

# Usefulness of Environmental RAAF in Metals Industry

## EXAMPLE OF THE PGM INDUSTRY

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LEGEND	
✓	Endpoints where reliable substance specific test data are available
NR	Not Required
○	Datagaps

### PLATINUM GROUP METALS ('PGM')

PGMs = Iridium, Palladium, Platinum, Rhodium, Ruthenium, Osmium and their compounds

Typically **low tonnage metals** and metal compounds with a **high monetary value**

Mainly used as **alloying elements, as catalysts or in electronics**

'Data poor' metals <-> 'data-rich' metals (like Zinc, Copper, Nickel, Lead...)

Precious Metals and Rhenium Consortium (PMC) will **register 60+ PGM substances under EU REACH Regulation (EC) n°1907/2006** (registration deadline = 31 May 2018)

### PMC REACH REGISTRATION APPROACH

**Intelligent testing strategy (ITS)** developed in 2011 for each metal group ('Platinum and Pt compounds', 'Palladium and Pd compounds'...)

Consideration of **available data** (public domain & company owned) **vs REACH requirements**

**Use of Read-Across** where possible to minimize (vertebrate) testing (cfr. 3Rs in chemical risk assessment) but ensuring conservatism

**Limited and scattered data available** within each metal group (cfr. example in Figure 1)

Figure 1: Overview of available test data within the group of Pt(IV) substances.

Endpoint	Pt(IV) substances WITH chloro ligand				Pt(IV) substances WITHOUT chloro ligand		
	Pt-Cl compound 1	Pt-Cl compound 2	Pt-Cl compound 3*	Pt-Cl compound 4	Pt-compound 1	Pt-compound 2	Pt-compound 3
96-h fish test	✓	○	NR	○	○	✓	○
48-h Daphnia test	✓	✓	NR	○	✓	✓	○
72-h Algae test	✓	○	✓	○	✓	✓	○
3-h STP micro-organisms test	✓	○	NR	○	✓	✓	○
21-d Chronic Daphnia test	✓	○	NR	○	○	○	○

\* Pt-Cl compound 3 is not registered under EU REACH

Figure 2: Overview of Read-Across within the group of Pt(IV) substances.

Endpoint	Pt(IV) substances WITH chloro ligand				Pt(IV) substances WITHOUT chloro ligand		
	Pt-Cl compound 1	Pt-Cl compound 2	Pt-Cl compound 3	Pt-Cl compound 4	Pt-compound 1	Pt-compound 2	Pt-compound 3
96-h fish test	✓		NR			✓	
48-h Daphnia test	✓	✓	NR		✓	✓	
72-h Algae test	✓		✓		✓	✓	
3-h STP micro-organisms test	✓		NR		✓	✓	
21-d Chronic Daphnia test*	✓		NR				

\* Read-across for this endpoint is for PNEC (Predicted No Effect Concentration) derivation only

LEGEND	
→	Indicates what test data ('source substance') is used to fill data gaps ('target substance')

### READ-ACROSS ASSESSMENT FRAMEWORK ('RAAF')

**RAAF published in 2015** by European Chemicals Agency (ECHA) for **human health endpoints**, updated in **March 2017** to also cover **environmental endpoints** (fate and ecotoxicity)

RAAF sets **framework for reporting and justifying Read-Across** in REACH dossiers

RAAF applied in **PGM REACH dossiers since 2017**

### EXPERIENCE FROM REPORTING READ-ACROSS FOR PGMs

Metal specific interpretation of terminology warranted

- **'structural similarity'** = same metal ion
- **'transformation'** = rate and release of dissolved metal ion cfr TDp (OECD29)
- **'fate'** = depending on physico-chemical properties of medium

Selection of RAAF **scenarios not clear**:

- **metals ecotoxicity** attributed to bioavailable metal ion ('(bio)transformation to common compound(s)')
- which approach to take: **analogue** ('small number of structural similar substances') **vs category** ('several substances with structural similarity')?

### PGM EXAMPLE

**Basis for environmental Read-Across within PMC:**

- **chemical composition of metal compounds** (including speciation & impurities)
- **potential contribution of ligands**
- **properties of source and target compounds** (physico-chemistry and ecotoxicity data) (cfr. Figure 2)
- **Seventeen ecotoxicity assays** (covering five ecotoxicity endpoints) **were instead completed using** a conservative and scientifically robust **Read-Across approach** minimising unnecessary testing

## CONCLUSION

Read-Across is applied in many metal REACH dossiers (incl. PGMs) to fill datagaps.

The RAAF Framework is suited for reporting Read-Across for PGM dossiers, provided metal specific interpretations of terminology are accepted.

