



European Precious Metals
Federation

Ag substances under REACH, CLH and BPR

European Precious Metals Federation

13 March 2019 | Meeting with European Commission

Participants

EPMF / Eurométaux (EM):

- Katrien ARIJS (EPMF)
- France CAPON (EPMF)
- Violaine VEROUGSTRAETE (EM)

European Commission:

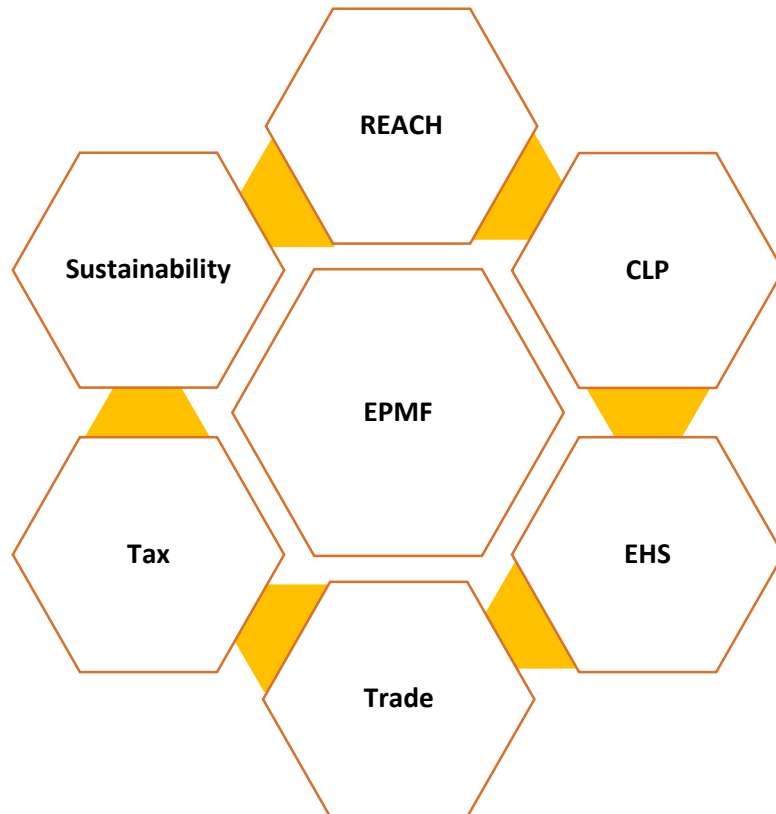
- Peter BARICIC (DG GROW)
- Sylvain BINTEIN (DG ENV)
- Ludovic CHATELIN (DG SANTE)
- Anrej KOBE (DG ENV)
- Katrin SCHUTTE (DG ENV)

Agenda

1. Introduction EPMF
2. Background and scope silver under REACH / BPR
3. EOGRTS TP
 - Background
 - Process and timing
4. CLH
 - CLH silver substances and reprotox
 - CLH silver nitrate process and timing
5. Summary EPMF position



About the European Precious Metals Federation



Website: www.epmf.be

Companies



National Federations



Precious Metals Industry



PRECIOUS METALS - ALL AROUND YOU.



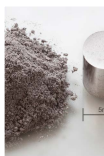
Precious Metals Industry



Mining



Refining,
recycling



Manufacturing,
Importing



Banking, Trading



Electronics



Glass/Mirrors



Jewellery



Automotive



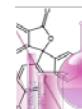
Alternative energy

Gold

Silver

Rhenium

Platinum



Catalysts/Chemical
production



Healthcare

Ruthenium

Palladium

Rhodium

Iridium



Investment



Aerospace



Photography



Background and scope silver under REACH / BPR

	Ag REACH	Ag BPR
Scope	EPMF Ag project includes 8 substances/Dossiers: 1. Silver (incl. nano) 2. Disilver oxide 3. Silver nitrate 4. Disilver sulphate 5. Disilver carbonate 6. Silver chloride 7. Silver bromide 8. Silver iodide	ESTF single core active substance dossier supporting 10 substances ('SCAS'): 1. Silver 2. Silver (reaction mass with SiO ₂) (nano) 3. Silver chloride 4. Silver chloride (reaction mass with TiO ₂) 5. Silver nitrate * 6. Silver sodium hydrogen zirconium phosphate * 7. Silver phosphate glass 8. Silver zeolite * 9. Silver zinc zeolite * 10. Silver copper zeolite *
Under review by	ECHA (Dossier Evaluation)	KemI, Swedish CA
CLH	Not a requirement	Requirement (* = CLH proposal submitted; * = CLH opinion adopted)

Regulatory decisions have shared relevance under both regulations

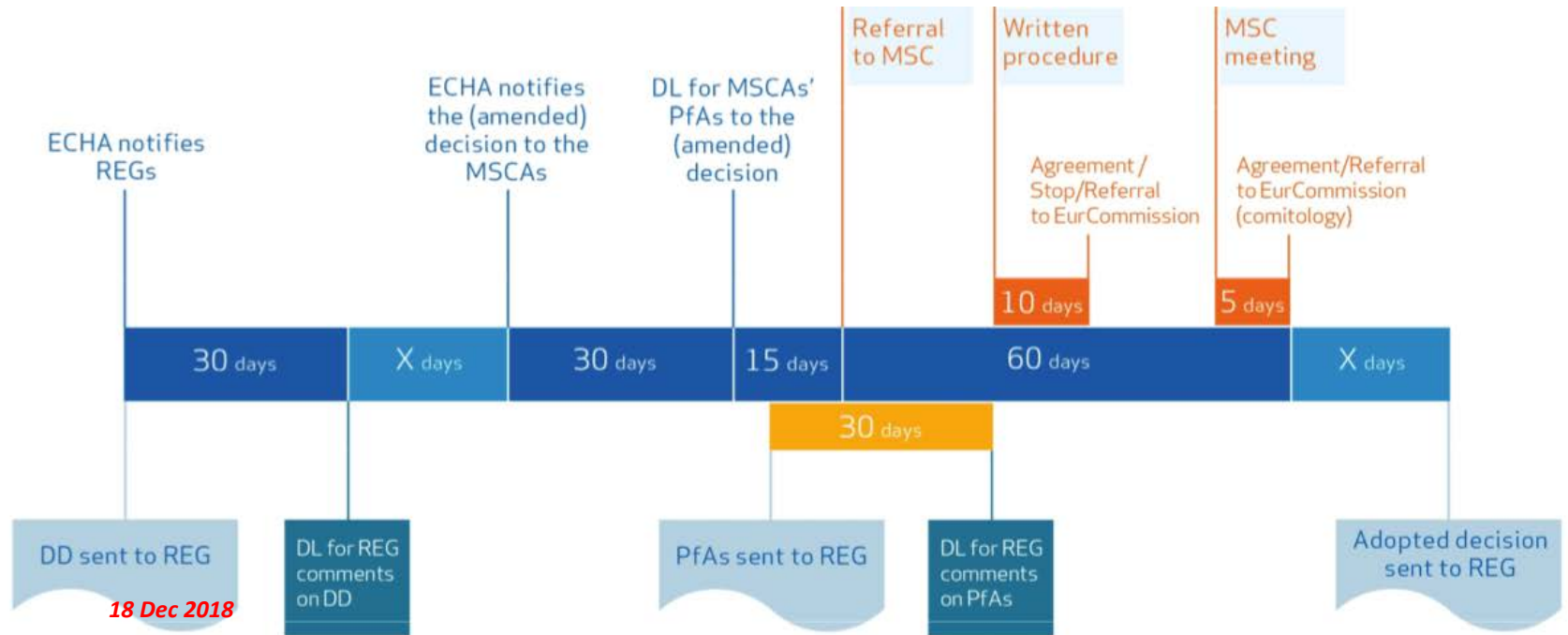


EOGRTS TP: Background

- **Data gap** on reprotox → EPMF submitted original **TP** for Extended One-Generation Reproductive Toxicity Study (**EOGRTS**; OECD TG 443) in 2015
 - proposed test substance: silver acetate
 - outcome of study anticipated to be applicable to ionic silver irrespective of donor silver substance forming this ion
- 2016-2017: further research published on reproductive toxicity potential of ionic silver
 - several weaknesses in research identified (compared to OECD TG 443 design) → data gap still remains
 - **update of TP** / test design necessary (e.g. inclusion DIT cohort)
- **TP updated** in April 2018 to reflect most recent scientific developments



EOGRTS TP: process and timing

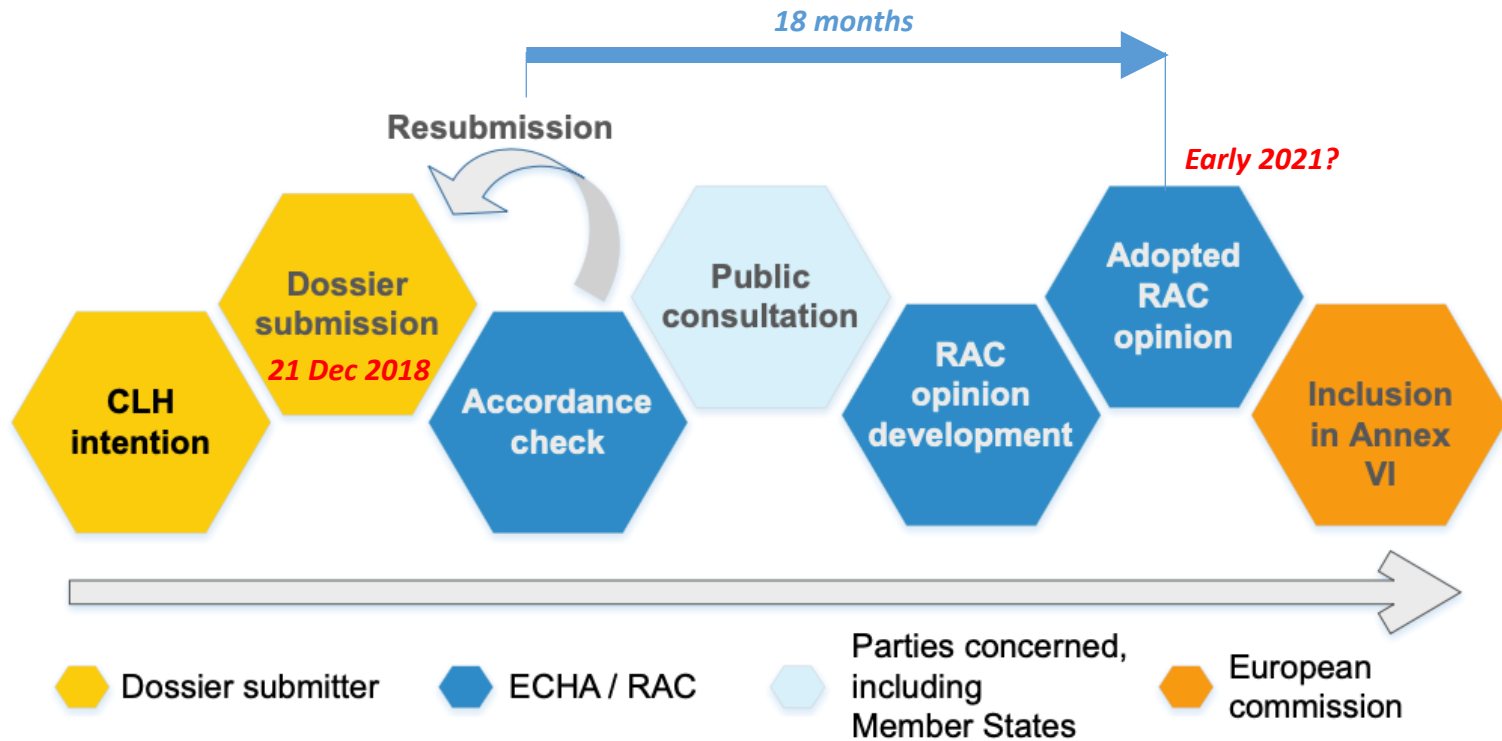


- Draft Decision Dec 2018: TP accepted so far by ECHA (with test design and test substance as proposed by EPMF)
- Final decision expected between Jun 2019 and Feb 2020
- EOGRTS test results not available before **mid-2021 at the earliest**

CLH: CLH silver substances under the BPR and reprotox

- **2015:** CLH silver zinc zeolite (SZZ)
 - Repr cat. 1B proposed by Kemi
 - Repr cat. 2 agreed by RAC
- **2017:** CLH proposals submitted by Kemi for:
 - Silver zeolite (SZ) and silver copper zeolite (SCZ): Repr cat. 2 proposed
 - Silver sodium hydrogen zirconium phosphate (SSZHP): no Repr classification proposed
 - Public consultation not yet started
- **Dec 2018:** CLH proposal submitted for silver nitrate (not compliant yet)
 - **Repr cat. 1B** proposed by Kemi
- **Soon?** CLH proposal for elemental silver and silver chloride: **Repr cat. 1B?**

CLH: CLH silver nitrate process and timing



→ **RAC opinion CLH before EOGRTS test results available?**

(EOGRTS test results may be available before inclusion in ATP)

Summary of EPMF position

- Data gaps regarding reprotox of Ag^+ → current data insufficient to classify AgNO_3 / Ag^+ as Repr 1B at this point
- Further significant data expected from REACH studies (cf. recent ECHA acceptance of EOGRTS TP) → would provide superior end result to hazard assessment and will ensure regulatory efficiency
- Conference call with Kemi scheduled on 21 March to discuss the proposal and the process





THANK YOU

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