



European Precious Metals
Federation

European Precious Metals Federation

Refinables Work Group Meeting

Conference call 21 April 2020



European Precious Metals
Federation

Welcome & Introduction



Confidentiality and Competition law

Tour-de-table and apologies

DO	DON'T
<u>Application of competition law</u>	
Art. 101 and 102 TFEU may be applicable to the conclusion of any preliminary agreement and activities of any preliminary phase.	Don't assume that conflicts with competition law are excluded simply by the fact that the Agreement complies with the provisions of the REACH Regulation.
<u>Consultation in Matters of Competition Law</u>	
Consult an in-house legal expert or the compliance officer of your company or an external lawyer whenever there are uncertainties respecting compliance with competition law. Stop all meetings/discussions which are not in compliance with these Compliance Guidelines until a legal expert has been involved.	Don't assume that these Compliance Guidelines deal with all competition law issues exhaustively. Basically, compliance with Art. 101 and 102 TFEU can be determined only on the basis of market impact in each individual case. These Compliance Guidelines may therefore be regarded only as a means of providing general conduct recommendations.
<u>Activities in any preliminary phase and at any other stage of operation of the Consortium</u>	
Restrict cooperation within the scope of the preliminary phase to the initially defined goals and purposes of the cooperation.	Pursuant to Art. 101 and 102 TFEU, activities which have the object of the effect of preventing, restricting and/or distorting competition are prohibited within the scope of this Agreement, including: <ul style="list-style-type: none">- Coming to agreement, including arrangements or collusions, about prices, markets and customers (see Art. 101 paragraph 1 a)-e) TFEU);- Joint boycotting of other companies;- The unjustified unequal treatment of trade partners;- The abusive exploitation of a dominating market position.
<u>Exchange of Confidential Information</u>	
Involve a Trustee for the exchange of Confidential Information.	The exchange of Information concerning market behaviour and having the object or the effect of preventing, restricting and/or distorting competition is inadmissible; in particular, this relates to : <ul style="list-style-type: none">- Production capacities;- Productions or sales volumes;- Import volumes;- Market shares;- Price policy;- Distribution and marketing terms;- Marketing strategies;- Information regarding the relationship with suppliers.
<u>Documentation on Cooperation</u>	
Keep minutes of all meetings which detail the subject of the meeting. In case of uncertainty, have the contents of the minutes reviewed by an external legal expert prior to sending them to all parties of the Agreement. Stop all meetings which are not in compliance with these Guidelines until a legal expert has been involved.	



Agenda

1. Welcome and Introduction

- Reminder on Confidentiality and Competition Law
- Tour de table and apologies
- Minutes of last meeting (B2B, 10/03/2020)

2. iUVCB Platform

- Results screening phase

3. iUVCB MISA 3

- Update reporting discussion

4. EPMF Refinables

- Plans and status activities
- 2020 budget: status

5. Draft workplan and budget 2021

6. AOB

FOR APPROVAL



Approval of the minutes of the last meeting

Draft minutes of the meeting on 10 March 2020 were circulated on 17 March 2020

FOR APPROVAL





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iUVCB platform

Goal

MISA 3 action point

- harmonize and align UVCB dossiers, ensuring consistent and coherent updates and refinements for the smooth submission of LR dossiers
- represents 5 consortia (EPMF, ECI, ILA, IZA and Nickel Institute) and covers refinement/preparing of approx. 45 registered Art.10 dossiers and approx. 20 split or new dossiers.

Technical working group (Arche and EBRC) will screen, develop and implement all the needed **multi-metallic refinements** for these dossiers to fulfill the minimal iUVCB dossier and assessment step requirements agreed upon on the MISA 3 WS

SID & CL	HA	EA/MvE	cRA	Uncertainty analysis	IU Templates & CSR
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Multi-metallic refinements

iUVCB constituent/AE-based assessment approach

- improvement of explanation/transparency of the methodology & the data selection and
- uniform/consistent data reporting in the IUCLID dossier and CSR

Preparation of AE lists and templates, a summary SID-CL-HA-cRA table listing all AEs and their speciation, harmonising UVCB specific waivers (e.g. biodegradation, hydrolysis) and ensuring the minimal requirements for:

SID	Consistent SID for all UVCBs in the platform (SID description, SIP, analytical data reports)
CL	Classification using MeClas – ‘substance’ constituent/AE speciation, MaxTyp conc
HA	Overall and ‘Lead’ Assessment entity (AE) identification and reporting AE HA using ‘exposure condition’ constituent/AE speciation
EA/MvE	Site-specific exposure assessments based on monitoring data
cRA	Harmonised explanations for combined risk assessment and reporting (additivity principle – CA concentration addition method - tiered approach)
Uncertainty	Preparation of a generic position paper on the uncertainty in the iUVCB risk assessment
IU & CSR	Provision of IU templates and consistent CSR refinements

+ compliance with upcoming revised TCC with extension to CSR



Dossier screening and quality scores/criteria

Screening to evaluate the completeness/information of the iUVCB dossiers to:

- Implement a fair & transparent cost sharing formula of the dossier updates
- Identify refinement needs to have harmonized UVCB dossier updates

Q _i SCORES	Platform effort	WEIGHING FACTOR
Q1	minor	0.1
Q1	minor	0.3
Q2	medium	0.5
Q3	significant	1

Generic formula for a given step_x:
COST dossier step_x = COST/SUB ×
Q_i step_x

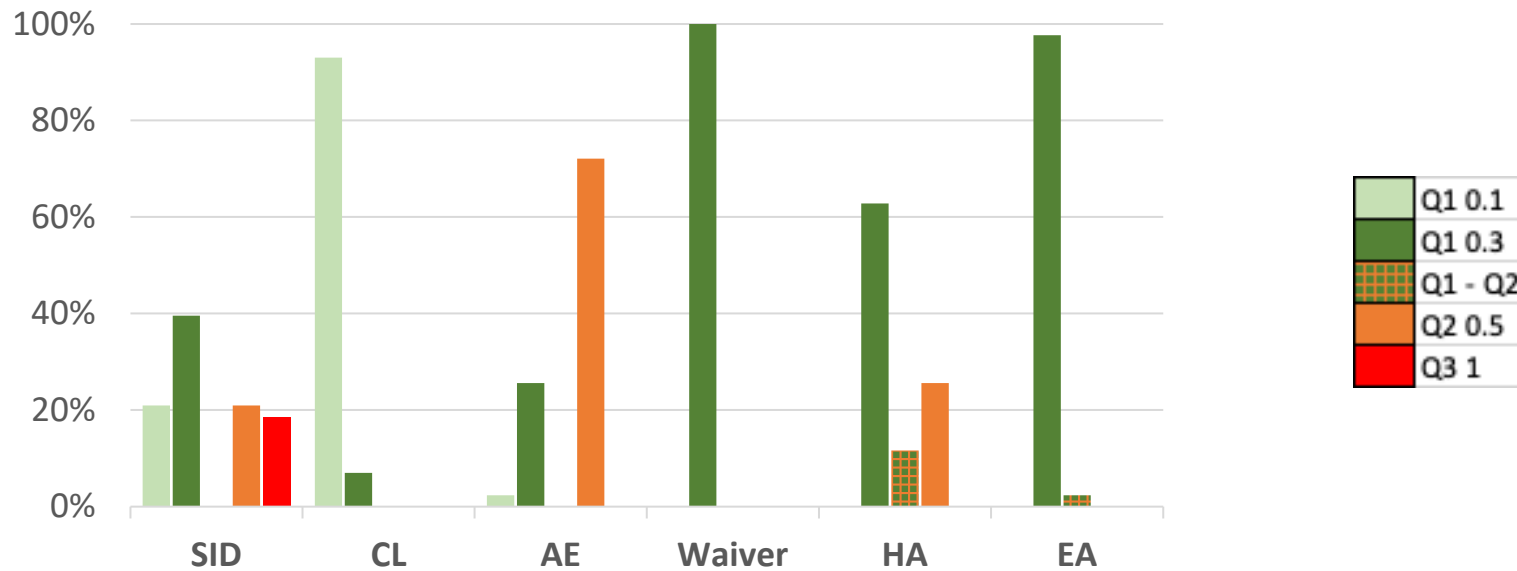
- Q scores (Q1, Q2, Q3) reflect the platform efforts needed for each dossier step update (SID&CL, HA, EA/MvE, cRA, uncertainty analysis, IU templates and CSR)
- Q scores are linked to weighing factors for cost sharing formulas



Screening outcome

All consortia (5)

All registered Art.10 dossiers (45)

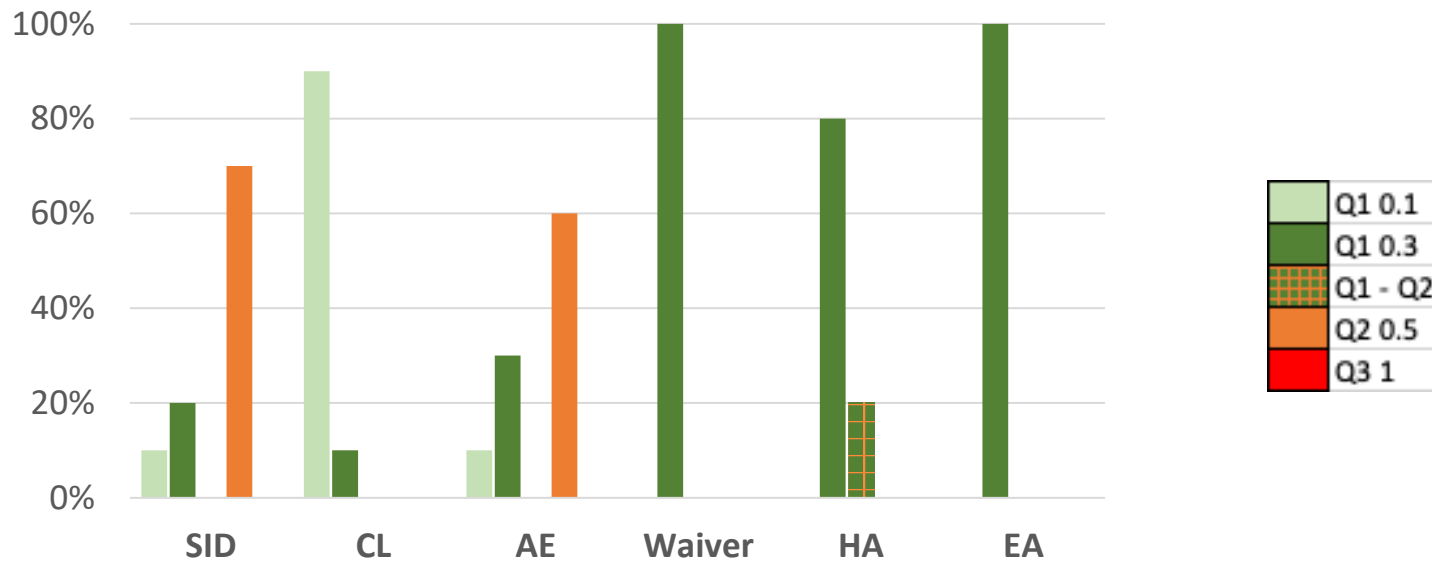


Overall good quality



Screening results EPMF dossiers

Registered Art.10 EPMF dossiers (10)

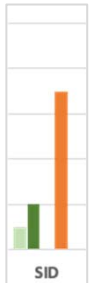


Similar, overall good quality level



Quality criteria assignment - EPMF

	Q1 0.1
	Q1 0.3
	Q1 - Q2
	Q2 0.5
	Q3 1

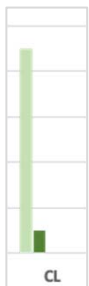


SID

Q 1-0.1: SIP included; elemental & mineralogical compositions are reported, analytical reports are available. Multi-metallic Platform task =

Q 1-0.3: SIP available BUT not included, composition details available (e.g. analytics report) but not included.

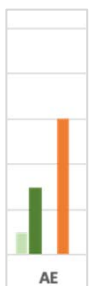
Q 2-0.5: SIP is available but not included *AND* mineralogy/analytical reports are not available.



CL - All consortia use MeClas for CL

Q 1-0.1: multi-metallic Platform task to align all speciation's with their rationale of worst-case selection when unknown species are assessed.

Q 1-0.3: if in addition split(s) envisaged



AE

Q1-0.1: AE approach explained, AEs reported

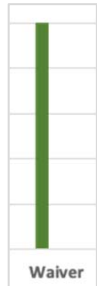
Q1-0.3: AE approach explained, but AEs identification and reporting is partial

Q 2-0.5: AE approach/AEs are not identified, but constituents are assessed in the HA



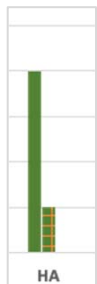
Quality criteria assignment - EPMF

Light Green	Q1 0.1
Dark Green	Q1 0.3
Grid Pattern	Q1 - Q2
Orange	Q2 0.5
Red	Q3 1



Waivers

Q1-0.3 multi-metallic Platform task to align/update waivers and ensure consistency in the dossiers reporting (e.g. biodegradation, hydrolysis, TDp reporting)



HA

Q1-0.1: AE approach/list is complete

Q1-0.3: AE approach/list is to be completed but all AEs are *de facto* assigned

Q 2-0.5: AE approach/list and list of AEs is to be completed/reported (e.g. because only CL AEs were selected for HA)



EA/MvE

Q1-0.3: EA approach is site-specific with monitoring data mainly; MvE refers to AE/constituents MvE assessment

As EA/CSR will be part of the revised TCC, platform attention in the overall building on the IUCLID Section 3 → EA → CSR is needed



Refinables platform update costs based on screening






19 Refinables dossiers

8 Registered dossiers

7 Split dossiers

3 SCC dossiers

1 New dossier

	Q1 0.1
	Q1 0.3
	Q1 - Q2
	Q2 0.5
	Q3 1

	SID	CL	AE	Waiver	HA	EA
1 Doré						
2 Matte, PM						
5.1 Matte leaching residue						
7 Flue dust, PM refining						
8 Residues cementation and reduction, PM refining						
9.1 Materials for reclaim, PM with or without support						
9.2 Materials for reclaim, PM in bricks, crucibles, trays, etc.						
9.3 Materials for reclaim, PM production by-products						
3 Slags, PM - 3.1 Slags, doré furnace						
4 Slimes and sludges, PM - 4.1 Slimes, Ag electrolysis						
6.1 Ag electrolyte (SCC)						
6.2 Au electrolyte (SCC)						
3 Slags, PM - 3.2 Slags, other						
4 Slimes and sludges, PM - 4.3 Residues from PM leaching and dissolution						
4 Slimes and sludges, PM - 4.2 Slimes, Au electrolysis (SCC)						
4 Slimes and sludges, PM - 4.4 Precipitates from PM refining						
6.1 Ag electrolyte (SCC) - 6.3 Nitric Acid solutions from PM leaching and dissolution						
6.2 Au electrolyte (SCC) - 6.4 Hydrochloric Acid solutions from PM leaching and dissolution						
NEW - 10.2 Iron bullion, PGM rich						



UVCB platform technical tasks for EPMF

General, screening-defined dossier needs

Refining/preparing of existing/split dossiers according minimal harmonised requirements

COST = 136.400 € (vs. worst-case 178.750 € (not considering new dossiers))

Additional work outside the iUVCB platform

EA

Update of emission/exposure monitoring data

cRA

Chesar implementation (development scenarios and harmonisation/synchronisation with IUCLID)

Other? Name refining, substance EC descriptions, ...





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iUVCB MISA 3

3rd MISA WS

AIM

- agree on iUVCB assessment strategy
- improve quality & compliance registration dossiers

iUVCB CHALLENGE: Variable concentrations and Unknown speciation

↳ CONSTITUENT / ASSESSMENT ENTITY APPROACH

STATUS

- ✓ **Formal agreement on iUVCB assessment approach**
- ✗ **Current hazard data AE reporting approach not approved**
AE upper study summaries (PNECs/DNELs/Kd/BCF)
 - Not legally compliant (REACH article 10)
 - Not accepted by ECHA completeness check/evaluation unit



Reporting issue

Hazard data reporting solutions

EPMF Slags, doré furnace Refinable examples

Initial request from ECHA (based on legal text)

Include in IUCLID for all AEs:

the full data sets (robust study summaries (RSS)) of all the parent substances

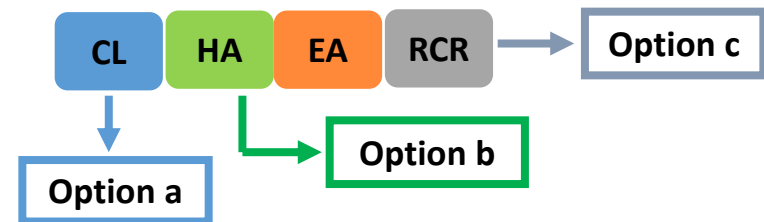
Not workable: IT issue (IU file sizes), data sharing agreements, overall administrative/cost burden

“Lead AE robust study summaries” approach

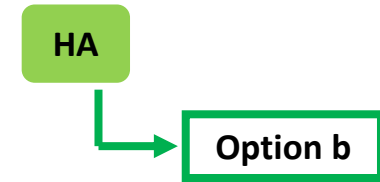
Identify lead AEs for which to include RSS, for other AEs include upper summaries

Feasible: different options to ID lead AE, new data sharing agreements needed

Question: Pros & Cons. Which method?



Reporting issue



Identification of the lead *AEs starting from the hazard assessment of the iUVCB**

$$\text{Lead AE} = \frac{\text{Concentration}}{\text{DNEL/PNEC}}$$

Eurometaux to prepare

- document detailing hazard assessment-based identification of lead AEs
- Slags, doré furnace IU example dossier with all info of “lead AEs” per exposure route

TCC and ECHA evaluation unit

formal agreement on “lead AE” RSS reporting strategy

- Impact on new data sharing negotiations/agreements and MISA timeline?

** aligned with the Lead Component Identification (LCID) Methodology principle developed by Cefic for mixtures assessment*





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EPMF Refinables



Activities and plans

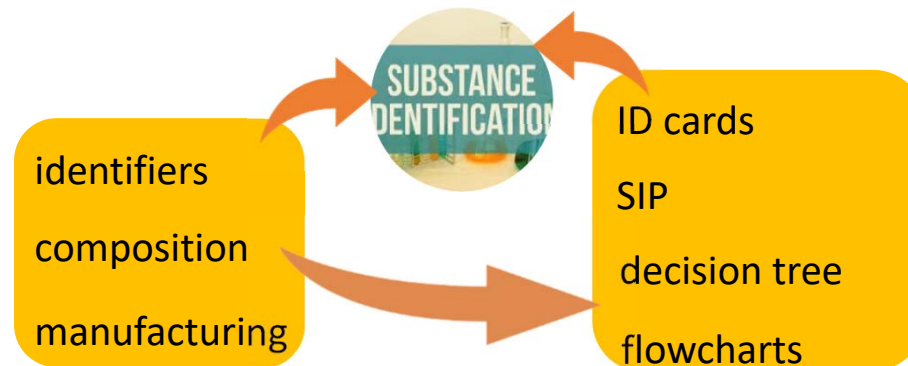
Data and information requirements for iUVCB platform and dossier updates/registrations

Testing



elemental and mineralogical/speciation analytical data reports
phys-chem Annex VII–X requirements for split dossiers
phys-chem data gaps or expert waiving existing dossiers

Information



Activities and plans

Testing



elemental and mineralogical/speciation analytical data reports
phys-chem Annex VII–X requirements for split dossiers
phys-chem data gaps or expert waiving existing dossiers

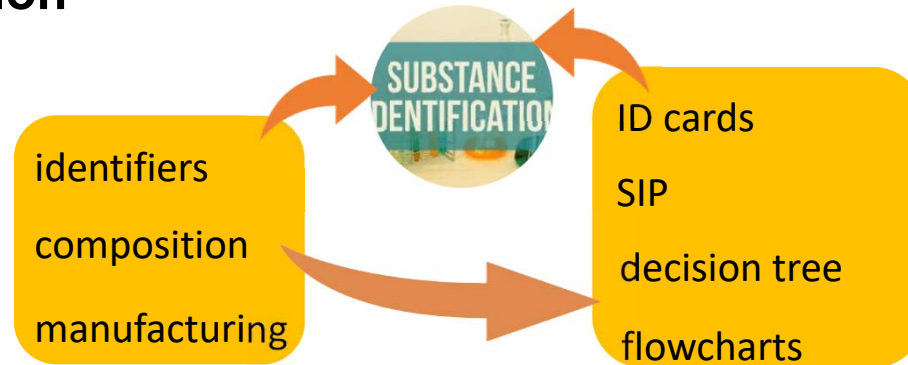
Status

- All CROs contracted
- All samples (ready to) send
- Data expected by end June/July



Activities and plans

Information



EPMF to update/prepare

- substance compositions (boundaries) and CL
- flowcharts and decision tree
- draft SIPs

ONGOING

EPMF & WG (registrants) to evaluate and review

- UVCB naming and description
- EC identifier names and descriptions

UVCB platform?



Budget 2020 status

	EPMF 2020		Committed
	2020 budget	FTE	
21. Refinables	635.800 €	0,5	585.800 €
21.1 REACH registration	0 €		
21.2 REACH dossier maintenance	180.000 €		320.000 €*
21.3 REACH evaluation	0 €		
21.4 REACH classification & labelling	0 €		
21.5 REACH authorisation	0 €		
21.6 Internal and external fixed Scientific Managers	105.000 €		105.000 €
21.7 IUCLID IT hosting system	400 €		400 €
21.8 Knowledge Management tool + hosting	400 €		400 €
21.9 MISA	350.000 €		160.000 €

N.B: *Conservative estimation of samples costs





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2021 Draft budget



Draft 2021 budget

	EPMF 2021	
	2021 draft budget	FTE
21. Refinables	147.000 €	0,3
21.1 REACH registration	0 €	
21.2 REACH dossier maintenance	82.000 €	
21.3 REACH evaluation	0 €	
21.4 REACH classification & labelling	0 €	
21.5 REACH authorisation	0 €	
21.6 Internal and external fixed Scientific Managers	64.200 €	
21.7 IUCLID IT hosting system	400 €	
21.8 Knowledge Management tool + hosting	400 €	
21.9 MISA	0 €	

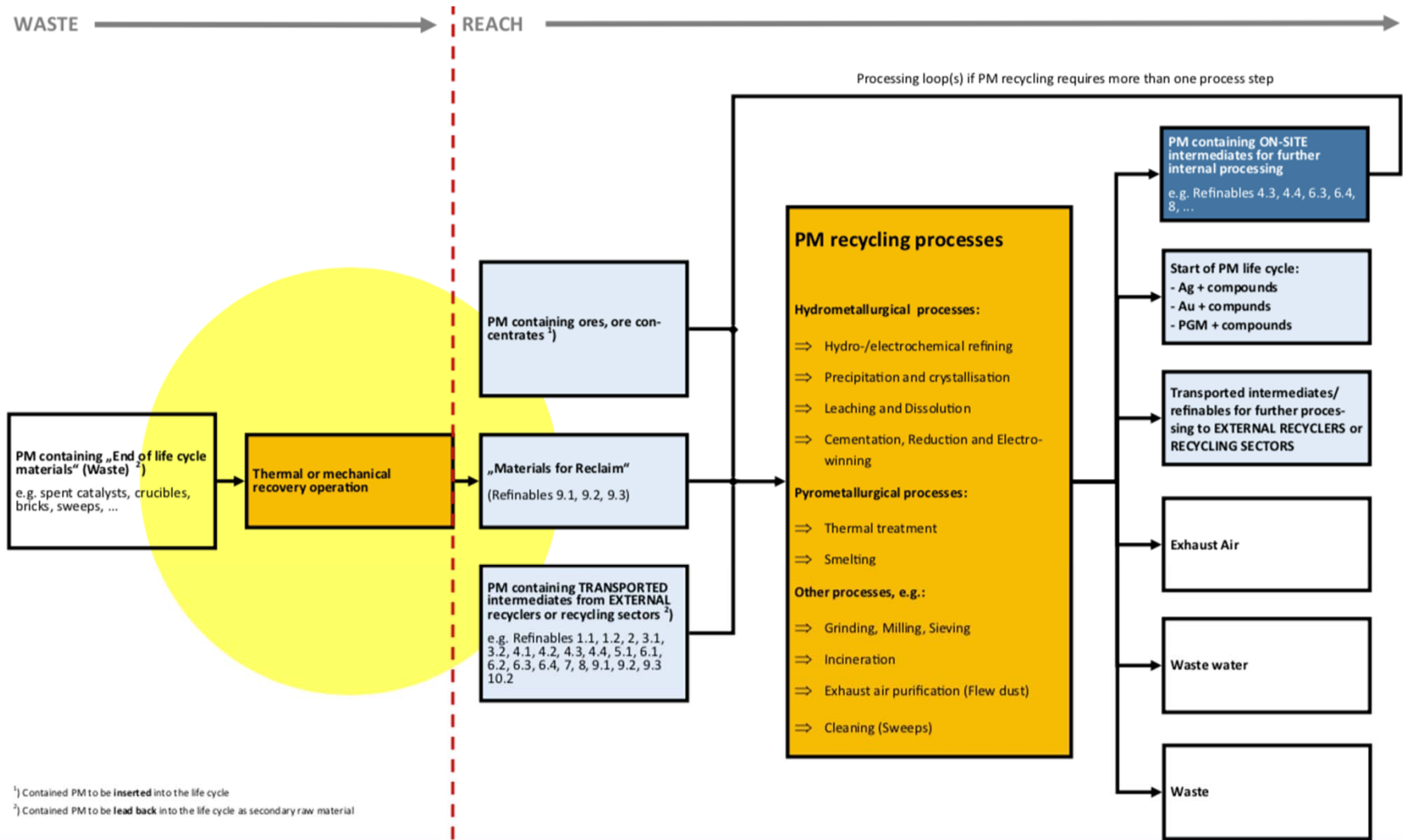
N.B.:

Does not include data sharing agreement costs

**FOR COMMENT /
RECOMMENDATION TO
THE BOARD**



AOB Organise call registrants of Materials for Reclaim substances



¹⁾ Contained PM to be inserted into the life cycle

²⁾ Contained PM to be lead back into the life cycle as secondary raw material





THANK YOU

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