Calculation of PMC Letter of Access cost
Date: 10 April 2014

I. INTRODUCTION

This document aims at describing the principles followed by the Precious Metals and Rhenium Consortium (PMC) c/o EPMF aisbl to calculate the price of a Letter of Access (LoA) and review this price when appropriate. A first version of this document was released on 30 May 2010 and the veracity of the predictions has been reviewed in October 2011 and May 2012. A review of the predictions was done in April 2014, following significant unexpected Registration and Evaluation related work items for two of the PMC projects in particular.

The purpose of a LoA is to enable a non-Member entity to be a legitimate joint registrant in a Registration Dossier prepared by the PMC. LoA will be available for each substance and intermediate in scope of one of the PMC projects, after the substance and intermediate has been registered.

An excel file describing the steps followed and the calculations/predictions made is available in an Annex which is an integral part of this document. This Annex is composed of several worksheets including:

- **1st** Recap of PMC meetings over 2007-2009
- **2nd** Recap of PMC teleconferences over 2007-2009
- **3rd** Outline of PMC expenses over 2007-2009 and expenses predictions for 2010-2020
- **4th** Number of potential registrants and entities having indicated an interest in purchasing a LoA
- **5th** Distribution of Generic costs for 2007-2020
- **6th** Distribution of Silver-specific costs for 2007-2020
- **7th** Distribution of Gold-specific costs for 2007-2020
- **8th** Distribution of PGM-specific costs for 2007-2020
- **9th** Distribution of Re-specific costs for 2007-2020
- **10th** Distribution of Refinable-specific costs for 2007-2020
- **11th** Cost of a Letter of Access per substance/intermediate and tonnage band in each project

II. REACH REQUIREMENTS

PMC commits to develop a method to calculate the price of a LoA that is fair, transparent, non-discriminatory and not aimed at generating profit.

Fairness: The contribution of legal entities that are Members of the PMC and of those that are not is calculated in such a manner that each potential joint registrant pays a proportionate and comparable price to comply with its joint submission obligations under the REACH regulation. Fairness is ensured by applying the same cost-sharing formula to all potential registrants, whether or not they are Members of PMC in which:

- Generic costs[1] are shared equally among all potential registrants
- Metal-specific costs[2] are distributed per project or substance family as follows:
  - 50% is distributed by applying a weighted approach[3] whereby:
    - Substances and non-SCC[4] intermediates in the > 1000 t/a tonnage band have a weight of 1000
    - Substances and non-SCC intermediates in the 100-1000 t/a tonnage band have a weight of 100

[1] Administrative costs including: PMC Officers (Secretariat & Trustee, Project Manager, and Scientific Manager), IT tools for SIEF communication, insurance, accountancy, legal support, and office, travelling and meeting costs, etc.
[2] Technical costs including: literature search, data-gap analysis, testing strategy, purchase of reference samples, testing programme, CSA/CSR, IUCLID 5 compilation and other *ad hoc* services of PMC's external Consultants and Experts
[3] Following the proportion of the ECHA fees for each type of REAH Registration
[4] Not handled under strictly controlled conditions as per the Dec 2010 ECHA Guidance on intermediates

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        - Substances and non-SCC intermediates in the 1-10 t/a tonnage band have a weight of 20
        - Substances and non-SCC intermediates in the 1-10 t/a and SCC[5] transported isolated intermediates in the > 1000 t/a tonnage band have a weight of 5
        - Any other SCC intermediate in any tonnage band but > 1000 t/a has a weight of 1
    - 50% is distributed according to the total number of PMC substances and non-SCC intermediates (SCC intermediates are excluded from this cost calculation) to be registered by each company in each project
- 100% of Refinable-specific costs are distributed according to the number of Refinables to be registered by each company which are assigned a weight of 1, no matter whether they are on-site or transported intermediates or the tonnage band in which they are registered (may be reviewed in 2015)

Transparency: All predictions and calculations are be based on clear, sound and objective hypotheses and assumptions that are described in this document, available to anyone requesting it

Non-discrimination: None of the principles, hypotheses or assumptions used by the PMC aims at excluding or preventing any potential registrant from participating to the joint registration and/or from complying with its obligations under REACH

Non-profit: None of the principles, hypotheses or assumptions used by the PMC aims at making profit through the selling of LoA

III. PRELIMINARY PRINCIPLES

- Membership remains open to any joint registrant, and remains associated to the rights and obligations outlined in the PMC Agreement in place
- Entities purchasing a LoA have no obligation towards the PMC with the exception of those outlined in the LoA contract
- The price of a LoA is reasonably attractive to promote this specific approach towards joint submission[6]
- The LoA is purchased per legal entity and is not valid for any other entity than the entity whose name is on the LoA[7]
- The LoA is purchased for each substance and each intermediate
- A legal entity purchasing a LoA pays its contribution to the Generic costs only once, no matter the number of LoA it is purchasing from the PMC
- A legal entity purchasing a LoA has no co-ownership right on the information contained in the dossier and does not receive a copy of the dossier submitted to ECHA – only those parts necessary to submit a harmonised set of information to ECHA are provided to LoA purchasers[8]
- In the event a legal entity wishes to obtain a copy of (part of) the content of the Registration Dossier in order to use it (or not) under REACH or another (legislative) context this legal entity will be charged an *ad hoc* Licence to Use price as per decision of the PMC Management Committee
- There is no reduction or premium applied on a LoA purchased earlier or later in the registration process, respectively
- The price of the LoA is reviewed regularly to determine whether the PMC expenses predictions can be confirmed or require adjustment

IV. ASSUMPTIONS, HYPOTHESIS AND PREDICTIONS

1. Applied to predict Future Expenses

[5] handled under strictly controlled conditions as per the Dec 2010 ECHA Guidance on intermediates
[6] Therefore preventing the membership of the PMC from becoming unmanageable; there is a need to guarantee a minimum quorum at PMC meetings, a proportionate technical input from Members, and a simplified communication, etc. to limit generic costs and ensure delivery of PMC objectives
[7] Affiliates of the legal entity purchasing a LoA cannot use this LoA
[8] E.g.: Chemical Safety Report (CSR), list of identified uses, joint submission object name and joint submission object token

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Expenses are calculated to cover the period of 2007-2020[9]. Confirmed expenses of the period of 2007-2009 were taken as a baseline to make 2010-2020 predictions and are then replaced by actual expenses every year (cf. 3rd worksheet).

- Predicted Generic costs:
  - A yearly increase/decrease is estimated as per PMC workload, Registration and Post-registration objectives applicable to each year (in yellow boxes)[10]
  - Where the budget item is known, the yearly percentage of increase/decrease is not applied but the actual figure is considered (indicated in blue in the excel file)
- Predicted Metal-specific costs: The above yearly increase/decrease percentage not always apply to predict project budgets; Consultants predictions together with the increasing experience are considered instead (also in blue)[11]
- Green lines are added in each budget to potentially cover for:
  - Future costs resulting from the minimum presence and organisation that is required to allow maintenance of PMC's projects and overall success and achievement of REACH obligations[12]
  - PMC Members's participation to meetings and teleconferences[13] are calculated for information, as an indicative expenditure incurred by PMC Members along the registration preparation and follow-up process, though they not considered in the calculation of the LoA price:
    - 2007-2009: based on real meetings and teleconferences (cf. 1st and 2nd worksheets of Annex)
    - 2010-2020: predictions calculated based on expected frequency of meetings by:
      - Generic, Ag, Refinables: multiplying (amount 2007-2009/3)*Yearly increase/decrease
      - Au, PM CN-, PGM: multiplying (amount 2007-2009)*Yearly increase/decrease
      - Re: (amount 2007-2009/2)*Yearly increase/decrease

2. Applied to derive the price of a LoA

- The price of the LoA is calculated on the basis of the PMC expenses and predictions, and the PMC cost-sharing formula
- The calculation takes account of the responses received to the Survey on Registration Intentions[14] (cf. 4th worksheet), and assuming only 80% of these companies will actually purchase a LoA (20% contingency applied as some companies may join the PMC in the meantime)
- For the purpose of the calculation of the price of a LoA, LoA purchasers are considered to be "Virtual" Members of the PMC (represented in line 'LoA' of each worksheet)
- The total cost of each project over 2007-2020 is distributed across all potential registrants (real and "virtual" PMC Members) as per the PMC cost-sharing formula:
  - Generic costs are distributed across PMC Members + Entities having confirmed interest in purchasing a LoA (-20% contingency) (cf. 5th worksheet of Annex)
  - Metal-specific costs are distributed across PMC Members + One virtual LoA entity assembling all indications of interest in purchasing a LoA in tonnage band and each project (-20% contingency) (cf. 6th-10th worksheets of Annex)
- In each distribution, the contribution made by a (real or virtual) Member for each substance and intermediate in each project is extracted in a separate table (cf. 11th worksheet of Annex)
- Where such an isolated case does not exist or cannot be derived, an *ad hoc* line is added to the cost-distribution at the bottom of the worksheet (usually for intermediates)

[9] 2007 corresponds to the creation of the PMC, and 2020 corresponds to 2018 as last registration deadline + 2 years buffer period to assimilate outcomes of last registration period
[10] The PMC's workload will evolve in parallel with the accomplishment of the Registration Dossiers for Ag and the Refinables >> PGM and Re >> Au and PM CN-
[11] The level of complexity (associated to the tonnage band, number and type (e.g.: UVCB) of substances involved, potential classifications, and overall data availability) of the metal-specific projects is: Ag > Refinables > PGM > Re > Au > PM CN-
[12] E.g.: inquiries from potential registrants, ECHA, authorities; update(s) of the Dossier(s); requests for additional information/tests as a result of the Evaluation or Authorisation; (ir)regular LoA requests, etc.
[13] Assuming that the time of PMC Members could be charged at a rate of 115 €/h in accordance with the hourly rate of PMC external Consultants (used as objective reference)
[14] Circulated through REACHsuite in December 2009

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- The exact figures resulting from the above calculation are assessed by the Management Committee of the PMC who agrees on min/max ranges and "round" figures to be proposed to potential LoA purchasers prior to every relevant registration deadline[15], following the approval of the above method and the ultimate LoA prices by the Assembly of the PMC at the relevant Assembly meeting

V. PRICES PMC LOA

Table 1. PMC LoA price proposals approved by the PMC Assembly in Jun 2010 (no longer applicable)

Project / Dossier	Band	Exact amount	+ 20% contingency	Min	Max
Generic	**N/A**	31.743,77 €	38.092,53 €	32.000,00 €	38.500 €
Ag	Intermediate	98,52 €	118,23 €	100,00 €	125 €
	1-10	5.394,41 €	6.473,30 €	5.500,00 €	6.500 €
	10-100	6.872,28 €	8.246,73 €	7.000,00 €	8.500 €
	100-1000	14.754,22 €	17.705,06 €	15.000,00 €	18.000 €
	> 1000	103.426,03 €	124.111,24 €	103.500,00 €	124.500 €
Au	Intermediate	1.217,67 €	1.461,20 €	1.500,00 €	1.500 €
	1-10	18.944,33 €	22.733,20 €	19.000,00 €	23.000 €
	10-100	37.209,38 €	44.651,26 €	37.500,00 €	45.000 €
PM CN-	Intermediate	1.161,96 €	1.394,35 €	1.500,00 €	1.500 €
	1-10	16.425,86 €	19.711,03 €	16.500,00 €	20.000 €
	10-100	33.855,23 €	40.626,27 €	34.000,00 €	41.000 €
PGM	Intermediate	1.709,45 €	2.051,34 €	2.000,00 €	2.500 €
	1-10	22.929,52 €	27.515,42 €	23.000,00 €	30.000 €
	10-100	48.571,31 €	58.285,58 €	46.000,00 €	60.000 €
Re	Intermediate	1.264,29 €	1.517,15 €	1.500,00 €	2.000 €
	1-10	15.197,18 €	18.236,61 €	15.500,00 €	20.000 €
	10-100	34.161,56 €	40.993,87 €	34.500,00 €	41.000 €
Refinables	Intermediate	8.514,91 €	10.217,89 €	9.000,00 €	10.500 €

The prices listed in Table 1 above were communicated to the respective SIEF in autumn 2010. Only Ag and Refinable LoA have been sold in 2010.

The review of the LoA prices performed in October 2011 indicates that the cost predictions made for 2011-2013 are reasonable for all projects except for Refinables, which is a special case subject to several uncertainties (ongoing advocacy programme on the interpretation of rigorous containment and SCC, development of rigorous containment assessment tools, upcoming advocacy on non-testing/read-across strategies for complex UVCB substances and intermediates, etc.). This review was presented to the PMC Assembly for information at the 6 December 2011 Assembly meeting held in Brussels. It was agreed to leave the prices of PMC's LoA unchanged and to review these once the 2011 expenses are confirmed and the cost of the Ag Evaluation can be predicted (~ 280 000 € had been foreseen for future Ag costs in May 2010 prediction but whether or not this amount will be sufficient was unknown at that stage). Also, it was recommended to delay the release of updated LoA prices and the selling of LoA as closely as possible

[15] 2010 for Ag and Refinables, 2013 for some PGM, 2018 for Au, PM CN-, Re and remaining PGM

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before the respective registration deadlines. SIEF members should be informed accordingly and made aware of the fact that LoA prices for the Silver and Refinables projects may be adjusted upwards.

The review of the LoA prices performed in May 2012 indicated that the cost predictions made for 2011-2013 are reasonable for all projects except for the Silver and the Refinables projects. The situation for the Refinables project is addressed in the paragraph above. The cost predictions for the Silver project underestimated the costs triggered by:

- The preparation of Dossier updates (for instance, those required by ECHA in follow-up of evaluations of testing proposals);
- The preparation of the Silver Dossier for its Evaluation phase (by The Netherlands in 2013); which will affect all other Ag compounds Dossiers in line with the read-across approach followed for those relevant endpoints; and
- Changes in the scope of the project (e.g. increases of tonnage bands, changes of status from scc intermediate to non-scc intermediate or substance, additions to the scope, etc.), which are unpredictable

The above learning lessons were considered to review the cost of the LoA of all PMC projects (Table 2). Only the LoA for the Generic costs, Ag 100-1000 t/a, PGM 1-10 t/a, and Re 1-10 t/a remain unchanged.

Table 2. Reviewed PMC LoA price proposals approved by the PMC Assembly in Jun 2012 (no longer applicable)

Project / Dossier	Band	Exact amount	+ 20% contingency	Min	Max
Generic	**N/A**	31.743,77 €	38.092,53 €	32.000,00 €	38.500 €
Ag	Intermediate	120,68 €	144,82 €	125,00 €	145 €
	1-10	6.607,50 €	7.929,00 €	7.000,00 €	8.000 €
	10-100	8.417,70 €	10.101,24 €	8.500,00 €	10.500 €
	100-1000	18.072,11 €	21.686,53 €	18.000,00 €	22.000 €
	> 1000	126.684,23 €	152.021,07 €	127.000,00 €	152.000 €
Au	Intermediate	1.881,88 €	2.258,26 €	1.900,00 €	2.500 €
	1-10	29.278,04 €	35.133,65 €	29.500,00 €	35.500 €
	10-100	57.506,27 €	69.007,52 €	57.500,00 €	69.000 €
PM CN-	Intermediate	1.678,93 €	2.014,72 €	2.000,00 €	2.000 €
	1-10	23.733,99 €	28.480,78 €	24.000,00 €	28.500 €
	10-100	48.917,96 €	58.701,55 €	49.000,00 €	59.000 €
PGM	Intermediate	2.099,77 €	2.519,72 €	2.000,00 €	2.500 €
	1-10	28.164,92 €	33.797,90 €	28.500,00 €	34.000 €
	10-100	59.661,41 €	71.593,69 €	60.000,00 €	71.500 €
Re	Intermediate	1.514,64 €	1.817,56 €	1.500,00 €	2.000 €
	1-10	18.206,38 €	21.847,66 €	18.500,00 €	22.000 €
	10-100	40.925,91 €	49.111,10 €	41.000,00 €	49.500 €
Refinables	Intermediate	9.731,33 €	11.677,59 €	10.000,00 €	12.000 €

The reviewed LoA prices in Table 2 were approved by the PMC Assembly at the 14 June 2012 Assembly meeting held in Antwerp. These should be used for internal reference/benchmarking LoA with PMC

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membership. In any case, the updated LoA prices will be announced to non PMC Members upon request or as closely as possible before the respective registration deadlines.

The review of the LoA prices performed in April 2014 indicated that the LoA for Generic costs would need to be reviewed upwards while for the other projects, the LoA prices appear acceptable (e.g. Ag and Refinables projects), or not due yet and should remain as draft estimates for now (for those projects subject to Registration in 2018, in *italics*).

Table 3. Reviewed PMC LoA price proposals approved by the PMC Assembly in Jun 2014

Project / Dossier	Band	Exact amount	+ 20% contingency	Min	Max
Generic	**N/A**	57.262,72 €	68.715,27 €	57.300,00 €	68.750 €
Ag	Intermediate	120,68 €	144,82 €	120,00 €	150 €
	1-10	6.607,50 €	7.929,00 €	6.600,00 €	7.950 €
	10-100	8.417,70 €	10.101,24 €	8.400,00 €	10.100 €
	100-1000	18.072,11 €	21.686,53 €	18.000,00 €	21.700 €
	> 1000	126.684,23 €	152.021,07 €	126.700,00 €	152.050 €
Au	Intermediate	1.881,88 €	2.258,26 €	*1.850,00 €*	*2.300 €*
	1-10	29.278,04 €	35.133,65 €	*29.250,00 €*	*35.150 €*
	10-100	57.506,27 €	69.007,52 €	*57.500,00 €*	*69.050 €*
PM CN-	Intermediate	1.678,93 €	2.014,72 €	*1.650,00 €*	*2.050 €*
	1-10	23.733,99 €	28.480,78 €	*23.750,00 €*	*28.500 €*
	10-100	48.917,96 €	58.701,55 €	*48.950,00 €*	*58.750 €*
PGM	Intermediate	2.099,77 €	2.519,72 €	*2.100,00 €*	*2.550 €*
	1-10	28.164,92 €	33.797,90 €	*28.150,00 €*	*33.800 €*
	10-100	59.661,41 €	71.593,69 €	*59.650,00 €*	*71.600 €*
Re	Intermediate	1.514,64 €	1.817,56 €	1.550,00 €	1.850 €
	1-10	18.206,38 €	21.847,66 €	18.200,00 €	21.850 €
	10-100	40.925,91 €	49.111,10 €	40.950,00 €	49.150 €
Refinables	Intermediate	9.731,33 €	11.677,59 €	9.750,00 €	11.700 €

The reviewed LoA prices in Table 3 were approved by the PMC Assembly at the 12 June 2014 Assembly meeting held in Bern. These should be used for internal reference/benchmarking LoA with PMC membership. In any case, the updated LoA prices will be announced to non PMC Members upon request or as closely as possible before the respective registration deadlines.

VI. COMMENTS OR QUESTIONS

Comments or questions on this document or its Annex can be forwarded to the Secretariat of PMC, at info@epmf.be

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