture assessment factor (MAF) & identify inorganic Priority Contributing Substances (I-PCS) to mixture toxicity, 2) regional exposure assessment, 3) sewage treatment plant exposure assessment, 4) mixture effects of metals, 5) mixture effects of metals with organics, and 6) ecological relevance. The timelines of the six projects are aligned to feed deliverables into the various regulatory debates (e.g. REACH Revisions and ZPAP) and to allow timely updating of the REACH registration dossiers.

The MEED program progressed well in 2023:

- The first project to run under the MEED Assessment was the mixture assessment factor (MAF) and the identification of Inorganic Priority Contributing Substances (I-PCS) to mixture toxicity. It aimed to identify I-PCS based on their estimated risk in the environment. Risk was assessed by comparing the occurrence of these metals in the environment (based on aquatic and soil databases) with their respective toxic threshold concentrations. Silver was identified as a possible I-PCS in freshwater. This does, however, not imply any direct consequences for silver as the I-PCS identification was instead an indicative and explorative exercise and served as a starting basis for the following MEED projects. The report has been finalised.
- Regional exposure assessment: available datasets and databases were accessed and assessed for the aquatic, soil and sediment compartments. Whereas the aquatic and soil compartments are well covered, there is a general absence of metal data in sediments (cfr. identified bias related to the presence of highly contaminated sediments in some databases). There is consequently a need for an additional monitoring campaign to reliably cover metals with little to no information (including gold and the PGMs). This will be done via a separate project. Reports for the assessment of three environmental compartments are finalised.

- Sewage treatment plant exposure assessment: available datasets and databases were accessed and assessed. Although some countries have excellent datasets, many countries have no datasets or those that are unsuitable. For silver and PGMs, data is limited, and an additional limited monitoring exercise was proposed to generate reliable data for these metals. The report of the prospective analysis is available, and the additional monitoring project is scheduled for 2024-2025.
- Mixture effects of metals: an extensive literature review has been finalised to explore whether metals mixtures can be considered separately and independently of each other in mixture assessment approaches. The report of this review was finalised and assisted in the design of a smart testing program covering quinary, quaternary, tertiary and binary metal combinations. The algae testing program was initiated in 2023. The testing with Daphnia will be performed in 2024.
- Mixture effects of metals with organics: an extensive literature review has been finalised to explore if metals-organic mixtures can be considered separately and independently from each other (or not) in mixture assessment approaches. The report of this review is finalised, and assistance has been provided in the design of a smart testing program. This testing program will be performed in 2024, covering relevant metal-organic mixtures and assessing effects on algae and Daphnia.
- Ecological relevance: a literature review was performed, and 3 levels of techniques were identified as part of a toolbox to assess the local or regional impact of metal releases on biodiversity and ecosystem functioning. A report of this assessment is available. The next step is a proof-of-principle on a field pilot study in a freshwater river in Belgium exposed to an industrially relevant metal mixture. This work is currently ongoing.

The (tentative) findings have been communicated to the scientific and regulatory community via scientific conferences (e.g. The Society of Environmental Toxicology and Chemistry - SETAC) or dedicated meetings to get buy-in on the data and concepts being generated or proposed for metals. In parallel, other countries are working on comparable projects (e.g. Japan and Canada), and the MEED team is keeping close contact with these countries in order to cross-feed and achieve the best outcome for metals. Ultimately, the output of the MEED project aims to ensure the continued safe manufacturing and use of metals.

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Pt
Platinum

Recycled **platinum** provides a sustainable and economically viable secondary source of one of the world's most limited natural resources. This ensures the impact on the environment is kept as low as possible.

VI. ENDOCRINE DISRUPTION (ED) GUIDANCE

1. The Issue

Endocrine Disruption (ED) has been included as an additional hazard endpoint in CLP since April 2023 after many years of scientific and regulatory discussions. This endpoint covers human health and the environment in two separate classification entries and consists of two categories: Category 1 for known or presumed endocrine disruptors and Category 2 for suspected endocrine disruptors. For existing chemicals, classification and labelling for ED is mandatory from November 2026 onwards.

Correctly identifying and assessing the relevant and reliable scientific data is critical to assess a substance's ED hazard. However, no guidance is available under CLP for ED. This guidance is under development, and the first discussions between regulators, industry, and other stakeholders were held in 2023.

2. The EPMF's contribution

As part of the ED guidance development, a Partner Expert Group (PEG) was established in 2023 and includes regulators, industry, and other stakeholders. The EPMF is part of the metals industry delegation that actively contributes to the guidance development. The primary aim is to ensure that the guidance applies to metals and adequately recognises their key features, like essentiality, natural occurrence and metal speciation and complexation.

The EPMF also contributed to the manuscript of Brix et al. (2023), which illustrated via metal case studies that effects on ED parameters should not always be classified as true ED effects but rather appear via indirect or compensatory mechanisms ('endocrine modulating effects').

3. The EPMF's key messages

- Metals can be present in various oxidation states and (in)organic complexes. The human health and/or environmental effects of different complexes of the same metal can differ extensively. Metal speciation and complexation need to be correctly recognised in ED assessment.
- Metal complexes might change depending on the physico-chemical conditions, e.g. the test medium, which might affect the ED properties. Therefore, the experimental conditions in (mainly) *in vitro* ED assays must be compatible with the tested complex to avoid re-complexation and consequent irrelevant ED conclusions. Validation of these assays for metals is required.
- Currently there is no specification of the information and assays that need to be considered for ED assessment under EU REACH and CLP. This adds to the confusion around data assessment of the conclusion on the ED hazard potential and should thus be clarified. Some experimental assays are already considered relevant for ED assessment (like *in vivo* test data for repeated dose toxicity or toxicity to reproduction). However, it needs to be ensured that only relevant effects in these assays are considered for ED assessment. For example, effects observed at high doses should not be regarded as appropriate if they are a non-specific consequence of other toxicities.
- A separate Annex should be developed for the ED assessment of metals, comparable to the aquatic toxicity assessment of metals (CLP Annex IV). This Annex would include metal-specific frameworks (like the one developed by Brix et al. 2023) for ED assessment. The metals industry will continue developing the necessary data & assessment schemes for this Annex.

4. Next steps

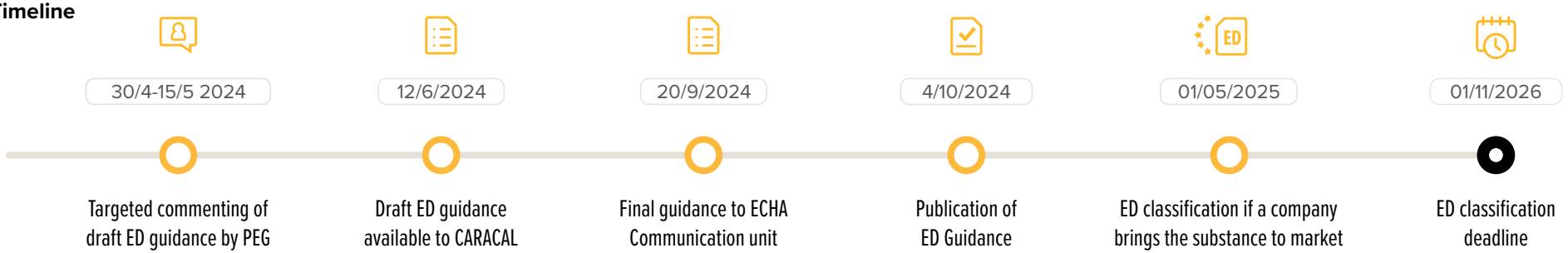
The PEG has provided oral and written feedback to the guidance developers. ECHA is currently reviewing the guidance. A new 'targeted' commenting stage is foreseen in the first half of May 2024. The metals industry stakeholders will respond (where needed) during this consultation process. After that, the drafting process will be finalised, and a draft version of the guidance will be prepared and proposed to the CARACAL for comment. Publication of the final ED guidance is foreseen on October 4th 2024. The metals industry will, in the interim, continue with the ED assessment of metals to ensure metal specificities are adequately recognised.

The EPMF is preparing internally for the ED assessment of its substances. As a first step, the existing experimental data is being reviewed to identify and assess all ED-relevant endpoints. The findings of this preliminary assessment will be the basis for the next steps of the assessment.

5. The EPMF is in dialogue with:

- ECHA
- The European Commission
- The Environment Toxicity Advisory Panel (ETAP)
- Academia

6. Timeline



PRIORITIES AND ACTIVITIES

SUSTAINABILITY

Which sustainability files kept us busy in 2023? The EPMF agenda continued with the Critical Raw Materials Act, Ecodesign for Sustainable Products Regulation and waste policies. We also added the environmental footprint, which is gaining momentum and requires our full attention.

I. THE CRITICAL RAW MATERIALS ACT

1. The Issue

Presented on March 16th 2023, the European Critical Raw Materials Act (CRMA) aims to secure a sustainable supply of critical raw materials in the EU. Notably, the CRMA is set to identify strategic projects along the value chain and to increase strategic reserves where supply is at risk. It will also address problems such as low diversification of EU supply sources and existing regulatory frameworks that must be revised to support circularity. Together with the proposed design reform of the electricity market and the Net-Zero Industry Act, the proposal aims to strengthen the competitiveness of European industries, as announced in the Green Deal Industrial Plan.

2. The EPMF's contribution

One of the EPMF's first steps was submitting the precious metals feedback to the impact assessment and public consultation. The EPMF also invited a Member of the European Parliament (MEP), Hildegard Bentele, to contribute to our external newsletter. MEP Bentele, also a Parliamentary Rapporteur of the CRMA, reiterated the strategic importance of the precious metals to EU projects and encouraged the avoidance of unintended regulatory hurdles. The EPMF couldn't agree more, we strongly advocate for coherence within chemicals legislation, including REACH revision. The CRMA must confirm the need for coherent and effective chemicals legislation. Without regulatory coherence, critical investments in raw materials in the EU are highly likely to be delayed due to lengthy processes followed by an uncertain or disproportionate outcome.

The EPMF also regularly contacted DG GROWTH regarding publishing the updated Critical Raw Materials and Strategic Raw Materials lists. Currently, PGMs are present on both lists.

3. The EPMF's key messages

The EPMF welcomed the Commission's initiative and provided the folokey recommendations on:

- the tangible actions and speed for the implementation of the CRMA. The EU precious metals sector is asking for more certainty and predictability regarding business projects. The provisions set up in the CRMA should be easily achievable and not scattered in lengthy and burdensome application processes,
- the reference to consistency with other EU policies. The EPMF suggests paying particular attention to this issue, particularly to the coherence with the REACH revision,
- to replacement of CRMA benchmarks for PGMs with effective measures. The occurrence of platinum group metals (PGMs) is limited; hence, setting targets and monitoring activities will not change the geological deposits of PGMs. On the contrary, recycling will play a pivotal role in the supply and availability of PGMs,
- and the effective implementation of the EU waste policy framework to boost the collection and sorting of products containing precious metals and to guarantee high-quality recycling.

These EPMF messages are elaborated in our position paper here.

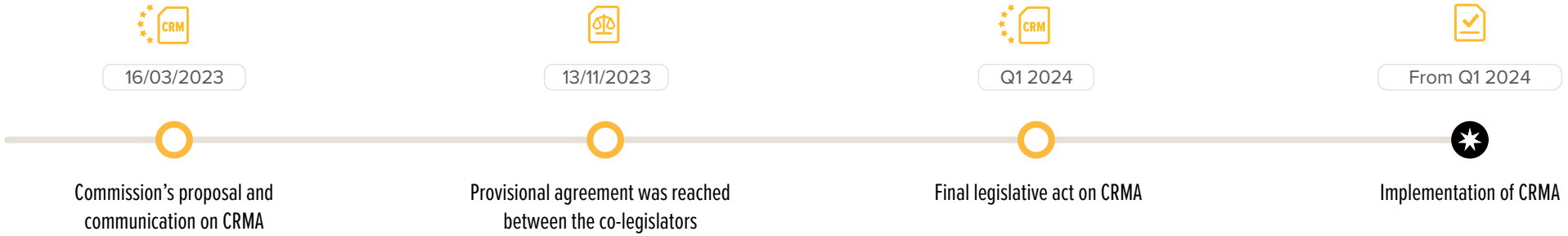
4. Next steps

Once CRMA is formally adopted, it will reach the implementation stage. For the EPMF, this will be an opportunity to see (i) how CRMA will align with chemicals management and (ii) developments and updates of the Critical Raw Materials and Strategic Raw Materials lists. Ultimately, questions remain about its coherence with REACH legislation and the benefits of being on any of those lists.

5. The EPMF is in dialogue with:

- The European Commission: DG GROWTH
- Members of the European Parliament
- Eurometaux and other non-ferrous metals associations

5. Timeline



II. ENVIRONMENTAL FOOTPRINT: THE EPMF PRIORITIES

1. The Issue

In 2023, the EPMF Assembly made the decision to expand the mandate of the EPMF Sustainability platform to include environmental footprint. We aimed to identify how the EPMF could support Members on this issue and where input was most needed. Hence, currently, our work is based on five pillars: (1) regulatory mapping, (2) methodology and related concepts, which includes the development of the EPMF guidance and communication towards the key regulators and other stakeholders, (3) definition of recycled gold, (4) potential work on the definition of recycled silver and PGMs, (5) Circular Footprint Formula (CFF). All pillars require active contributions from the EPMF Members.

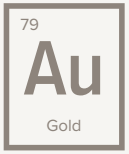
2. The EPMF's contribution

Throughout 2023, the EPMF focus remained on (i) regulatory mapping, including industry and NGO initiatives on environmental footprint methodology and calculation, (ii) clarifying concepts (e.g. recycled gold definition) as well as on (iii) methodologies and values for key parameters in the CFF (Circular Footprint Formula). The first is an internal living document with regular updates available for the EPMF Members. The second, work on the definition of recycled gold, is progressing moderately well, and the EPMF has already shared key recommendations on the definition of recycled gold with the Responsible Jewellery Council and Eurometaux.

3. The EPMF's key messages on 'recycled gold definition'

In a nutshell, we are calling for:

- the decision process on the definition for 'recycled gold' should be considered **universal** and applicable to all (precious) metals,
- before establishing the definition, all the consequences must be assessed and weighed. In particular, the definition should be **aligned** with existing examples within the regulatory context,
- the definition of recycled gold (and other precious metals) **should not be seen and used** as a solution or prevention for greenwashing issues. Neither should it serve as a problem-solving principle in due diligence and responsible sourcing questions,
- the consideration **of End-of-Life (EoL) and End-of-Use (EoU) concepts** as defined within the UNEP circularity framework for the (precious) metal industry. Both concepts provide a logical and robust approach when defining 'recycled material',



Gold is non-reactive when used in instruments and is highly reliable in electronic equipment and life-support devices. Therefor, many surgical instruments, electronic equipment, and life-support devices contain small amounts of **gold**.

- the **concept of pre- and post-consumer** to be considered. This concept is of paramount importance as it allows differentiation (e.g. for jewellery) between (i) material available for recycling after being used by consumers and (ii) material originating from industrial production processes which can be reintroduced into the system (e.g. scrap materials, filter dust). This material has never reached the consumer stage and also pre-consumer includes materials from industrial production through to mining (e.g. carbon spent),
- **abstain from the use of thresholds**. The threshold approach is questionable and is mainly based on other regulations/legislations, such as customs rules with different backgrounds and consequences. Setting a threshold would inherently limit the applicability domain and risks rejection of materials such as end-of-life jewellery. Hence, using a threshold is severely limiting and overly strict in the qualification of what can be considered recycled (precious) metal.

4. Next steps

The EPMF aims to present further guidance on the definition of recycled gold to other stakeholders, including the ISO TC 174 Working Group.

The EPMF will continue working on the other aspects of the environmental footprint identified in 2023.

5. EPMF is in dialogue with:

- Eurometaux and other non-ferrous metals associations
- Responsible Jewellery Council (RJC)
- Precious Metals Impact Forum (PMIF)
- LBMA
- Downstream users
- ISO TC 174 WG members

III. ECODESIGN FOR SUSTAINABLE PRODUCT REGULATION

1. The Issue

The European Commission proposed the Ecodesign for Sustainable Products Regulation (ESPR) on March 30th, 2022. It addresses the design of every product placed on the EU market in order to ensure products are more durable, reliable, reusable, reparable, maintainable, recyclable, and energy and resource-efficient. It also aims to ensure better tracking of Substances of Concern (SoC) along the supply chain.

In parallel with ensuring that the ESPR is appropriately implemented, the Commission has begun preparatory work to identify the first priority products and horizontal measures under the ESPR.

The preliminary study by JRC analysed several products and horizontal measures (their environmental, sustainability and circularity impacts, what potential for improving the product aspects there might be and the extent to which regulatory gaps exist). Based on this, several new products and horizontal measures were identified as suitable for first action under the ESPR. The Non-Ferrous Metals (incl. precious metals) were identified as intermediary products, meaning that they are potentially suitable for first action under ESPR.

2. The EPMF's contribution

The EPMF sees an issue in the definition of SoC, which was introduced under the ESPR proposal. The proposal's definition of SoC has a blanket approach, meaning all substances are included. Inevitably, the EPMF disagrees with this generalistion. We advocate for a consistent approach, especially with the upcoming REACH revision and its objective of protecting consumers. The SoC definition should cover relevant substances and not create a blanket definition covering every substance used in products put on the EU single market. The EPMF co-signed a joint industry letter supported by 24 other organisations, including Cefic, Eurometaux and the Cobalt Institute. This letter aimed to address the Parliament's ENVI Committee members engaged in compromise discussions to determine their stance on the matter.

The EPMF, Eurometaux, and other non-ferrous metals associations met with the JRC team working on this issue of intermediate products. We aimed to understand JRC's position and work on the priority products list, data sources, and Digital Product Passport. The EPMF asked for more clarification on defining intermediate products and coherence with REACH.

3. The EPMF's key messages

The EPMF strongly advocates that the ESPR should only apply to product groups which do not have sustainability requirements covered by other specific regulations. To achieve this, we need:

- a definition of SoC that is fit for the purpose of sustainable products,
- clarity that substance restrictions driven by safety concerns will remain under REACH, while restrictions on SoCs under the ESPR should only address the recyclability and reusability of products.

4. Next steps

The Commission is expected to publish a Communication in Q1 of 2024, including a list of new products and horizontal measures to prioritise under the proposal for ESPR. Once both become available, the EPMF will analyse the impact on precious metals and decide what measures to take.

5. The EPMF is in dialogue with:

- Eurometaux and other non-ferrous metals associations
- JRC
- Cefic

6. Timeline

IV. WASTE SHIPMENTS

1. The Issue

Since the Commission's proposal on the Waste Shipment Regulation (WSR) on November 17th 2021, the EPMF actively provided the precious metals industry's views on this proposal. As a reminder, the proposal sets out new rules on waste shipment to ensure more harmonised regulations across the Union, a shift to digital solutions, further recoverability of waste and restricting the export of all waste to non-OECD countries while effectively tackling illegal waste shipments. It also amends provisions concerning waste shipments to non-OECD countries to limit and ensure better monitoring of EU waste exported to OECD countries. Within the EU, the WSR fosters digital solutions for issuing and exchanging information and documentation necessary for waste shipment, and strengthens the fast-track procedure for waste shipments to recovery facilities.

2. The EPMF's contribution

Throughout 2023, the WSR was in the trilogue phase, informal interinstitutional negotiations between the representatives of the Parliament, the EU Council, and the Commission. The EPMF and Eurometaux maintained contact with the key policymakers, providing input on the issues most relevant to the non-ferrous and precious metals industry, especially on pre-consented facilities and environmentally sound management.

3. The EPMF's key messages

The remaining issues for the EPMF are primarily related to the pre-consented facilities. We ask:

- that the status of the pre-consented facilities should be accepted across the Member States,
- for the provision of automatic recognition of pre-consented status issued by a Competent Authority in one Member State by all EU Member States.

4. Next steps

The final legislative act is expected in Q2 2024, and then the Waste Shipment Regulation will be implemented across the EU Member States. The EPMF's main task is to evaluate and deliver to the key policymakers the gaps and difficulties this Regulation faces.

It is estimated that four million people worldwide have Parkinson's disease. Neural implants made from **platinum** and **iridium** generate electrical impulses to help stimulate a targeted area of the brain and reduce shaking and rigidity almost immediately.

5. The EPMF is in dialogue with:

- The European Commission: DG Env
- Members of the European Parliament
- Eurometaux and other non-ferrous metals associations

6. Timeline

COMMUNICATION

I. THE EPMF KNOWLEDGE EXCHANGE: MEMBERS MEETING ON HYDROGEN AND PREPARATION FOR THE 2024 ELECTIONS

Twice a year, the EPMF arranges General Assembly meetings for its members. The EPMF invited external guests to speak on hydrogen and EU election preparations to maximise the benefit and trigger additional thought. Philipp Walter from Heraeus covered the hydrogen topic. He explained why PGMs are indispensable elements for new energy and feedstock regimes. An active Q&A session with the EPMF Members followed his lively presentation. As it was time to consider the EU elections in December, we invited a public affairs specialist - Aaron McLoughlin, from FleishmanHillard. Following his presentation and analysis of what the next EU Parliament could resemble, there was much food for thought, particularly concerning the future of chemical regulations and green policies.

II. 'METALS DAY' IN STRASBOURG

In late spring, the EPMF joined the Eurometaux's 'Metals Day' at the European Parliament in Strasbourg. Non-ferrous metals associations and industry representatives came together for panel debates and a high-level dinner with the Members of the European Parliament (MEPs). The EPMF co-sponsored a panel on 'Sustainable raw materials: from the mine to circularity' with the fellow mining association Euromines. Wouter Ghyoot (Umicore, President of the EPMF) represented the precious metals industry. It was an excellent opportunity to share our views with the MEPs. At the same time we gained insight on their position regarding the Critical Raw Materials Act (CRMA), environmental and circularity aspects and position towards the EU metals industry in general. The main takeaways for the MEPs from our President were:

- coherence with other EU policies, especially chemicals legislation,
- the need to boost the recycling of metals and understanding that metals are closely connected in recycling and sourcing,
- efficient and quick implementation of the CRMA, it is time for a clear direction and strong leadership.

What about the MEPs' messages to us? – they need transparency, cooperation, and our industry to share firsthand experience with them. Our knowledge and contribution to a more circular economy and green transitions are what matter. The precious metals sector's willingness to contribute will always be seen as a significant positive.

Our visit to Strasbourg was about more than just debates. The EPMF Secretary-General France Capon attended a high-level dinner including approximately 30 MEPs from varied political groups and countries. France was seated at the Nordic table. Some guests were familiar with precious metals issues, and some less so. Hence, delivering our industry messages in a friendly and relaxed atmosphere was a welcome opportunity.

The EPMF closed the Strasbourg trip by meeting with MEP Spyraki's senior policy advisor, Christos Vasilakos on the CLP revision. At the meeting, we emphasised our priorities (e.g. efficient grouping based on science and improved expertise and resources for ECHA) and we gained a better understanding of their position. We agreed to further exchange information on matters relating to CLP and chemicals policy in general.

III. THE EPMF AT THE REACH CONFERENCE IN BRATISLAVA

In May, the EPMF, Eurometaux and Cefic co-organised a Chemicals Management workshop in Bratislava with a local partner, Ekotox.sk. The workshop aimed to share information on the REACH revision and discuss the details with authorities and industry from the Visegrád countries (Czech Republic, Hungary, Poland, and Slovakia). The European Commission presented the current status of the REACH revision and their perspectives on the matter. The EPMF and Eurometaux provided input on the MAF (Mixture Assessment Factor), the 4C concept (chemicals, climate, circularity and criticality) and critical aspects that are expected for the Risk Management update, e.g. the Generic Risk Assessment (GRA) and the essential use concept (EUC). All the presentations lead to fruitful panel discussions.

IV. EPMF AND EUROMETAUX EVENT 'REACH AND RAW MATERIALS: ACHIEVING EUROPE'S GREEN DEAL GOALS TOGETHER'

'Coherence, efficiency and predictability' were the concluding words of Wouter Ghyoot (Umicore, President of EPMF), at the 'REACH and Raw Materials: Achieving Europe's Green Deal goals together' debate organised in conjunction with Eurometaux. It was a timely and topical debate bringing together policymakers, NGOs and industry. Our panellists, Aurel Ciobanu-Dordea (DG Environment), Hélène Duguy (ClientEarth) and Adly Manseri (Belgian Permanent Representation), delved into the potential of REACH regulation to enhance certainty and environmental protection within Europe's raw materials investment agenda. They also explored solutions and optimal paths forward, whilst focussing on ensuring coherence between the EU's chemicals and raw materials policy actions. If you missed the discussion, you can watch the recording here.

V. THE EPMF AS VICE-CHAIR OF THE CHEMICALS COMMITTEE AT BIAC, OECD

The EPMF Secretary General France Capon was nominated as Vice-Chair of the Chemicals Committee of Business at OECD (BIAC). The BIAC Chemicals Committee helps the private sector with access to a wide range of OECD activities on chemicals management and safety. This Committee also contributes to developing policies and instruments for chemical testing and assessment, fosters the exchange of information, and provides an institutional framework for private sector engagement. France Capon regularly participates in bi–annual and thematic ad-hoc sessions, where she contributes her expertise to specific OECD workstreams in an ongoing capacity.

78
Pt
Platinum

Hydrogen fuel cells are expected to prove essential in reducing global carbon emissions. **Platinum** and platinum alloys are the most efficient catalysts for expediting chemical reactions in hydrogen fuel cells.

VI. SCIENCE AND THE EPMF

Science is at the core of the EPMF's work. In 2023, the EPMF published the following scientific articles:

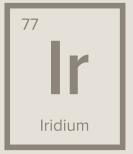
- Katrien Arijs and Jelle Mertens: 'European freshwater silver monitoring data do not suggest a potential European-wide risk'.
- Katrien Arijs and Jelle Mertens: 'Comparative in vivo toxicokinetics of silver powder, nanosilver and soluble silver compounds after oral administration to rats'.
- Jelle Mertens: 'Evaluation of effects-based methods as monitoring tools for assessing ecological impacts of metals in aquatic ecosystems'.
- Jelle Mertens contributed to 'Challenges and Recommendations in Assessing Potential Endocrine-Disrupting Properties of Metals in Aquatic Organisms'.

Answers:
1: (a) 2: (b) 3: (b) 4: (c) 5: (c) 6: (a)

TIME FOR A QUIZ!

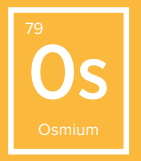
1 **The element iridium is named after the Latin word ‘iris’; what does ‘iris’ mean?**

a. rainbow
b. flower
c. waterfall



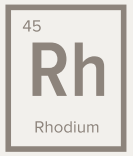
2 **What iridium and osmium alloys are used in our daily lives?**

a. for glass making
b. for pen tips and compass bearings
c. for circuit boards



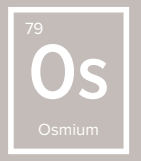
3 **What is the significant use of rhodium, accounting for more than 80%?**

a. mobile phones
b. catalytic converters for automobiles
c. jewellery



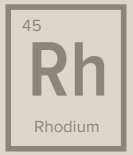
4 **What other metal was discovered together with iridium by Smithson Tennant?**

a. rhodium
b. platinum
c. osmium



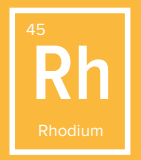
5 **What is rhodium used for in nuclear reactors?**

a. for safety
b. to produce more power
c. to measure neutron flux levels



6 **Rhodium is an excellent plating material. Why is it used in silver jewellery making?**

a. to prevent tarnishing during wear
b. to raise the costs
c. to make it harder



THE EPMF TEAM

Are you familiar with all the persons assisting the EPMF Members and working on Chemicals Management, Sustainability and Communication?

©Alice Piemme

The EPMF Staff

Secretary-General: Ms France Capon

Senior Scientific Manager: Dr Jelle Mertens

EU Policy Manager: Ms Zinaida Nazarenko

Office Manager and Advocacy Support: Ms Audrey Rondepierre

Back-Office Assistant: Ms Cathy Martin

The EPMF Consultants / Project Facilitators:

Ms Katrien Arijs

Mr Maxime Eliat

Ms Aurine Verkest

PRECIOUS METALS ARE...

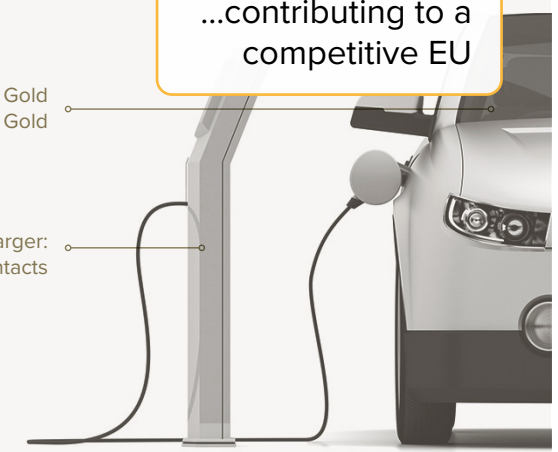
...indispensable for new, innovative technologies.

Platinum-containing molecules in 3 different cancer drugs

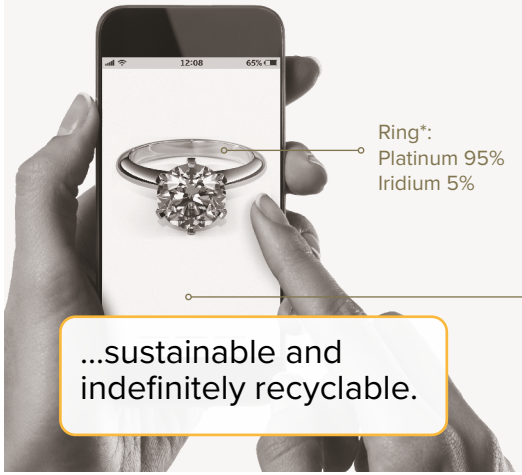
...contributing to a competitive EU

Circuit boards: Silver & Gold
Airbag sensor: Gold

Fast charger: Silver contacts



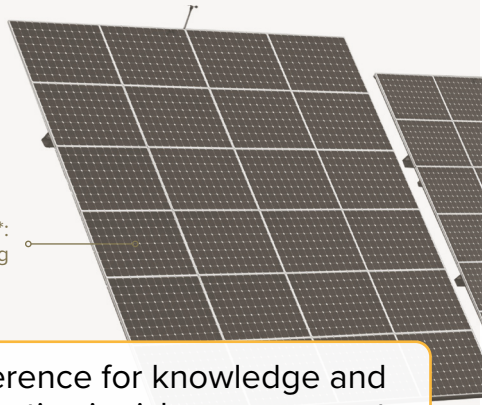
Circular · Recyclable · Scarce
Innovative · Materially Efficient
Industrial · Valuable · Emotional
Intrinsically Exceptional



Ring*:
Platinum 95%
Iridium 5%

Smartphone*:
Gold - 0.034g
Silver - 0.34g
Palladium - 0.015g
Platinum - 0.00034g

...sustainable and indefinitely recyclable.

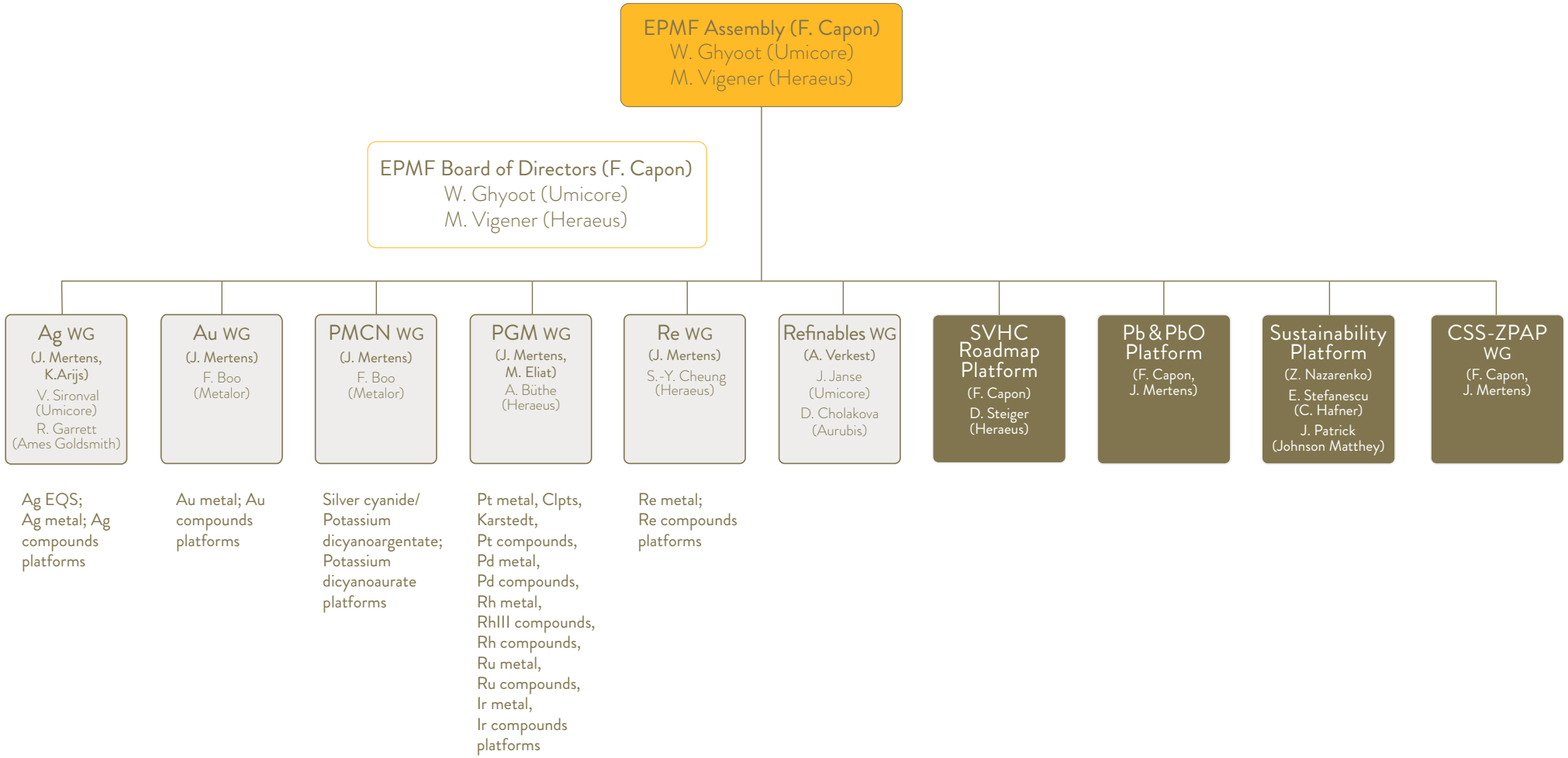


PV panel 1.8m2*:
Silver - 20mg

...a reference for knowledge and expertise in risk management

* All figures/constituents are estimates and will differ according to type and manufacturer

STRUCTURE


EPMF Assembly (F. Capon)
W. Ghyoot (Umicore)
M. Vigener (Heraeus)
EPMF Board of Directors (F. Capon)
W. Ghyoot (Umicore)
M. Vigener (Heraeus)
Ag WG
(J. Mertens, K.Arijs)
V. Sironval (Umicore)
R. Garrett (Ames Goldsmith)
Au WG
(J. Mertens)
F. Boo (Metalor)
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J. Patrick (Johnson Matthey)
CSS-ZPAP WG
(F. Capon, J. Mertens)
Ag EQS; Ag metal; Ag compounds platforms
Au metal; Au compounds platforms
Silver cyanide/ Potassium dicyanoargentate; Potassium dicyanoaurate platforms
Pt metal, Clpts, Karstedt, Pt compounds, Pd metal, Pd compounds, Rh metal, RhIII compounds, Rh compounds, Ru metal, Ru compounds, Ir metal, Ir compounds platforms
Re metal; Re compounds platforms

STRUCTURE

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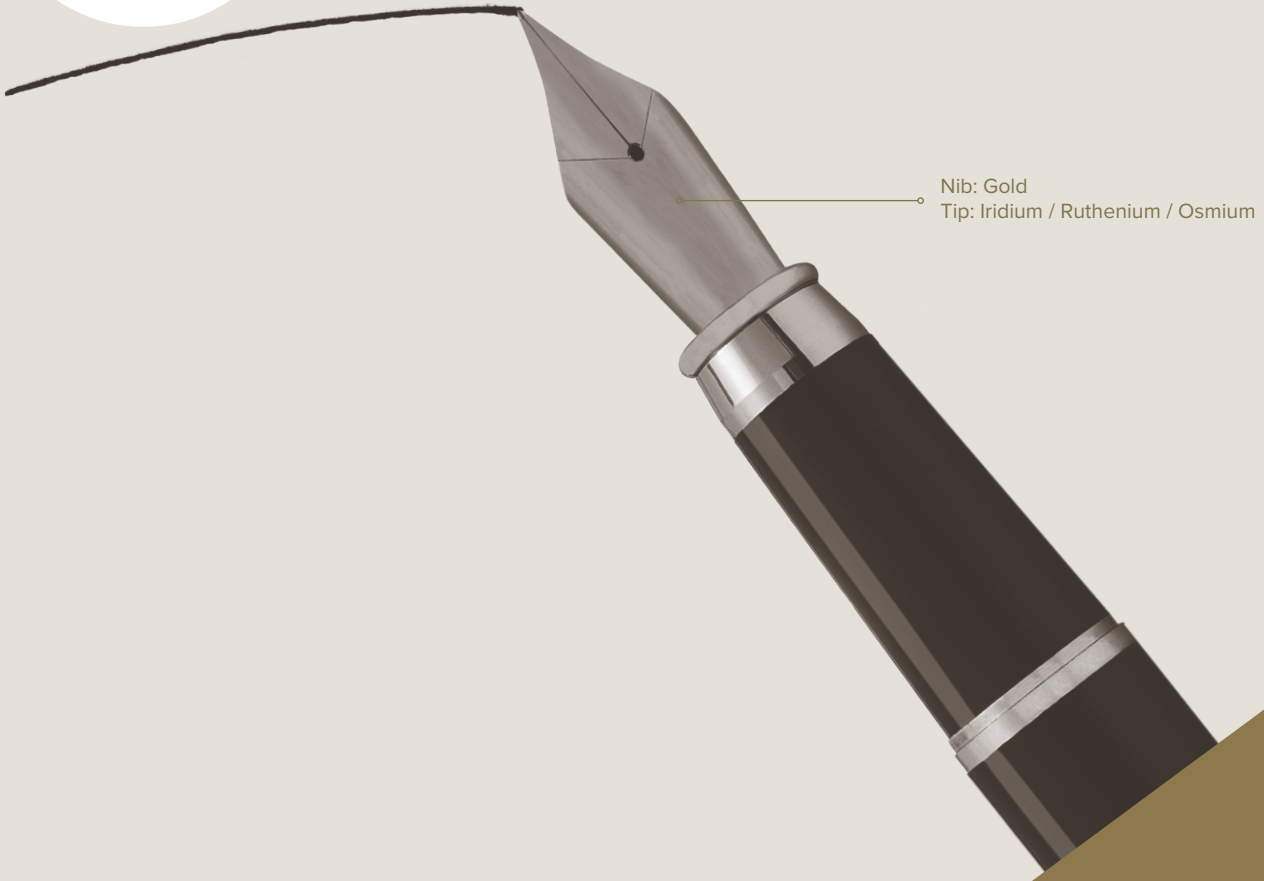
National Associations

PRECIOUS METALS, ALL AROUND YOU



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