PMC substances regulatory overview

1. Introduction

By May 2018 deadline, all the registration dossiers of PMC substances will have been submitted. However, the regulatory activities will continue and some of the PMC substances will get under scrutiny. The aim of this note is to give an overview of the regulatory status of the PMC substances and identify the potential regulatory pressure in the future.

2. Regulatory overview by group of substances

PMC substance group*	ENVIRONMENT		HUMAN HEALTH				OTHER ECHA PRIORITIZATION CRITERIA		EU REGULATORY PRESSURE
	Hazard	Risk assessment	Hazard			Risk assessment	High tonnage	WDU/ASL	
			Genotox	Reprotox	Sensitisation				
Ag&Ag cmpds	+++	++		+++			+++	+++	+++
Au&Au cmpds								+	
PM Cyanides	+		+++		+			+	
Pd&Pd cmpds	+	+			+			++	
Pt&Pt cmpds	+		+++	+++	+++	+++		+++	
Rh&Rh cmpds	+		+++		+			++	
Ru&Ru cmpds	+				+			++	
Ir&Ir cmpds									
Re&Re cmpds									

WDU = Wide Dispersive Use, ASL = Article Service Life
*Categorisation is reflected per metal group, but relates for most metals groups to some group members.

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	hazard	Risk assessment	Hazard			Risk assessment	High tonnage	WDU/ASL	
			Genotox	Reprotox	Sensitisation				
Ag&Ag cmpds	Aquatic Acute/ Chronic cat1	PNEC review		TP			>100 tpa	ASL	REACH SE, WFD, biocides CLH
Au&Au cmpds								ASL, Consumer uses	
PM Cyanides	Aquatic Acute/ Chronic cat1		TP		Skin cat1			Widespread Uses	
Pd&Pd cmpds	Aquatic Acute/ Chronic cat1	Generic PNECs			Skin cat1			ASL Car catalysts	
Pt&Pt cmpds	Aquatic Acute/ Chronic cat1		TP	TP Karstedt Repro cat 2	Resp&Skin cat1	Qualitative RA		ASL Car catalysts, Karstedt Conc	
Rh&Rh cmpds	Aquatic Acute/ Chronic cat1		Muta2, Bioelution testing – TP (to be submitted)		Skin cat1			ASL Car catalysts	
Ru&Ru cmpds	Aquatic Acute/ Chronic cat1				Skin cat1			ASL Car catalysts	
Ir&Ir cmpds									
Re&Re cmpds									

SE = Substance Evaluation, WFD = Water Framework Directive, TP = Testing Proposal, RA = Risk Assessment
*Categorisation is reflected per metal group, but relates for most metals groups to some group members.

For all the substances, the Secretariat has established from one side an OFI ('Opportunities for Improvements') tracker and on the other side some prioritisation criteria based on ECHA prioritisation criteria to develop a rolling plan for the maintenance and update of the registration dossiers. The main triggers are the data gaps and the potential regulatory pressure due to classification or risk linked to potential exposure.

You will find here below comments related to the above table mapping the PMC substances regulatory overview:

- **Ag and Ag compounds:**
  - EOGRT testing proposal will be discussed and reviewed in 2018. The key issue will be to defend the testing proposal to ensure the existing data gap id filled properly. But it will be also very important to link this discussion to the CLH process for silver which is ongoing under the biocides and the business impact of a potential classification of silver and compounds as reprotox cat 1B. A strategy is under development to address these different issues in a consistent way.
  - Water framework directive: although there is not yet clarity on the prioritisation of silver for the derivation of an EQS (Environmental Quality Standard), the regulatory pressure is still high and a lot of technical work is ongoing at Member State and Commission level where PMC is contributing too. The outcome of these discussions is critical and

especially for the REACH registration file where an update will be required to reflect the most recent technical discussions.

- **Au and Au compounds:** no immediate regulatory threat identified so far but some attention must be put on the nanogold and the potential need to update REACH registration dossiers to include the nanos.
- **PM cyanides:** the testing proposal for an OECD 474 (in vivo genetic toxicity) has been submitted to ECHA in 2016. Therefore, further work on genotoxicity is expected. Depending on the outcome, the regulatory pressure could vary in the future. The existing classifications for skin sensitisation and aquatic toxicity, and the wide spread use justify the dossier maintenance on a regular basis. However, no immediate threat has been identified.
- **Pd and Pd compounds:** to avoid an increasing regulatory pressure on Pd, the improvement of the environmental assessment including a review of the PNEC is foreseen. Also, some weaknesses in the ITS/read-across have been identified (such as repeated-dose toxicity and reproductive toxicity). Knowing that read-across has been identified in the MISA (Metals & Inorganics Sectorial Approach) as a high priority by ECHA and the industry, the scrutiny on Pd and Pd compounds could increase.
- **Pt and Pt compounds:** there is a high risk to see chloroplatinates screened for potential SVHC concerns. Therefore, a shadow RMOAs (Risk Management Option Analysis) supported by an AoA (Analysis of Alternatives) is already available and a series of improvements of the registration dossiers are foreseen to ensure the best quality dossiers in case of prioritisation after the ECHA screening. In addition, several testing proposals have been submitted to address remaining data gaps on genotoxicity and will be addressed in a grouped way by ECHA in 2018. This could also trigger important discussions on the read-across approach. Lastly, for Karstedt concentrate, a testing proposal on reprotox (EOGRTs) has been, submitted and, depending on the outcome, this could trigger additional regulatory pressure in the future.
- **Rh and Rh compounds:** especially Rh(III) compounds will require further attention on mutagenicity and a testing proposal for genotoxicity will be submitted to address the existing data gap.
- **Ru and Ru compounds:** The existing classifications for skin sensitisation and aquatic toxicity and wide spread use justify the dossier maintenance on a regular basis. However, no immediate threat has been identified.
- **Ir and Ir compounds:** no immediate threat identified.
- **Re and Re compounds:** no immediate threat identified.

Refinables have not been listed since the concerns are very different**:** the SID issue is still ongoing as well as the discussions on the methodology used and how this is explained in the registration dossiers. The regulatory pressure could become very high in the future due to the CMR cat 1 classification but also because of their importance for the circular economy in the EU.

N.B.: for all the substances which have been registered as Annex III exempted substances (>30 in total in all the groups – see list on http://www.epmf.be/datasharing-loa/), there is a risk that this exemption will not be maintained in the future requiring upgrades of these dossiers to higher data requirements.

On this basis, a risk register will be developed in more details and will help to prioritize future work.