



# PMC 2018 Workplan and budget

## 1. Introduction

2018 will be an important milestone for the Precious Metals Consortium (PMC) and the European Precious Metals Federation (EPMF) because of the finalisation of the REACH registration process. It will be also a hinge year due to the ongoing discussions on EPMF/PMC restructuring. Based on this, the Secretariat with the support of the relevant work groups identified a series of activities to be conducted in 2018 mainly in the context of the maintenance of the registration dossiers but also related to testing proposals which have been submitted to ECHA and the preparation to the switch from registration to risk management process.

To better address the new challenges faced by the Precious Metals industry, the overall structure of the work is under reorganisation with the aim to have a fully integrated structure between EPMF and PMC in 2019. This reorganisation will also better take into account the different requirements related to a substance or group of substances in terms of maintenance, regulatory pressure etc. To ensure a smooth transition towards the new structure, it is therefore suggested to already implement in 2018 the new organisation at least, regarding the platforms related to REACH and especially to REACH registration. This will also facilitate the cost sharing process and the increasing itemisation requests.

## 2. The new structure and 2018 workplan

REACH platforms (linked to registration dossiers)	Other platforms
1) Au metal	1) SVHC Roadmap
2) Au compounds	2) Ag EQS
3) Potassium dicyanoaurate	3) Chemicals/waste/products Roadmap
4) Ag metal (including nano)	4) Development and maintenance of Risk Register
5) Ag compounds	5) Occupational Health
6) Ag cyanide/Potassium dicyanoargentate	6) Water Framework Directive and PGMs
7) Ir metal	7) Responsible sourcing
8) Ir compounds	8) Tax
9) Pt metal	9) Communication and advocacy platform
10) Chloroplatinates	10) Food contact materials
11) Karstedt Concentrate	11) Other?
12) Pt compounds (others)	
13) Pd metal	
14) Pd compounds	
15) Rh metal	



16) Rh(III) compounds	
17) Rh compounds (others)	
18) Ru	
19) Ru compounds	
20) Re	
21) Refinables	

For all the substances, the Secretariat has established from one side an OFI ('Opportunities for Improvements') tracker (which will be available end of 2017 to the members) and on the other side some prioritisation criteria (see Annex 1) to develop a rolling plan for the maintenance and update of the registration dossiers.

In general, 2018 will be dedicated to generate new data in view of potential updates of the dossiers in 2019 and beyond.

For all platforms, a budget has been foreseen for conducting a literature review, for the IUCLID hosting and potential updates of uses and ES (e.g.: following a DUs request or newly available data). This will not lead automatically to a need to update the dossiers in 2018/19.

More specific work has been identified on critical substances:

- **Silver and silver compounds:**
  - EOGRTs testing proposal will be discussed and reviewed in 2018: a significant budget has been including to be able to include a DIT cohort in the testing. This issue is of course critical since this will be the key element for the reprotox classification discussion.
  - due to the high volume, widespread use and classification of silver and silver compounds and the fact that the dossiers were submitted in 2010 and 2013, it has been agreed to conduct a complete review of the uses and related exposure scenarios to ensure consistency in the exposure assessment with other PMC dossiers submitted more recently.
  - In the context of the EQS work, a data gap was identified in ecotox to derive PNEC for sediments. A budget has been included in 2018 budget to address this data gap.
- **Au metal:** some preliminary work is foreseen on nanogold due to increasing pressure from Commission and Member States to include nanoforms in registration dossiers.  
**N.B.:** It is worth to note that similar work on **PGMs nanoforms**
- **Potassium dicyanoaurate:** the testing proposal for an OECD 474 (in vivo genetic toxicity) has been submitted to ECHA in 2016 and could be reviewed and assessed in 2018. It is therefore proposed to include the equivalent budget in the 2018 budget.
- **Chloroplatinates:** due to the high risk to see chloroplatinates screened for potential SVHC concerns, a series of improvements of the registration dossiers have been foreseen (secondary poisoning, an external peer review to better identified potential additional improvement areas)
- **Pt compounds (others):** during the dossier review process, some weaknesses in the ITS/read-across have been identified (such as repeated-dose toxicity and reproductive toxicity)



for Pt nitrate). It is therefore proposed to include the budget of an OECD 422 test in the 2018 budget.

- **Pd compounds:** most of the work will be dedicated to an external peer review of key dossiers, as an improvement of the environmental assessment including a review of the PNEC. Also, during the dossier review process, some weaknesses in the ITS/read-across have been identified (such as repeated-dose toxicity and reproductive toxicity). It is therefore proposed to include the budget of 3 OECD 422 test in the 2018 budget to address the read-across weaknesses identified by the WG.
- **Rh III compounds:** most of the activities will be related to mutagenicity and the follow-up of the testing proposal submitted in 2017. For all Rh compounds, a budget is foreseen for additional requests from ECHA following registration of the dossiers Q3/4 2017.
- **Refinables:** it is worth to note that these dossiers will probably need to be updated thanks to the finalisation of the discussions on substance ID but also the need to refine and update the exposure assessment and exposure scenarios. However, no significant budget will be needed due to the 2015-2017 carry over available now in the reserves.
- **Ag EQS:** limited work is expected in 2018 but follow-up on EQS proposal (if any) will be needed.

Again, all these activities will not automatically lead to an update of the registration dossiers, except if needed due to a significant change in classification or/and risk assessment. These activities will be part of the duty of care and maintenance work which will lead in the future to a dossier update. This will also be in line with the sectorial approach developed by ECHA for which a baseline scenario will be developed in 2017 and could again influence our workplan since focusing on >100 t substance like silver and some Ag compounds <2020, but paving the way for the next steps of ECHA sectorial approach for the substance >1t/y.

**N.B.:** other regulatory developments can influence PMC 2018 workplan, like the impact of TiO<sub>2</sub> appeal on nano registration and the potential new enforcement project on nanos or the ongoing discussions on increasing the obligations related to 1-10t (potential withdrawal of Annex III exemption and additional data requirements like OECD 422)



### 3. 2018 budget based on the new structure

#### Costs overview

	2018 Draft Budget
<b>Administrative costs</b>	<b>601.700 €</b>
Salaries and salary-related costs	250.000 €
Office costs	80.000 €
Meeting, travel and accommodation costs	55.000 €
<b>External costs</b>	<b>196.700 €</b>
<i>Eurométaux REACH package</i>	58.000 €
<i>ICMM membership</i>	2.700 €
<i>Knowledge Management tool</i>	10.000 €
<i>Communication tool for SIEF Mgt</i>	10.000 €
<i>IUCLID IT Hosting system</i>	10.000 €
<i>Liability Insurance</i>	6.000 €
<i>Legal support</i>	50.000 €
<i>Accountancy and audits</i>	25.000 €
<i>ETAP membership + project</i>	20.000 €
<i>HETAP membership + project</i>	5.000 €
<b>Restructuration</b>	<b>20.000 €</b>



	2018 Draft Budget
<b>REACH Platform costs</b>	<b>3.638.924 €</b>
Ag metal (including nano)	937.603 €
Ag compounds	954.103 €
Au metal	48.258 €
Au compounds	37.008 €
Ag cyanide/Potassium dicyanoargentate	14.255 €
Potassium dicyanoaurate	106.010 €
Pt metal	10.264 €
Chloroplatinates	59.927 €
Karstedt	50.047 €
Pt compounds (others)	296.393 €
Pd metal	10.097 €
Pd compounds	700.001 €
Rh metal	8.020 €
Rh III compounds	203.740 €
Rh compounds (others)	26.140 €
Ru metal	9.627 €
Ru compounds	55.773 €
Ir metal	6.180 €
Ir compounds	27.620 €
Re metal & compounds	22.325 €
Refinables	55.531 €
<b>Non-REACH Platform costs</b>	<b>48.600 €</b>
SVHC Roadmap	28.600 €
Silver EQS	20.000 €
<b>GRAND TOTAL</b>	<b>4.289.224 €</b>



**Platforms costs details**

	Ag metal (incl. Nano)	Ag remaining compounds	Au metal	Au compounds	Ag cyanide/Potassium dicyanoargentate	Potassium dicyanoaurate	Pt metal	Chloroplatinates
<b>Total Budget</b>	<b>€ 937.603,17</b>	<b>€ 954.103,17</b>	<b>€ 48.257,83</b>	<b>€ 37.007,83</b>	<b>€ 14.255,22</b>	<b>€ 106.010,44</b>	<b>€ 10.264,29</b>	<b>€ 59.926,97</b>
<b>REACH PLATFORMS</b>								
REACH registration	€ -	€ -					€ -	€ -
REACH dossier maintenance	€ 80.250,00	€ 111.750,00	€ 39.375,00	€ 28.125,00	€ 8.333,33	€ 4.166,67	€ 7.307,69	€ 29.230,77
REACH evaluation	€ 750.000,00	€ 750.000,00	€ -	€ -	€ -	€ 90.000,00	€ -	€ -
REACH classification & labelling	€ 15.000,00	€ -						
REACH authorisation	€ -	€ -	€ -	€ -	€ -	€ -	€ -	€ 10.000,00
Internal and external fixed Scientific Managers	€ 92.353,17	€ 92.353,17	€ 8.882,83	€ 8.882,83	€ 5.921,89	€ 11.843,78	€ 2.956,60	€ 20.696,20



	Karstedt	Pt compounds (others)	Pd metal	Pd compounds	Rh metal	Rh III compounds	Rh compounds (others)
<b>Total Budget</b>	<b>€ 50.047,29</b>	<b>€ 296.393,45</b>	<b>€ 10.097,01</b>	<b>€ 700.000,99</b>	<b>€ 8.020,00</b>	<b>€ 203.740,00</b>	<b>€ 26.140,00</b>
<b>REACH PLATFORMS</b>							
REACH registration	€ -	€ 15.000,00	€ -	€ -	€ -	€ 7.500,00	€ 7.500,00
REACH dossier maintenance	€ 32.307,69	€ 263.653,85	€ 6.842,11	€ 638.157,89	€ 6.250,00	€ 75.000,00	€ 6.250,00
REACH evaluation	€ -	€ -	€ -	€ -	€ -	€ 100.000,00	€ -
REACH classification & labelling			€ -	€ -			
REACH authorisation	€ -	€ -	€ -	€ -	€ -	€ -	€ -
Internal and external fixed Scientific Managers	€ 17.739,60	€ 17.739,60	€ 3.254,90	€ 61.843,10	€ 1.770,00	€ 21.240,00	€ 12.390,00



	REACH PLATFORMS (linked to registration dossiers)						NON REACH PLATFORMS	
	Ru metal	Ru compounds	Ir metal	Ir compounds	Re	Refinables	SVHC Roadmap	Ag EQS
<b>Total Budget</b>	<b>€ 9.627,14</b>	<b>€ 55.772,86</b>	<b>€ 6.180,00</b>	<b>€ 27.620,00</b>	<b>€ 22.325,00</b>	<b>€ 55.531,33</b>	<b>€ 28.600,00</b>	<b>€ 20.000,00</b>
<b>REACH PLATFORMS</b>								
REACH registration					€ -	€ -	€ -	
REACH dossier maintenance	€ 7.857,14	€ 22.142,86	€ 5.000,00	€ 17.000,00	€ 18.500,00	€ 20.000,00	€ -	€ -
REACH evaluation	€ -	€ -	€ -	€ -	€ -	€ -	€ -	€ -
REACH classification & labelling					€ -	€ -	€ -	€ -
REACH authorisation	€ -	€ -			€ -	€ -	€ -	€ -
Internal and external fixed Scientific Managers	€ 1.770,00	€ 33.630,00	€ 1.180,00	€ 10.620,00	€ 3.825,00	€ 35.531,33		€ -
Building reserves					€ -	€ -	€ -	€ -
<b>NON REACH PLATFORMS</b>								
SVHC Roadmap							€ 28.600,00	
Silver EQS								€ 20.000,00



## Annex 1: Criteria for prioritisation of substances in view of maintenance/update of registration dossiers

The criteria selected by PMC in order to identify priority substances are mainly based on ECHA's screening criteria for further regulatory measures.

**Hazard criteria:** In line with ECHA's screening approach, the first category of criteria applied by PMC relates to hazards. A distinction is made between the hazards which are screened in priority by ECHA since they may lead to the SVHC status, in the case of PMC substances **sensitization (skin and respiratory) and STOT**, and **other relevant hazards**, in particular aquatic toxicity, which may trigger other risk management measures such as a REACH restriction or Substance Evaluation.

**Non-hazard criteria:** Non-hazard criteria are used by ECHA on top of hazard criteria in order to assess the risk dimension. Non-hazard criteria relate primarily to exposure and volumes. Widespread uses (professional or consumer uses) get prioritized over fully contained uses. Similarly, high tonnages get prioritised over lower tonnages. On this basis, PMC selected the following three non-hazard criteria to guide prioritisation: **1/ tonnage registration band; 2/ existence of a CSR/exposure scenarios and 3/ Widespread use.**

**Data improvement needs:** Authorities need to have a good understanding of both hazards and exposure aspects of a substance. This requires testing results, monitoring data, precise use descriptions and tonnage information. PMC has set up an internal tracker of 'Opportunities for Improvement' for registration dossiers to report areas with data gaps. As regards **hazards**, data improvement needs relate for instance to pending testing proposals on critical endpoints or weaknesses in read-across. As regards **exposure**, it covers aspects such as lack of monitoring data, RCRs above 0,7 or unclear use descriptors.

**Other criteria:** This last category includes complementary criteria that may be useful to refine the assessment. Whether the substance is an **Annex III exempted substance** or not belongs to such criteria. While it may not be a decisive criterion, it may support prioritisation where needed and especially depending on the outcome of the discussions related to the increase of 1-10t related requirements.

There is also a criterion indicating the **number of identified uses for the substance**. Substances with a similar profile but with a higher number of uses may have to be prioritised over substances with a more limited number of uses, unless widespread.

Finally, we have added the criterion of **relevant regulatory developments** in order to include information on regulatory actions or trends that may impact our substances and therefore their prioritisation.