



Precious Metals and Rhenium Consortium *Plenary Meeting*



17 June 2011
Cambridge, UK



1. Welcome and introduction

G. Ethier, Umicore

Welcome



Welcome and introduction



- Confidentiality and Competition Law
- Objective of today's meeting:
 - Review representation and secretariat of PMC
 - Update Members on latest REACH & CLP developments
 - Present 2011 work programme, budget and timeline
 - Present 2012-2013 budget forecasts



Agenda



1. Welcome and introduction



2. PMC organisation



3. Cost-sharing, expenses and budget forecasts



4. Recent developments on REACH & CLP



5. Status and progress of PMC projects



6. AOB, next meetings and closing remarks



Approval of the Agenda



Ag

Actions agreed at the last PMC Assembly meeting (1)



Au

1. Return the completed and signed revised Consortium Agreement, including updated substance and tonnage band declaration (clarifying scc status of intermediates) - **Ongoing**, 8 declarations pending



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2. Return the completed and signed Declaration of Commitment - **Ongoing**, 1 declaration pending



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3. Submit all proprietary data generated over 2007-2010 (Article 3.2.2 (c) of PMC Agreement) to PMC Secretariat - **Done** (mainly PGM)



Pd

4. Update Management Committee (MC) mailing list - **Done**



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5. Arrange a MC conference call to address ongoing/pending actions - **Done**, three cc during Q1 and Q2 2011



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6. Send a formal/legal notification letter to SEKOM to inform the company on its exclusion - **Done**



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7. Discuss CSIRO proposal and revert with revised proposal for approval by Mgmt Cttee - **Done**



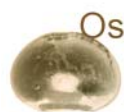
Actions agreed at the last PMC Assembly meeting (2)



8. Launch, supervise and validate additional T/D work on silver to resolve outstanding questions on non-classification of massive silver metal - **Ongoing**



9. Consider revising scope of silver metal registration following release of revised ECHA Guidance on substance identification - **Done**, see item 5.1 below



10. Obtain updated sample trail from Harlan, agree on way forward to return/reimburse samples to sample providers - **Ongoing**



11. Present a formal 2010 budget status report as well as a 2012 and 2013 budget forecasts at the next Plenary Meeting - **Done**, see item 3 below



12. Clarify remaining open questions on OECD HPV programme and add to next Plenary Meeting's Agenda for discussion - **Done**, see item 4 below



Approval of the Minutes of 12 Jan 2011 Meeting



2. PMC organisation

C. Braibant, EPMF





2.1 PMC Chairmanship



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2.1 2011-2013 Management Committee



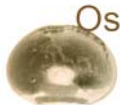
Au

Guy ETHIER, Umicore, Belgium - **Interim chairman**



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Ron DAVIES, Ames Goldsmith, United States



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Gerhard GUTEKUNST, Wieland Edelmetalle + Technologie, Germany



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Marcus HANNAKAM, Heraeus, Germany



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Mohammed MOUKASSI, Société des Fonderies de Plomb de Zellidja, Morocco



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Neville PLINT, Anglo Platinum, South Africa



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Mark RAFFRAY, Johnson Matthey, United Kingdom - **Co-chairman**

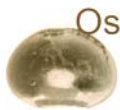


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Jacques SCHAFFNIT, Metalor, France



2.1 PMC Chairmanship



- On 12 Jan 2011 G. Ethier elected as interim chairman of PMC, till Jun 2011 Plenary Meeting:
 - In the absence of nominees
 - According to Article 4.2.1.2 of the PMC Agreement, elections of (Co-)Chairperson must take place every two years
 - A. Griffiths and M. Raffray originally appointed in December 2009
 - Next elections due in December 2011
- **Proposal: Extend interim chairmanship of G. Ethier till December 2011 and proceed to (re-)election at next Assembly meeting**

Vote on the proposal



2.2 Volunteers for (Co-)Chairmanship



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2.2 Volunteers for (Co-)Chairmanship



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- According to Article 4.2.1.2: "*The members of the Management Committee shall elect between themselves a Chairperson and a Co-chairperson for a period of 2 (two) years.*"
- MC members to volunteer for 2012-2014 (Co-)chairmanship
 - Deadline for nominations 1 Nov 2011



2.3 Resources at PMC secretariat



2.3 Resources at PMC secretariat (1)



- Background:
 - Project Manager's employment contract discontinued in Nov 2011
 - Secretariat and Trustee on maternity leave from 1 Feb till 1 Jun 2011



Special thanks to Klaus & Audrey for their hard work and commitment!





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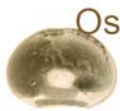
2.3 Resources at PMC secretariat (2)



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- Additional PM Refinables Project Manager approved by Members at 12 Jan 2011 meeting (see item 5.5 below)
- WCA agreed to produce and keep up to date project overviews for projects placed with them (see handouts/to be circulated)
- Need to identify additional Project Manager to cope with upcoming workload
 - Business case will be prepared with MC and presented for discussion/approval at December 2011 meeting



2.3 Resources at PMC secretariat (3)



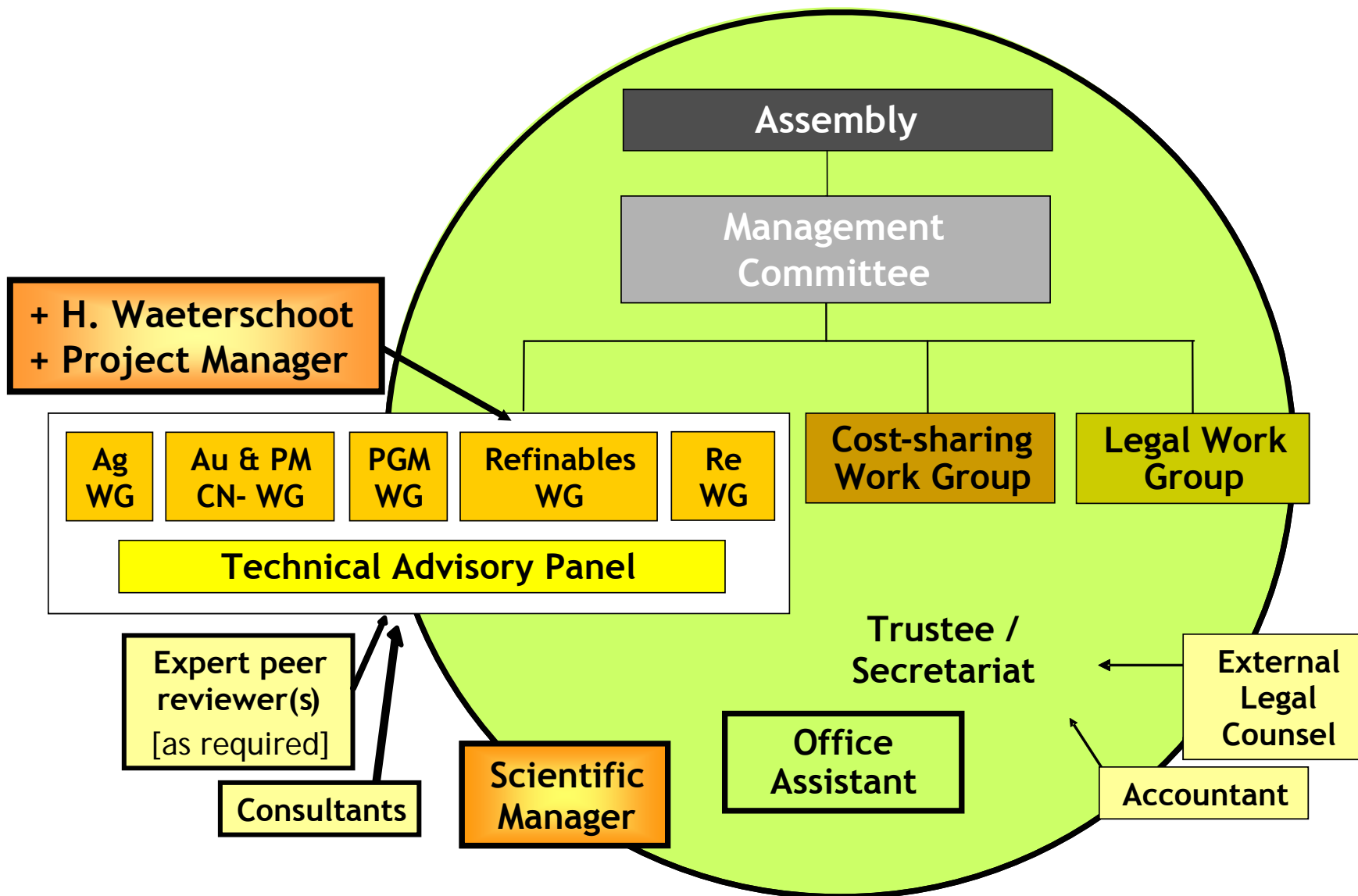
- PM Refinables Project Manager:
 - Job description circulated among Members and PMC consultants based in Belgium
 - Only one profile proposed, distributed to PM Refiners WG for opinion

→ Request from Assembly to support decision of PM Refiners WG

Vote on the request



2.3 PMC secretariat as from mid 2011 (1)





2.3 PMC secretariat as from mid 2011 (2)



Q1+Q2 2011	Ag	Au + PM CN-	PGM	Re	Ref
Coordination	KR	CB	KR	CB	CB
Phase I	-	-	-	-	-
Phase II	KR	CB	KR	-	-
Phase III	KR	*	*	CB	-
Phase IV	KR	*	*	*	-
Phase V	EBRC + WCA	WCA	WCA	WCA	-
Registration update	KR	*	*	*	PM
LoA	AR	*	*	*	AR
Membership applications	AR				
Budget tracking and invoices	AR				
Communication & logistics	AR				



2.4 Internal rules



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2.4 PMC Internal rules



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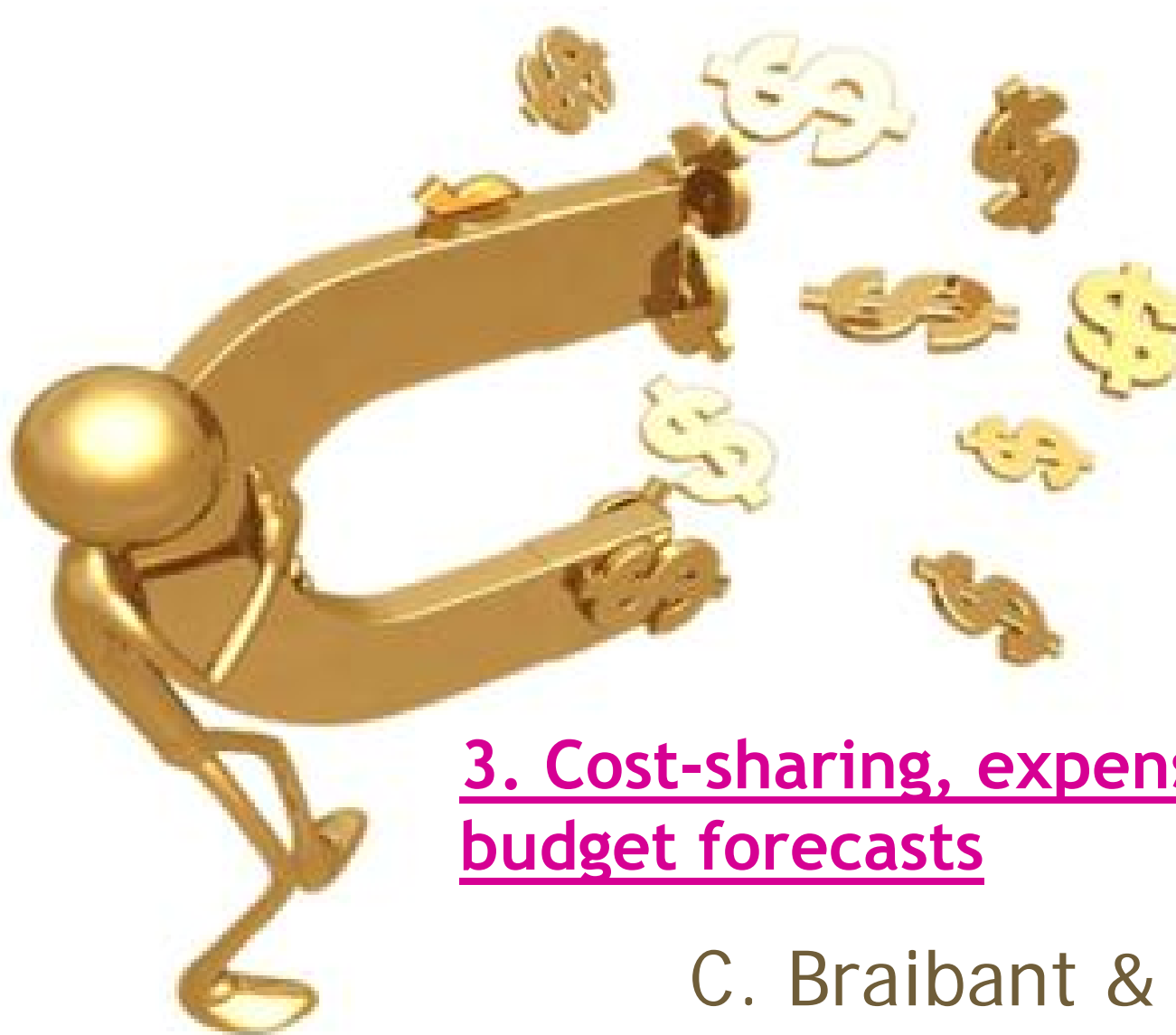


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- To address items which are not detailed in PMC Agreement

- Will also include recommendations from auditors on EPMF-PMC relationship and responsibilities

- Draft will be prepared with MC and presented for discussion/approval at next meeting



3. Cost-sharing, expenses and budget forecasts

C. Braibant & A.
Rondepierre, EPMF



3.1 PMC Cost-sharing formula



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3.1 PMC cost-sharing formula (1)



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Reminder:

- Generic costs distributes evenly
- Metal-specific costs distributed proportionately:
 - Number of substances
 - Tonnage band of each substance
 - Application of "weights"
 - Intermediates = 1 (assumed to be handled under SCC)
 - Transported intermediates > 1000 t/a = 5
 - Substances 1-10 = 5
 - Substances 10-100 = 20
 - Substances 100-1000 = 100
 - Substances > 1000 = 1000



3.1 PMC cost-sharing formula (2)



Recently:



- Dec 2010 ECHA Guidance on Intermediates → adjusted interpretation of strict control



- PMC Members submitted updated substance and tonnage band declarations (8 pending!)



- Consolidation into updated inventories showed following scenarios:

1. Material A as substance and as intermediate
2. Material A as scc and non-scc intermediate



- Scenario 1 already foreseen in existing PMC cost-sharing formula



- Scenario 2 not...





3.1 PMC cost-sharing formula (3)



Proposal for “simple intermediates”:



- Substances **and** non-scc simple intermediates have same information requirements → same weight (according to tonnage)



- Substances/Non-scc simple intermediates **and** scc simple intermediates have different information requirements → different weight:
 - SCC Intermediates: 1
 - Non-SCC intermediates & substances: according to tonnage





3.1 PMC cost-sharing formula (4)



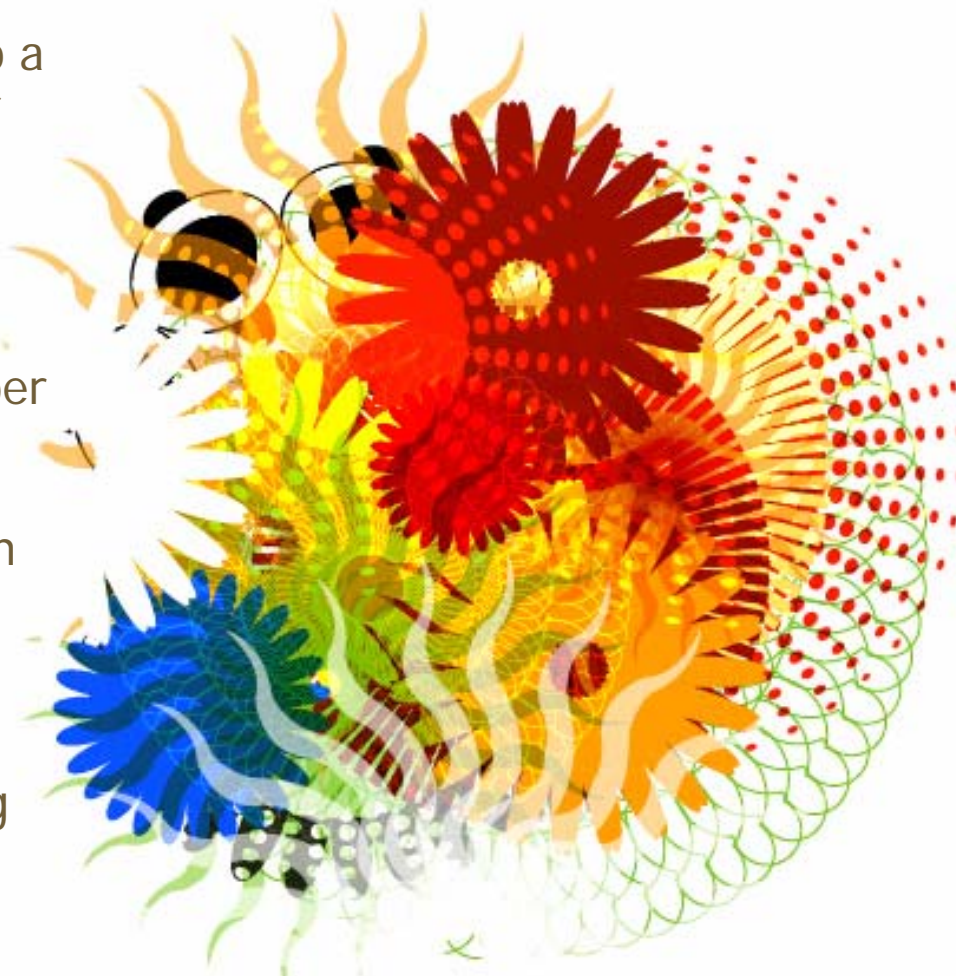
And for complex intermediates...?



- Eurométaux' advocacy strategy:
 - Aims at bringing detail of information requirements to a reasonable/realistic level → UVCB cannot be treated/tested as any other mono- or multi-constituent substance!
 - Will not deliver before Fall 2011 after CARACAL's October meeting



- Assuming it succeeds information requirements are equivalent for scc and non-scc Refinables
- PM Refiners WG therefore recommend keeping cost-sharing formula for PM Refinables unchanged





3.1 PMC cost-sharing formula (5)



Summary:



- Substances and non-scc simple intermediates weighted according to tonnage band
 - Different tonnage bands = different information requirements



- Scc and non scc complex intermediates keep a unique weight of 1
 - Different tonnage bands ≠ different information requirements (as of yet)



All laid down in Addendum to PMC Agreement

Vote on the addendum



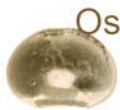
3.2 Final 2010 accounts



3.2 Final 2010 accounts (1)



- 2010 accounts submitted to a voluntary audit to Callens, Pirenne, Theunissen & Co (Belgium)



- Audit completed in May 2011, report expected Q3 2011



- Preliminary conclusions received:

- Accounts ok:

- Total balance of 3.872.525,68 EUR
- Reserve of 3.737.010,98 EUR (including 2010 LoA incomes)



- Need more structure vis-à-vis:

- EPMF c/o Eurométaux, and
- PMC c/o EPMF → From now on one unique budget sheet





3.2 Final 2010 accounts (2)



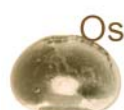
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YEAR	Previous	2010
Budgeted		
EPMF	129.251	103.595
PMC	2.975.290	4.009.742
Consolidated	3.104.541	4.113.337
Incomes		
EPMF	112.709	85.700
PMC	2.975.290	4.083.956
Consolidated	3.087.998	4.169.656
Expenses		
EPMF	81.221	121.504
PMC	1.389.411	1.928.507
Consolidated	1.470.632	2.050.011
Delta		
EPMF	31.488	-35.805
PMC	1.585.878	2.155.450
Consolidated	1.617.366	2.119.645
Produits à reporter		
EPMF	31.488	-4.317
PMC	1.585.878	3.741.328
Consolidated	1.617.366	3.737.011

Approval of 2010 accounts



3.3 Status of 2011 accounts



3.3 Status of 2011 expenses



	Budgeted for 2011 (€)	Spent by 31 May 2011 (€)	Comment / justification
Generic costs	433.626,25	128.043,06 (~30%)	3 mo maternity leave, most salary-related costs occur at the end of the year
Metal specific costs Ag	654.024,00	27.050,33 (~4%)	CSIRO project will run over two years (charged fully in 2011)
Metal specific costs Au	91.980,00	1.893,93 (~2%)	Invoice for work done on CLP and ITS to come
Metal specific costs PM CN -	22.980,00	11.537,30 (~50%)	Invoice for work done on CLP received, invoice for ITS to come
Metal specific costs PGM	766.980,00	5.190,90 (< 1%)	Invoice for work done on CLP and ITS to come Samples not yet reimbursed
Metal specific costs Re	300.955,00	9.125,25 (~3%)	Testing programme recently launched, invoices for test programme to come
Metal specific costs Refinables	792.480,00	120.200,08 (~15%)	Invoice for work done on CLP received, 2011 work not yet invoiced
TOTAL	3.063.025,25	303.040,85	



3.4 Update on LoA costs



3.4 Update on LoA costs



- LoA prices announced in 2010 for Ag and Refinables need to be revised in light of the additional work that is required for these registrations in 2011 and 2012
- LoA prices for other projects may need to be adjusted too
- MC recommendation:
 - Calculate and announce LoA costs after work is finalised (LoA generally sold a few months prior to registration deadline)
 - Have estimated LoA costs at hand and share upon request on a case-by-case basis only with (potential) Members



3.5 2012 & 2013 Budget forecasts



3.5 2012 and 2013 Budget forecasts (1)



- Assembly requested 2012 and 2013 forecasts:
 - 2012 in order to predict likelihood of having a payment holiday in 2012
 - 2013 for information (approval of budgets occur at December Assembly meetings)
- Budget forecast prepared considering:
 - Generic costs:
 - 2-3% inflation
 - 2% salary raises/miscellaneous
 - Proportion of time of each EPMF a.i.s.b.l officer that is invested in REACH and non-REACH activities
 - Belgian workers legislation principles (e.g.: gross salaries multiplied by 13,92 to obtain an annual figure + 0,35% to cover social charges)
 - Agreed fees with external service providers (office rental, insurance, accountancy, etc.)



3.5 2012 and 2013 Budget forecasts (2)



- Budget forecast prepared considering (cont.):



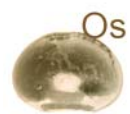
- Metal-specific costs:

- Consultants' (evolving) budget predictions for each phase
- Peer reviewers' and *ad hoc* Consultants' time
- Testing programme's potential costs + 5% for monitoring
- Lump sums or (0-20%) contingency to cover uncertainties/unexpected costs occurring on agreed projects



- More information in cover note to EPMF budget





2012 forecast



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3.5 2012 and 2013 Budget forecasts (3)



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2012 forecast:



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- Most testing programmes will run from mid 2011 till mid/end 2012, followed by CSA/CSR or IUCLID 5 preparation



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- 2012 likely to be “expensive” year



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- However, possibility to use “reserves” in order to enable:
 - Payment holiday for Members, and
 - Decreasing reserves to more manageable figures



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- Simulation prepared by secretariat (cf. next slide)
 - **N.B.:** Reserves subject to review by Accountant, i.e. simulation subject to review too



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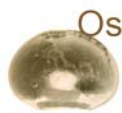


3.5 2012 and 2013 Budget forecasts (4)



- 2012 budget:

- Generic costs: 539 968 €
- Ag-specific costs: 107 980 €
- Au-specific costs: 226 111 €
- PM CN- -specific costs: 159 290 €
- PGM-specific costs: 2 025 744 €
- Re-specific costs: 48 695 €
- Refinables-specific costs: 1 002 980 €



- Simulation performed to evaluate possibility of payment holiday:

- Full payment holiday of 2012 invoices not possible
 - **Proposal 1:** Payment holiday for those projects where reserve is likely to cover 2012 expense predictions
 - **Proposal 2:** Proposal 1 + exclusion of Refinables until further details on ECHA expectations are received (currently worst case assumption, to be discussed at Dec 2011 PMC Assembly meeting), then *ad hoc* invoicing



2013 forecast



3.5 2012 and 2013 Budget forecasts (5)



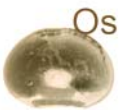
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	2011	2012	2013	
Ag	Soil + water + classification		IUCLID 5?	
		90d?		
Au	Phys-chem + ecotox + bio- accessibility	Mamm tox testing?	CSA/CSR?	IUCLID 5?
PM CN-	Phys-chem + modelling	(Eco-)tox testing?	CSA/CSR	IUCLID 5?



3.5 2012 and 2013 Budget forecasts (6)



	2011	2012	2013	
PGM	pH + H2O sol. + phys-chem + dustiness + T/D + bio- accessibility + <i>in vitro</i> mamm	(Eco-)tox testing	CSA/CSR?	IUCLID 5?
		CSA/CSR?		
Re	Mamm tox testing	IUCLID 5? CSA/CSR?		
Ref	Exposure data generation / collection + revise classification	Dossier update / upgrade		



Ag

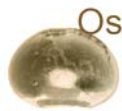
3.5 2012 and 2013 Budget forecasts (7)



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- 2013 forecast:
 - From above tables, if all projects run as planned, 2013 should be a year of CSA/CSR and IUCLID 5 finalisation
 - Already (partially) considered in 2012 budget
 - Metal-specific costs limited to IUCLID 5 Hosting System and 50 000 € lump sum
 - Will be reviewed in mid 2012 and adjusted in line with progress made in the coming year



4. Recent developments on REACH & CLP



Content

- Some generic learning lessons
- Intermediates
- Updates of Registration files
- CLP challenges
- Authorisation (Hydrazine and Borax)
- OECD I-HPV program

4.1 Some generic lessons from...



V. Verougstraete
& H. Waeterschoot,
Eurométaux

...Helsinki

based on experience with:

- ✓ Borates, Lead (Restrictions)
- ✓ First dossier evaluations
- ✓ Harmonised classifications
- ✓ Authorisation
- ✓ ECHA cooperation with OECD
- ✓ ...

EXPERTISE/EXPERIENCE
is still minimal but
certainly already quite
indicative



Student Life
@ the University of Denver

**first & second
year
EXPERIENCE**

... from the ECHA Committees

Risk Assessment Committee (RAC)

Socio-Economic Assessment Committee (SEAC)

Member States Committee (MSC)

1. Content wise

- **Assessment factors (AF):** ECHA Guidance Default AF should be strictly followed unless substance specific justification. Those cases are reviewed *in extenso* during dossier/substance evaluation
- **Exposure assessments** of downstream users are CRITICAL !!! Assumptions always modelled in case of absence of trustful data!

- ★ ■ **Metals experience** of ECHA team is limited. Eurometaux has therefore set up extensive training for ECHA evaluators
- ★ ■ ***Prioritisation and selection*** schemes for R, A, Cl&L, and presumably also for Evaluation are not recognising metal specificities !

★ **Conclusion:** invest in data gathering (tox, exposure DU's, SEA,...). Assessments for Restrictions/Authorisations /Evaluation went always ***FAR beyond*** regulatory REACH minimum !



★ 2. Process wise



- **ECHA formal programs** run fast & according to strict time schedules



⇒ Carefully follow agenda planning on Evaluations, Testing planning, Restrictions and Authorisations



- **Non-PM substance aspects** may have impact on sector



⇒ Borax on Candidate list and potential prioritisation for annex XV in 2012 ?



⇒ Hydrazine potential Candidate substance





■ Aspects discussed on **other substances may have impact on PM:**



⇒ **Harmonised classification of UVCB's**: Coal Tar Pitch setting precedence for UVCB intermediates



⇒ **Restrictions** on Lead in jewellery and Borates in Photographic application setting precedence on assessment methods for Ag



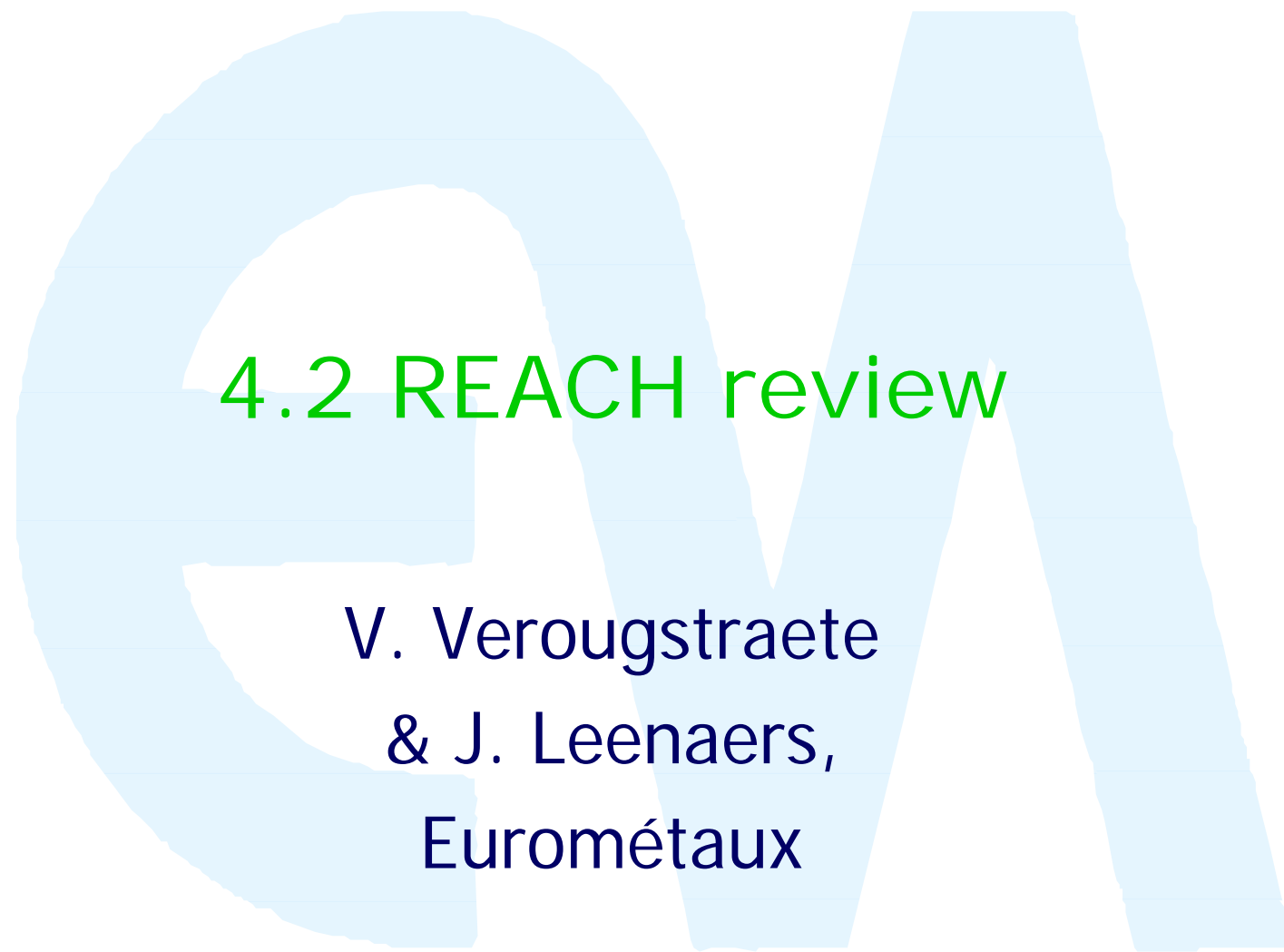
⇒ Cu and Cu compounds **Environmental Hazard review** (end 2011) : set precedent for Ag environmental assessment (assessment factors, statistics, ...)



⇒ Minimal **Testing requirements**: 90 days repeated dose is often obligatory and cannot be waived that simply



⇒ ...



4.2 REACH review

V. Verougstraete
& J. Leenaers,
Eurométaux



REACH Review

Background

- According to Articles 138 (3), (6) and (7), the Commission has an obligation to assess whether there is a need to review the legislation:
 - on the scope by 1 June 2012
 - on the scope of article 60 (3) to substances identified under Art. 57 (f) as endocrine disruptors by 1 June 2013
 - requirements for substances manufactured or imported in the tonnage band between 1-10 tonnes (on the basis of art. 117 (4))
- Experiences gathered by the Commission will also be taken into consideration
- Other issues
 - ✓ Information requirements for nanomaterials
 - ✓ Combined exposure
 - ✓ Authorisation requirements

REACH Review

- The Commission is currently assessing how they want to handle this review exercise. They have already indicated that they are not keen to open the text for review
- The Commission will be launching a series of 12 projects, carried out in view of the assessment of the need to review the REACH Regulation
- Interim results from the studies are not foreseen to be made available by the COM

Whether a review is to take place and to which extent still remains an open question !!!

REACH Review:

COM projects carried out in preparation of the review

1. Assessment whether or not to amend the scope of REACH to avoid overlaps with other relevant Community provisions. – contractor: Milieu
2. Experience acquired with the operation of REACH – contractor: RPA
3. Nanomaterials in REACH registration dossiers and adequacy of available information – in-house (JRC)
4. Inspections requirements for REACH and CLP – contractor: Milieu
5. The (nominal) risk caused by chemicals in 2012 compared to the 2007 (a follow-up of the baseline study of REACH) – contractor: DHI
6. Functioning of the European Chemical market after the introduction of REACH regulation – contractor: CSES
7. Impact of the REACH regulation on the innovativeness of EU chemical industry – contractor: CSES
8. Health and environmental benefits of REACH – to be decided
9. Registration requirements for 1 to 10 tonnes substances and polymers – to be decided
10. Review of the European Chemicals Agency (ECHA) based on Article 75 of Regulation (EC) N° 1907/2006 – contractor: PWC
11. The REACH contribution to the development, commercialisation and uptake of products of emerging technologies – to be decided
12. Implementation and enforcement of restrictions in Member States – contractor: Milieu

REACH Review

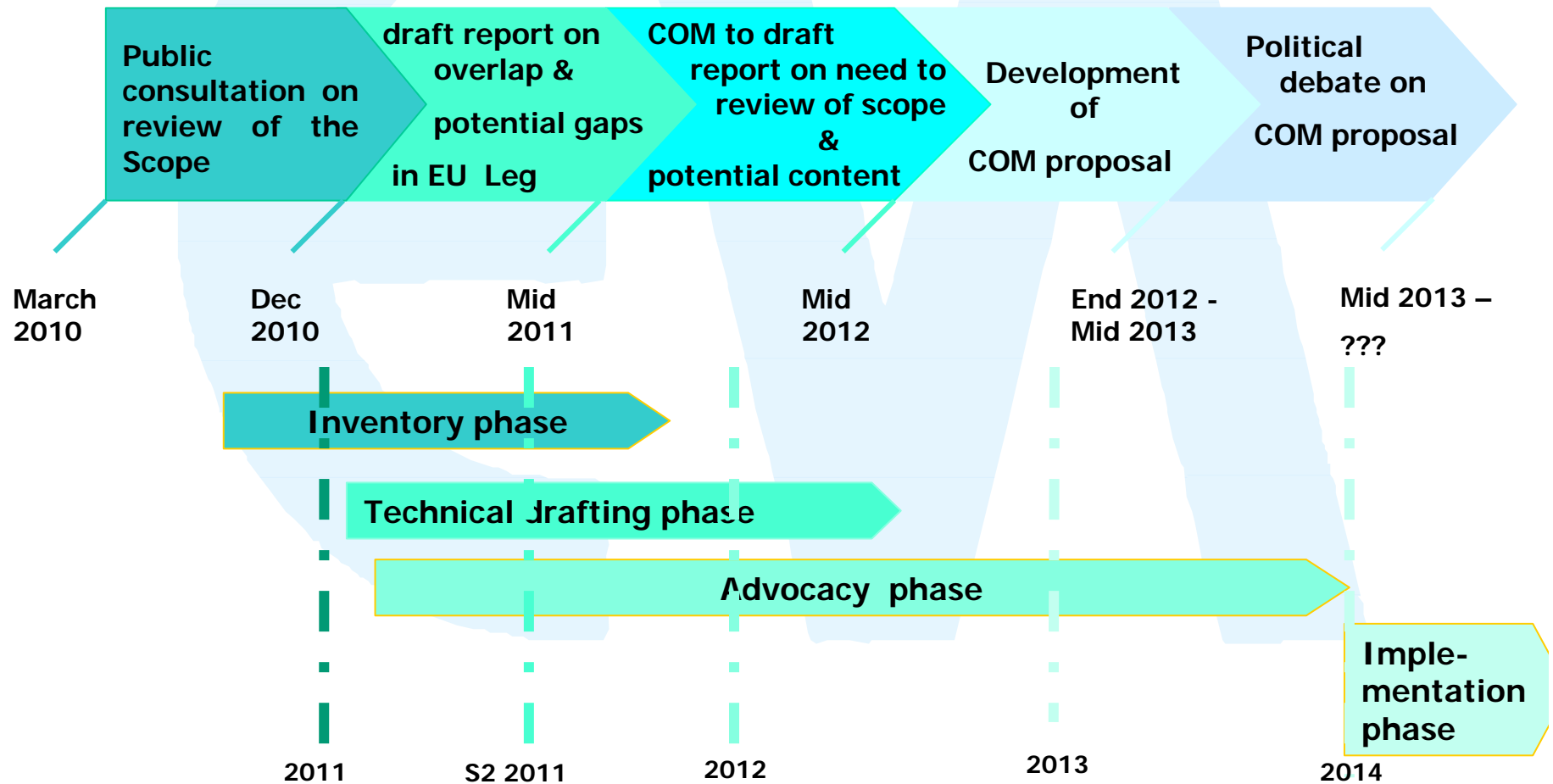
EM strategy

Eurometaux has developed an action plan consisting out of 3 major phases

- 1) Inventory phase: Identification of potential changes: treats and opportunities, review of experience with consortia
- 2) Technical development phase : define key messages, examples, possible solutions
- 3) Advocacy phase : search and identify for relevant alliances & advocacy plan

REACH review

Potential timeline



REACH Review

Key policy statements (1)

Ensure that REACH implementation practices are consistent with the principle of proportionality and not prejudicial to other Community policies and goals. This “policy coherence” dimension needs to be respected at all levels of operation

- ✓ Alignment of the REACH objectives with the latest EU goals on climate change, energy and resource-efficiency, security of supply of raw materials, critical material initiatives, and sustainable development
- ✓ Application of the precautionary principle in ECHA decision making
- ✓ Increased transparency of the agency

REACH Review

Key policy statements (2)

Recognition of the specificities of metals to ensure fair treatment versus organics

- ✓ Adaptation of certain methodologies and recognition of specific metal properties (e.g. statistical corrections for (very) data-rich substances, bioavailability corrections, correction for essentiality, particle size deposition modelling, special mixtures)
- ✓ Availability of monitoring data

Greater recognition of industry as a equal partner towards ECHA and the Authorities.

4.3 Strictly controlled conditions

V. Verougstraete
& H. Waeterschoot,
Eurométaux





Issue

- **New Intermediate guidance** published in December 2010

- ✓ Much stricter interpretation of SCC
- ✓ Beyond what industry was expecting as “update”
- ✓ Identified the need for Industry position and alternatives (see Eurometaux position)

What to do?

- SCC or “not” : RCoG can help !!!
- Ongoing policy discussion: resolution not that simple but door not closed !
- Update of in-house documentation (Appendix 2) and Registration file information (Appendix 3) required
- Pragmatic Technical solution is a must to avoid irrelevant testing in case SCC cannot be proven (also for PM refinables)

RICoG

- SCC interpretation will depend (anyway) on "**Hirst *et al. (2002) scheme***" (see next slide)
- RICoG forms ***assessment tool*** based on Hirst scheme
- RICoG is an ***electronic support tool*** for decision making but leaves final judgement/interpretation to company
- ***Investment***: 5.000-10.000 € depending on n° of Consortia that join

Strategy 1: Controlled general ventilation



No special engineering requirements; adequate control is achieved by general ventilation of the process area.
(This strategy is not covered further in this guide)

Strategy 2: Local exhaust ventilation



A Local Exhaust Ventilation (LEV) system is used to contain the contaminants within a defined area and draw airborne contaminants away from the operators' breathing zone. This can involve either:

- a good point exhaust ventilation; or
- a unidirectional air-flow booth.

This can achieve significant reductions in operators' exposures to the concentrations of airborne dusts and vapours generated during open transfer operations of hazardous materials.

Strategy 3: Open handling within isolator



or

High-integrity closed coupling without external containment

Open transfer or handling of hazardous materials takes place within an isolator.

Typically this might involve surrounding the transfer operation with a fixed or flexible air-tight barrier. Containers of process material may be placed in or removed from the isolator only in a way that does not compromise the integrity of the containment it provides. The operator uses a glove-port to effect the transfer of material to or from the open container and to clean empty containers.

This Containment Strategy can also cover transfers effected by means of a high-integrity coupling between closed containers without an external isolator.

Strategy 4: Closed handling within isolator



Closed transfer or handling of the hazardous material takes place within an isolator.

This is similar to the preceding strategy except that open transfer is not permitted even within the enclosure. The operator, again using a glove-port or similar device, attaches the closed container directly to the access port for the process to form a closed connection and then opens the valve to effect the transfer of material.

Strategy 5: Robotic handling, contained system



This strategy is adopted for materials so hazardous that even with a closed transfer system the use of a glove-port represents an unacceptable risk because of the possibility that the gloves could rupture. The transfer therefore has to be effected by a fully automated enclosed process. The strategy requires highly specialized training and should be prepared and implemented only after consultations with experienced health and safety professionals and the HSE.

Rigorous containment guide (RiCoG)

1st step:
Assessment of exposure potential

BETA-VERSION DO NOT USE FOR REGISTRATION!!!

© 2011 EBRC Consulting GmbH
D. Vetter
Hannover, Germany

Assessment of exposure potential (EP)

Boiling point (°C) of intermediate

not known
none (liquid)
< 1 L

Parameter

1st output:
Group of exposure potential

2nd step:
Hazard group determination

EP3

Hazard group determination

Occupational exposure limit (vapour) or DNEL/DMEL
H303, H304, H305, H313, H315, H316, H318, H319, H320, H333, H336, H-numbers not listed
H302, H312, H332, H371

50 - 500 ppm

None of the H-numbers assigned to intermediate
No
No
No
No
Not applicable

Parameter / Remarks

2nd output:
Hazard Group

3rd step:
Parameterising of containment strategy

EL/DMEL not set/derived.

A

Implementation of containment strategy (CS)

Description	Controlled general ventilation
Used equipment	No special engineering equipment
Level of containment	none
Breaching occasions	undefined
Leakage prevention	none
Treatment of contaminated air	undefined
Maintenance	undefined
Level of contact	undefined

Suggested improvements

Open handling within isolator OR high integrity...
Fixed or flexible air-tight barrier...
Plant and equipment totally enclosed

3rd output:
Containment strategy

Main output:
Evaluation of containment strategy

Currently implemented containment strategy

Evaluation of containment strategy

Containment strategy to be implemented (minimum requirement is CS3)

Demonstration of rigorous containment

Not achieved

Policy solution:

- Eurometaux/Cefic suggestion: turn back to compromise reached at PEG level in October where matrix form and knowledge on hazards recognised!
- Advocacy campaign started
- CARACAL meeting (7-10 June)
 - Discussion took place in closed session
 - Aligement between Cefic and Eurometaux at high level
 - Netherlands made opening!!!!

Conclusion: door is not (yet) closed but far from open too and reaching the goal will be difficult and very time-consuming!!!

To conclude

- **New guidance** would lead to more than 80% of Refinables requiring upgrading!!!
- **Political compromise** required for a reasonable solution (< end of 2011) !!
- **Prepare updates** (in-house documentation and Registration) before end of 2011 to avoid non-compliance
- Several Refinables will anyway require **upgrades**:
 - ✓ Start with tiered exposure data collection program (anyway required)
 - ✓ Wait with further effects work until political and technical clarification on test waiving and SCC conditions



4.4 Authorisation

V. Verougstraete
& H. Waeterschoot, Eurométaux
M. Raffray, Johnson Matthey

Authorisation

★
★ **BORAX:** used for slag formation, ...

- ★ ■ On candidate list and reviewed for prioritisation for Annex XIV
- ★ ■ This year not selected (first grouping) but chances for selection next year (very) high (unless exempted!)
- ★ ■ ***Consequences*** for Ag sector :
 - ★ ■ Prepare for Authorisation applications (costly !) and difficult
 - ★ ■ Prepare for AoA : Analysis of Alternatives
 - ★ ■ Prepare for SEA : Socio Economic Analysis (unless threshold is accepted)
 - ★ ■ Prepare for Safe Use demonstration: (unless non threshold)

★ **All this may need to be launched almost immediately in 2012**
★ **Has sector experience or AoA or SEA evidence gathered?**

★
★ **Hydrazine:** used in refining

- ★ ■ Proposed for Authorisation candidate list !
- ★ ■ Will be reviewed for prioritisation for Annex XIV from next year on. Unknown what priority would be.
- ★ ■ Please use Public Consultation to:
 - ★ ■ Submit data that could lower the prioritisation: safe use demonstration, low exposure, n° of workers exposed, ...

★
★ **Learning lesson** from Arsenic and Borates case :

- ★ -Do not underestimate impact on resources and data gathering needs
- ★ -Experience with system is critical
- ★ -Do not necessarily expect producer/importer takes lead on Authorisations



Ag

Hydrazine - Candidate List inclusion



Au



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Pd



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Ru

- Hydrazine included in latest 7 substances agreed as SVHC added to REACH Candidate List
 - Based on CMR properties
 - Member State Committee 18th meeting; end May
 - Why ► visibility from less contained & dispersive uses ?
 - Experience of prior Annex XV proposals ► likely this was going to be agreed by MS
- Why is this important to sector
 - Hydrazine used extensively as reductant in PM refining
 - But in contained manner ► minimal exposure & emissions



Hydrazine - Candidate List inclusion

- Implications/threat

- Real concern would be if hydrazine was **Prioritised** for inclusion in Annex XIV (requiring **Authorisation**)
- Burdensome & costly Authorisation duties for users (+ producers)
- Uncertainties about security of supply

- Actions so far

- Sector contributed to report produced by ECHA's consultant
- Important point: case for lack of alternatives in refining applications
- Degree of containment ► low exposure/low emission



Authorisation threat - Strategy



What next ?



Track developments ► will it be prioritised for Annex XIV ?



YES



EXEMPTION

- Annex XIV proposals undergo consultation period
- Make case for exemption of PM sector uses of hydrazine



AUTHORISATION

- Fallback if exemption pitch does not succeed
- Alternatives issue crucial





Exemption route



Basis

Article 58(2) of REACH: possible to exempt from the authorisation requirement some **uses or categories of uses** provided that based on **existing** specific EU legislation imposing minimum requirements for protection of human health & environment the risk is properly controlled



Arguments

(a) contained and non-dispersive/non-diffuse use in this application



(b) that existing regulatory controls are adequate in this instance



May be able to leverage secondary argument on absence of reliable substitute technologies



Authorisation route



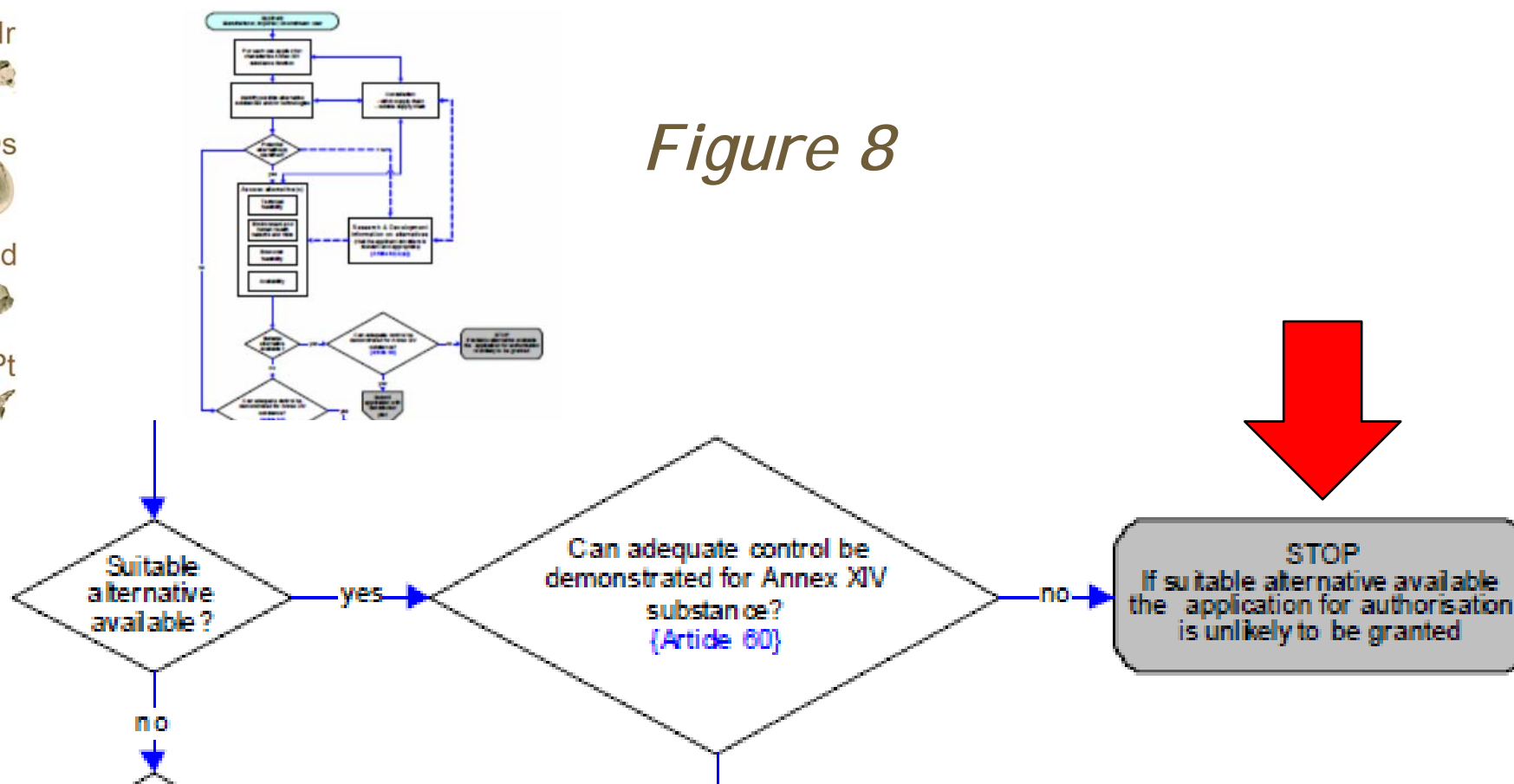
- Non-preferred as option
- Non-threshold CMR ► “adequate control of risks” not an option in Authorisation procedure
- Need for SEA triggered
- **Key success criterion would hinge on Analysis of Alternatives (AoA)**



Authorisation route

ECHA Guidance document on Authorisation

Figure 8



★ CRITICAL for REACH in the future

★

★

★

★

★

★

★

★

★

★

**Follow the FORECAST
and ANTICIPATE NEEDS**





4.5 Registration dossier updates

V. Verougstraete
& H. Waeterschoot,
Eurométaux

Content wise...

- Guidance on “New endpoints” requires updates of existing registration dossiers:
 - ✓ *Waste and end-of-life*:
 - ✗ important endpoint for the PM sector
 - ✗ so far not included
 - ✗ preferably to be done before the end of the year
- Update due to new information from ongoing/additional testing programmes:
 - ✗ If covered by Testing Proposal: MSC review binding
 - ✗ If voluntary: Update registration asap
- Update RC or ES as a function of other dossiers:
 - ✓ Requires *continuous attention!!!* and follow up (e.g. Assessment factors)

Process wise...

- Registration dossier submitted by LR on behalf of co-registrants
- Co-registrants contribute to cost of joint dossier via:
 - ✓ Consortium membership
 - ✓ LoA
- When new information becomes available or upon request by ECHA a Dossier may need to be updated...:
 - ✓ Update submitted by LR on behalf of co-registrants
 - ✗ Consortium members contribute to cost of update
 - ✗ What about LoA purchasers?
- ECHA to consider mechanism by which cost of update is shared by all co-registrants in a proportionate manner

★
★
★
★
★
★
★
★
★
★
★

4.6 Update for 2010 CLP notifications

V. Verougstraete
& H. Waeterschoot,
Eurométaux

C. Braibant, EPMF



CLP challenges

STOT:

- Inhalation studies for poorly soluble particles of low toxicity often lead to STOT classification for non-toxic substances, due to:
 - Low cut-off levels
 - Inappropriateness of rat model
- Raised at UN
- Inhalation workshop will be held before end 2011

Chronic Environmental Ecotox:

- New hazard endpoint (ex GHS)
- To be assessed, notified & labelled < 1 December 2012
- Recommended to start assessment in 2011
- Endpoint contains ***new aspects***:
 - New concept: Removal from the water column
 - Different classification triggers if (non) removal
 - Different M factors (critical for alloy use and prioritisation schemes)



★
★ → Requires:

- ★ ✓ Determining chronic reference values
 - ★ ✗ No new testing required
 - ★ ✗ Update/review of existing aquatic data base
- ★ ✓ Determining “Removal from water column”
 - ★ ✗ Unit World Model (UWM) → new demonstration tool
 - ★ ✗ Combined exercise by Eurometaux for the metals sector (July)

★ UWM will **not necessarily change classification** BUT:

- ★ - If positive, will lower ranking in prioritisation schemes!
- ★ - Influences the M factor so benefits the alloys case



4.5 Update of 2010 CLP notifications (cont. 1)

- Notifications submitted in 2010 contained all information available by 30 Nov 2011
- Since, additional information has/will become available from PMC testing programmes and/or Members



Late sample supply = delayed results!

Expert judgement vs. Testing results

Default vs. Refined read-across

Parallel testing work:

- Communicate with PMC secretariat
- Avoid duplication of work/costs!



Ag

4.5 Update of 2010 CLP notifications (cont. 2)



Au

How to prepare update?



Ir



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Ru

What?	Who?
1. Gather new/corrected data	All
2. Derive applicable DSD/CLP classification and prepare submission	Consultants
3. Inform relevant sector	PMC secretariat
4. Update classification in REACH-IT	Each notifier



4.5 Update of 2010 CLP notifications (cont. 3)



How to submit update?



Company

Pre-registration

Pre-SIEF

Online dossiers

Phase-in Information

Registration / notification

Joint submission

Classification and Labelling

Message box

User account

Legal entity change

Invoices

Search

You are connected as [braibant](#) on behalf of EPMF - [Preferences](#) - [Logout](#)

[Home](#) > [Online dossier creation](#) > [C&L notification](#) > [Dossier selection](#)

You have selected to work with **C&L notification** dossier.

You have three possibilities to create an online dossier in REACH-IT:

Create a new dossier

Continue/finish the creation of a dossier

Update a completed submission?

Notification number that has been granted after a successful submission of a C&L notification.

Fields marked with an asterisk (*) are mandatory.

Reference number: [Validate number](#)

[Cancel](#) [Next >>](#)

Next steps are equal to those followed to submit the original notification



4.5 Update of 2010 CLP notifications (cont. 4)

When to submit update?

- Article 15(1) of CLP:
 - *Manufacturers, importers and DU shall take all reasonable steps to **make themselves aware of new scientific or technical information** that may affect the classification of the substances or mixtures they place on the market.*
 - *When a manufacturer, importer or DU becomes aware of such information which he considers to be adequate and reliable, [...] (he) shall **without undue delay** carry out a new evaluation in accordance with this Chapter.*
- **Make ourselves aware:** through Consultants, Members, ongoing REACH test programme
- **Without undue delay:** need to determine/justify best approach
 - *Ad hoc* → following availability and validation of data
 - By batches → on a regular (frequency tbd) basis
 - Not before registration → when all data is collected, evaluated and validated, and then regularly after that
- **Best approach will be prepared with each project WG and presented for discussion/approval at December 2011 meeting**



4.7. Remaining questions on OECD programme

Background



- **SIACM** requires UN countries to implement Chemicals management strategies < 2020
- Several UN countries prepare **REACH look-a-likes** (Korea, Japan, China, ...)
- **IUCLID 6** will be a joint OECD-EU database
- **ECHA outsources** all new “read-across” and test guideline developments to OECD
- CLP changes and guidance only when approved and implemented by UN (alloys,...)
- ...

Chemicals management internationalises
and REACH is a reference

I-HPV

- **I-HPV:** Voluntary program of metals and mining sector with **OECD:**
 - OECD Workshop 7-8 September on metals effects assessment for Chemicals management
 - 2011-2014 voluntary submissions/reviews of metals files
- **Aim:** obtain OECD quality label on REACH effects dataset to allow companies using it for other jurisdictions
 - More and more countries are joining the Mutual Acceptance of Data (MAD) agreement
- **Benefits:** avoids retesting for other jurisdictions
- **Data protection:** assured by OECD. Data ownership must be demonstrated before use!
- **Workload:** +/- 2 to 3 months 1 FTE (= fraction of any additional Chemicals management requirement)

Eurometaux recommendation:

- Follow activities of OECD
- Consider voluntary submission (2012-2014)



Q&A

At 12 Jan 2011 Assembly meeting, following questions were raised:

- Which other commodities have agreed to participate in this initiative?
- What is its/their experience with OECD in previous and the current programme?
- How faithfully is the data contained in the REACH file summarised and do owners have commenting rights?
- How would new data be considered/added in the SIAR and when?

OECD- IHPV program

1. Which other Commodities agreed to participate in the OECD program?

- ✓ OECD-IHPV program is a **voluntary program** (2011-2014) so formal commitments are not required but intentions are collected for planning purposes.
- ✓ Cu, Cu compounds, Zn, Ni (compounds), Co (compounds), Sb (compounds) and others indicated intentions. Moreover, it is expected that many others will follow as soon as authorities in other jurisdictions start announcing reviews*. Cu expressed willingness to act as test case after the OECD workshop.

* Problem is however that the OECD system is not fast so if Japan would screen Ag they may request testing requirements and reviews before the OECD comes to a SIAP report.

OECD- IHPV program

2. What is their **experience with OECD** in previous and current program?

- ✓ *No experience yet with the new system* but process and procedures are the same as with the old system (EDF, SIAM, SIAP, SIAR, (in)direct submissions,...). The difference lays in the recognition of different / amended effects assessment guidance requirements for metals and metal compounds. Cu and Cu compounds will test this and the Italian government has indicated to be eager to introduce the case.
- ✓ Cd and Cd compounds, Zn and Zn compounds and Ni and Ni compounds passed the OECD HPV-SIDS *programs in the last years*. Overall conclusions are :
 - ✗ Much more neutral science technical based discussion than at EU level
 - ✗ Even the more political cases like Cd or Ni got a neutral technical review
 - ✗ Providing good network with relevant authorities in other jurisdictions
 - ✗ SIAP reports were effective to stop / steer reviews in countries
 - ✗ ...



OECD- IHPV program

3. **How faithfully** is data contained in REACH files summarised and do owners have **commenting rights**?

- ✓ *How faithfully is data contained in REACH files summarised:* The OECD IHPV programme reviews quality and relevance of existing info and does not judge what additional work should/could be done.
- ✓ Owners (PM industry) remain always (10 y's) the owner of the data (they gathered) and owners are full participants in the process (like countries).
- ✓ Owners get BIAC status and can participate in discussions and reporting as any OECD country can.
- ✓ Under the voluntary program owners would even have the possibility to draft the conclusion report (SIAP) for the SIAM meeting and discuss it with the MS's.

OECD- IHPV program

4. How would **new data be considered/added** in the SIAR and when?

- ✓ The EDF and SIAM meeting focus on submitted evidence from the submitter and review the quality of that.
- ✓ Other MAD parties can submit other existing studies they are in possession of and which were not included in the original submission. The submitter can comment on these (on the EDF) and include the new references, or not if they do (not) meet the quality criteria.
- ✓ The outcome of this discussion is then presented at the SIAM meeting.
- ✓ Data approved by SIAM can not be contested in other jurisdictions and can be used by the owners for chemicals management obligations or other purposes. Additional new info can of course be introduced at that stage.



5. Status and progress of PMC projects



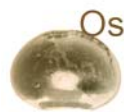
5.1 Ag Project

K. Rothenbacher, EPMF





5.1.1 Ag - Adjusted scope



Registration by	Name	Type of Dossier	Tonnage Band (t/a)	N° of PMC registrants	Lead Registrant
2010	Silver	Substance	> 1000	33	Aurubis
	Silver nitrate	Substance	100-1000	12	Ames Goldsmith
	Disilver oxide	Substance	10-100	6	Ames Goldsmith
2011	<i>Disilver (1+) sulphate</i>	<i>Substance</i>	<i>1-10</i>	<i>2</i>	<i>Johnson Matthey</i>
	<i>Silver carbonate</i>	<i>Substance</i>	<i>1-10</i>	<i>3</i>	<i>Johnson Matthey</i>
2011	<i>Silver chloride</i>	<i>Non-scc Intermediate</i>	<i>100-1000</i>	<i>7</i>	<i>Umicore</i>
2013	<i>Silver bromide</i>	<i>Non-scc Intermediate</i>	<i>10-100</i>	<i>1</i>	<i>Umicore</i>
	<i>Silver sulphide</i>	<i>Non-scc Intermediate</i>	<i>1-10</i>	<i>1</i>	<i>Umicore</i>



5.1.2 Ag - 2011 work programme



- Publish environmental monitoring data
- Additional soil tests
- Finalise BLM feasibility study
- Finalisation of pending Ag registrations
- Classification of Ag



5.1.2.1 Publication of environmental monitoring data

Environ Monit Assess (2011) 166:637–641
DOI 10.1007/s10661-011-1288-w

Occurrence and Concentration of Dissolved Silver in Rivers in England and Wales

A. Peters · P. Simpson · G. Merrington ·
E. Rothendacher · L. Sturdy

Received: 10 March 2011 / Accepted: 15 April 2011 / Published online: 24 April 2011
© Springer Science+Business Media B.V. 2011

Abstract There is a paucity of monitoring data for silver in freshwater environments in Europe. There are several reasons for this, including the relatively low levels of silver in the aquatic environment and the requirement for concomitantly low levels of detection (<100 ng l⁻¹), which are generally not routinely achieved in analytical laboratories. In this study 25 separate analytical determinations for dissolved (<0.45 µm) silver from 84 Environment Agency monitoring stations were carried out. Sampling was carried out on a monthly basis over a period of 6 months. Of the 425 samples, 346 were reported as having dissolved silver concentrations below the limit of quantification (6.6 ng l⁻¹) and, of these, 280 samples were reported as below the reporting limit of detection (3 ng l⁻¹). The mean of the maximum dissolved silver concentrations reported at each station was calculated as 61 ng l⁻¹ using a statistical extrapolation technique to allow for the high level of censorship in the dataset. The maximum mean dissolved silver concentration recorded at a station was 19.8 ng l⁻¹. A freshwater Predicted No Effect Concentration (PNEC) of 40 ng l⁻¹ was used in this study.

Keywords Silver · Exposure · Freshwater · Monitoring

There is a paucity of monitoring data for silver in freshwater environments in Europe. There are several reasons for this, including the relatively low levels of silver in the aquatic environment and the requirement for concomitantly low levels of detection (<100 ng l⁻¹), which are generally not routinely achieved in analytical laboratories. Use of silver and silver-containing compounds in England and Wales include their use as laboratory reagents, in allow use in the photographic industry. Silver is also employed in biomedical, dentistry and therapy applications.

To assess potential aquatic risks of silver there is a requirement for both effects and exposure data. A draft freshwater long-term predicted no effect concentration (PNEC) for dissolved silver of 40 ng l⁻¹ has been derived by the Environment Agency of England and Wales (Paul Whitcombe personal communication). The objective of this paper is to describe the collection of the silver exposure data from England and Wales surface waters that provides context to this PNEC and to measure how monitoring data in accordance with European regulatory drivers such as REACH and the Water Framework Directive (WFD).

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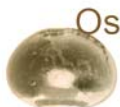
Materials and Methods

Site selection and sampling were undertaken in collaboration with the Environment Agency of England and Wales, one of the principal environmental regulators in the UK. The monitoring programme was based on 86 sampling stations selected from the Environment Agency's network of river monitoring sites. The selected sites were from

- DONE
- Publication accepted in April 2011
- Printouts available



5.1.2.2 Additional soil work (status)



- Background

- Last Assembly Meeting: general agreement on scope/cost, provided Ag WG and TAP agree

- Status

- “Fine tuned” and agreed scope with Ag WG and TAP
 - Choice of actual soils to test
 - Tested species
- Contract finalised, approved by MC, and signed
- Tests initiated



5.1.2.3 BLM feasibility study (status)



- Objective



- Demonstrate reduced availability (= toxicity) of Ag in the environment due to (insoluble) sulphide formation



- Status



- Ongoing
- Monitoring study (chromium reducible sulphides and Ag in EU waters) finalised
- Currently evaluating results
- Report expected in Q3 2011





5.1.2.4 Pending Ag registrations



- Substances:

- Scope:

- Disilver (1+) sulphate
- Silver carbonate



- Decision to register by summer 2011

- Dustiness work conducted to confirm absence of inhalation risk



- Intermediates:

- All non SCC = no "light" registration possible

- Silver chloride: Environmental classification + revision of tonnage

- Registration due by Dec 2010
- Need to register asap!

- Proposal

- Register silver chloride together with -sulphate and -carbonate
- Silver bromide and - sulphide: register later



Vote on proposal



5.1.2.5 Classification of Ag



- Background

- Massive Ag not classified, but some open questions remain on T/D tests
- Agreed to clarify questions in 2011. To be used in later dossier update

- Status

- Delayed due to other priorities / workload
- Currently discussing scope with consultants/CRO and possibility of applying UWM
- Tests expected to commence in Q3 2011



5.1.3 Nanosilver



- At 12 Jan 2011 meeting it was agreed to foresee revision of the silver metal registration following the release of the revised ECHA Guidance on substance identification to address nanomaterials
- Revised ECHA Guidance on substance identification not yet released
- Advisory report prepared by JRC on the basis of four nanomaterial case studies (including nanosilver) released in late May 2011:
 - Clear disagreement: ECHA, MS and NGO versus Industry
 - Recommendation to address nanomaterials' identity under REACH case-by-case
 - Advocacy report allows flexibility - **PMC approach not to include nanosilver in silver registration dossier remains acceptable**

To be continued... Next steps in the hands of CARACAL!

Need to remain vigilant on discussions regarding possible identifiers:

- Particle size/surface area and other associated properties (e.g. solubility)
- Surface treatment



5.1.4 Timeline



Project	Timeline
Publish environmental monitoring data	Done
Additional soil tests	2011-2013
Finalise BLM feasibility study	Q3 2011
Register Silver sulphate, - carbonate, - chloride	Summer 2011
Classification Ag (T/D, UWM, etc.)	Q3 2011
Register Silver bromide, - sulphide	?



Ag

5.1.5 Ag - 2012 work programme (Reminder)



Au

Human Health



Ir



Os



Pd



Pt



Re



Rh



Ru

- Testing proposal for 90d feeding study
- ECHA approval not expected before 2012
- May require preparation in late 2011
 - Locate suitable CROs
 - Get quotes
 - Discuss and finalise testing plan



5.2 Au + PM CN- Projects

C. Braibant, EPMF





5.2.1 Au - Scope



Registration by	Name	Status	Tonnage Band (t/a)	N° of PMC registrants	Lead Registrant
2018	Gold	Substance	10-100	23	Carl Hafner
	Tetrachloroauric acid	Substance	10-100	4	Johnson Matthey
	Aurio(1+) 2,6,6-trimethylbicyclo[3.1.1]heptanethiolate	Substance	1-10	1	Johnson Matthey
	Balsams, copaiba, sulfurized, mixed with turpentine, gold salts	Non-scc Intermediate	1-10	1	Heraeus



5.2.1 PM CN- - Scope



Scope unchanged



Registration by	Name	Status	Tonnage Band (t/a)	N° of PMC registrants	Lead Registrant
2018	Potassium dicyanoargentate	Substance	10-100	5	?
	Silver cyanide	Substance	1-10	6	?
	Potassium dicyanoaurate	Substance	10-100	8	Umicore
	Potassium tetrakis (cyano-C)aurate	Substance	1-10	2	?

Especially considering upcoming testing/modelling programme

LR still needed!



Ag

5.2.2 Au + PM CN- - ITS development (1)



Au



Ir



Os



Pd



Pt



Re



Rh



Ru

- Draft ITS recommendation from WCA received in March and April
- Discussion and finalisation of tiered testing programme design at WG meeting on 7 Jun 2011
- In summary (for detail cf. next slides):
 - Au: read-across from Tetrachloroauric acid
 - PM CN-: avoid testing and privilege modelling



5.2.2 Au + PM CN- - ITS development (2)



Au	Physico-Chemical	Ecotox/Env fate	Tox
Gold	None	Read-across from TCA	Bio-accessibility in gastric fluid
TCA	Recommendation to be adjusted for aqueous solution	<i>Daphnia</i> Algae Micro-organisms (Check pH impact)	Check pH impact in mamm tox tests, neutralisation possibilities, and read-across from sodium tetrachloroaurate
Aurio...	Boiling point, Density, Solubility, Vapour pressure, Partition co-efficient	Confirm predicted bioaccumulation (4,2) with experimental partition co-efficient	Annex III exemption to be confirmed following result of partition co-efficient test
Balsams ...	Need composition to confirm some waivers	Annex III exemption assumed. Confirmation dependent on composition	



5.2.2 Au + PM CN- - ITS development (3)



PM CN-

Physico-Chemical

Ecotox/Env fate

Tox

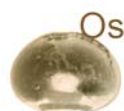


Silver CN-

None

Annex III exemption

Annex III exemption



K Silver
CN-

Density, solubility
Dustiness (MMAD)

Test:
Daphnia, Algae
Micro-organisms

Prediction of
dissociation species
via modelling*



K Gold
CN-

Density
Dustiness (MMAD)

Model prediction of
dissociated species
Fish toxicity
predicted by
modelling mixture
toxicity (validation
with above test
data)

Predict
LD50/classification
based on theoretical
dissociation
predictions
Decide whether to
read-across from CN-
or test



K tetrakis
(Cyano-C)
aurate

Density, solubility

Annex III exemption

Annex III exemption



Ag

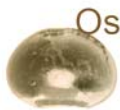
5.2.3 Au + PM CN- - Timeline (1)



Au



Ir



Os



Pd



Pt



Re



Rh



Ru

- Q3 2011:
 - Au: Set-up of phys-chem, eco-tox and bio-accessibility testing programme (including collection of samples)
 - PM CN-: Set-up of CN- Expert Group to tackle dissociation/solubility of PM CN- in environmentally and physiologically relevant waters
- Q4 2011:
 - Au: Start of testing programme
 - PM CN-: Development modelling approach



5.2.3 Au + PM CN- - Timeline (2)



• Q1-Q2 2012:

- Au: Finalisation of testing programme
- PM CN-: (Eco-)tox tests and fine-tuning of modelling approach



• Q3-Q4 2012: Evaluation of test results to consider next steps:

- Update of classification
- If hazard → CSA/CSR
- If no hazard → Registration preparation





5.3 PGM Project



K. Rothenbacher, EPMF



5.3.1 PGM - Scope



Registration by	Family	Type of dossier	Highest tonnage Band (t/a)	N° of PMC Members registrations	Lead Registrants*
2013**	Platinum	11 substances 3 non-scc intermediates	Sub: 10-100 Int: 100-1000	58	Vale , JM, Umicore, Heraeus
	Palladium	16 substances 4 non-scc intermediates	Sub: 10-100 Int: 100-1000	73	Umicore , Heraeus, JM, C. Hafner
	Rhodium	13 substances 3 non-scc intermediates	10-100	46	Anglo , Heraeus, Umicore, Vale
	Iridium	4 substances 2 non-scc intermediates	1-10	20	JM , Umicore
	Ruthenium	6 substances 3 intermediates 1 non-scc intermediate	10-100	27	Heraeus , Umicore, Vale

* Names in pink constitute LR for PGM metals in each case

** Deadline applicable to two high-tonnage intermediates; other substances due by 2018



Ag

5.3.2 PGM - 2011 Work Programme (1)

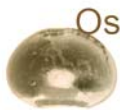


Au

- 66 Substances x 35 Reach endpoints x n-Studies = complex discussions



Ir



Os

- PGM Expert Group (PEG) group formed as interface between consultants and PGM WG/TAP



Pd



Pt

- Regular conference calls and meetings to evolve ITS proposal



Re

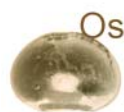


Rh

- WCA+BIBRA as main consultants + EBRC as peer reviewers on a case-by-case basis + external consultants if needed (e.g. D. Kirkland, etc)



Ru



5.3.2 PGM - 2011 Work Programme (2)

- CLP
- ITS development
 - Refine scope
 - Data gap analysis
 - Enabling tests
 - Final ITS
- Testing Programme
 - Non CLP physico-chemical tests
 - First round of toxicology tests



5.3.2.1 CLP - 2011 Progress



- New data available
 - Only available after 2 Dec 2010 CLP meeting
 - CLP testing: late arrival of some samples = late receipt of test results
 - New proprietary data



- CLP Changes
 - Discussed/agreed with PGM WG
 - New strategy on oxidising properties under development
 - Review read-across strategy in the frame of ITS development



Substance	Notified Classification	New Classification
Pt-, Pd-, Rh-, Ru- and Ir-blacks	Self heating category 1 (H251)	No classification for self heating needed
Tetraammine-platinum compounds	No classification for aquatic toxicity	Aquatic chronic 3 (H412)
Hexachloroplatinic acid	Acute tox 3 (oral) (H301)	Acute tox 2 (oral) (H300)
Diammonium sodium hexakis(nitrito-N) rhodate	No classification for self heating	Self heating 1 (H251)
All	Oxidising properties	Strategy under revision by PGM WG



Ag

5.3.2.2 ITS - 2011 Progress (1)

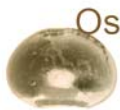


Au

Refined Scope



Ir



Os

- Identified reduced data requirements

- Intermediates survey

- But: most intermediates not handled under SCC (63/66)

- Annex III exemptions

- For substances 1-10 tpa, if

- substance is not CMR (cat 1 or 2)/PBT or

- Environment/human health classification but no dispersive/consumer use

- 38/39 substances exempted! (overlap with above SCC intermediates)



Pd



Pt



Re



Rh



Ru

→ Significant reduction in scope/cost



5.3.2.2 ITS - 2011 Progress (2)



Completed Data Gap Analysis / Draft ITS

- Main area of 2011 work of PGM Expert Group (PEG)
- Efficient use of data: where possible
 - make use of exemptions
 - read across data
- PEG meeting 5/6 May 2011
 - Reviewed available and relevant data
 - Agreed on read across strategy
 - Agreed on data gaps
 - Put together draft testing strategy (ITS)



5.3.2.2 ITS - 2011 Work plan (1)



Complete Enabling Tests



- Needed for refining ITS



Test	Rationale	Timeline
pH	Information on skin/eye irritation	Done Results already considered in ITS
Water solubility	Ecotox properties	Ongoing Q2 2011
Dustiness	Relevance of inhalation exposure	Q3-4 2011
Bioaccessibility	Route-to-route extrapolation tox data, relevance of route of exposure	Q3-4 2011



Ag

5.3.2.2 ITS - 2011 Work plan (2)



Au

- ITS



Ir

- Complete enabling tests



Os

- Refine ITS based on data from enabling tests



Pd

- First round of toxicology tests



Pt

- Start with skin/eye irritation (*in vitro*)



Re

- Complete remaining physico-chemical tests



Rh



Ru



5.3.2.2 ITS - 2011 Work plan (3)

Test	No of substances Estimates
Phys.-chem. tests	
Melting point	4
Boiling point	4
Rel. density	34
Vapour pressure	25
Flammability	5
Self ignition	3
Oxidising prop.	6
Hydrolysis	4
Enabling tests	
Dustiness	12
bioaccessibility test	13
TD test	3
Mammalian tox	
In vitro eye and skin irritation	7
Sensitisation	6
Genetic toxicology	10
In vivo acute studies	6
Repeated dose/reprotox	ca 15
Environment	
Algae/fish/daphnia	8
Activated sludge	6



Ag

5.3.2.2 Timeline



Au

Q3+Q4 2011:

Launch part 1 of testing programme:

- Enabling tests
- First *in vitro* tests
- Remaining physico-chemical testing



Ir



Os



Pd

2012:

Part 2 of testing programme:

- Remaining tox/eco-tox testing



Pt



Re

2013:

Prepare Phase IV: Learning from Ag

1. Proper development of effects data (Phase III),
2. Assessment of effects data to identify hazards,
3. Determine need for monitoring data and exposure routes,
4. Launch data generation/collection process
5. Perform CSA and iterative refinements



Rh



Ru



5.4 Re Project



C. Braibant, EPMF



5.4.1 Re - Scope



Registration by	Name	Status	Tonnage Band (t/a)	N° of PMC registrants	Lead Registrant
2013	Rhenium	Substance	1-10	6	KGHM Ecoren
	Perrhenic acid	Substance	1-10	2	Heraeus
	Ammonium perrhenate	Substance	10-100	7	Heraeus
	Potassium perrhenate	Non-scc Intermediate	1-10	1	Heraeus
	Sodium rhenate	Sc Intermediate	1-10	1	Climax Molybdenum
	Dirhenium heptasulphide	Sc Intermediate*	1-10	1	Johnson Matthey

* Assumed scc



5.4.2 Re - Testing programme



Study	Lab	Proposed start date	Status
<i>In vitro</i> eye irritation	Harlan	3 Jun 2011	Suitable (20%) suspension difficult Isolated Rabbit Eye (IRE/REET) assay recommended (tbd)
<i>In vivo</i> eye irritation	Harlan	After <i>in vitro</i> eye irritation	Awaiting <i>in vitro</i>
LLNA	Harlan	7 Jun 2011	Ongoing
MLA	Covance	21 Apr 2011	No mutagenicity observed
Micronucleus	Covance	20 Jun 2011	No mutagenicity observed in MLA, need for micronucleus tbd
28-day repeated dose/reprotox screening	Charles River	Jul 2011 (tba)	Start with (external) substance analysis in formulation



5.4.3 Re - Timeline



Q3 2011 - Q1 2012:



Finalise Phase III:

- Finalise 28 d tox tests



Q4 2011 - Q1 2012:

Evaluate tox test results:



Q2 2012 { - If no hazard identified → Finalise registrations for all Re materials



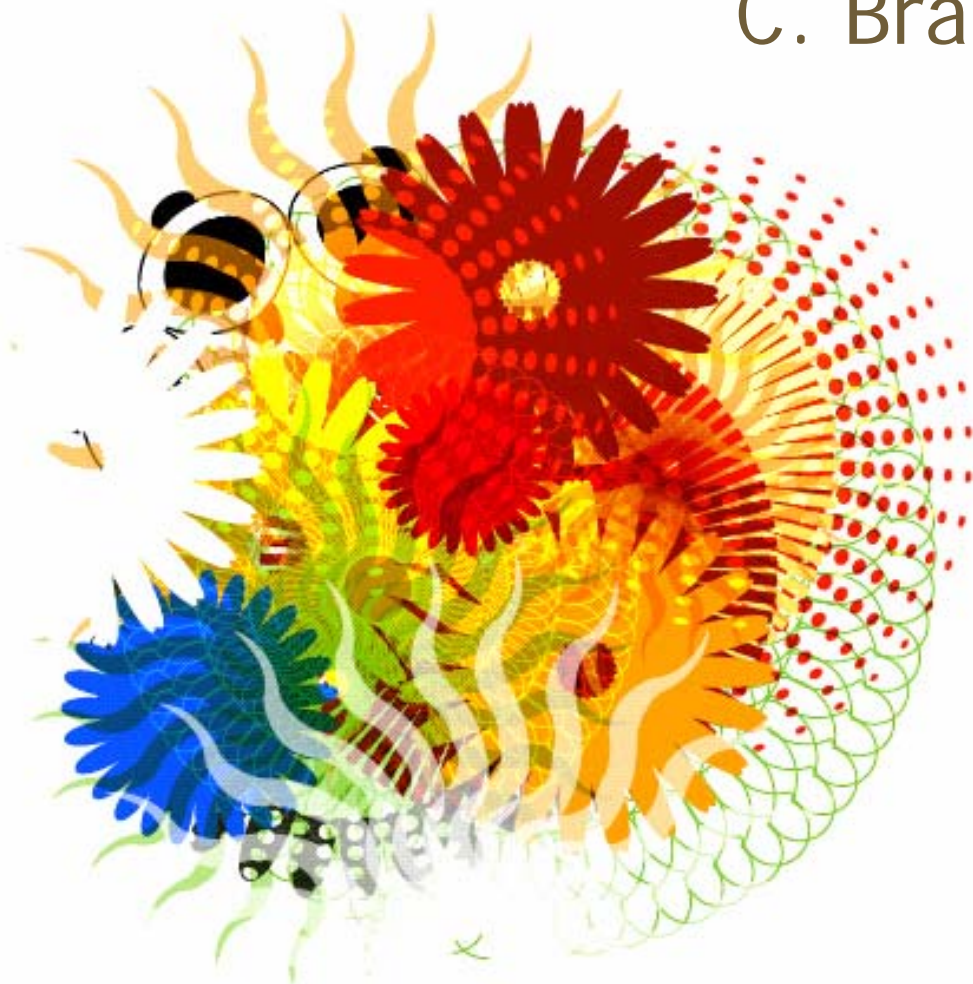
- Q4 2012 { - If hazard identified:
- Refine read-across strategy on the basis of sodium rhenate,
 - Plan CSA/CSR for APR, and
 - Plan classification update and registrations for other Re materials





5.5 PM Refinables Project

C. Braibant, EPMF





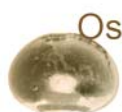
5.5.1 Ref - Scope



1. Doré (Aurubis)



2. Matte, PM refining (Umicore)



3. Slags, PM refining (Umicore)



4. Slimes & Sludges, PM refining (Aurubis)



5.1 Residues, matte leaching (Umicore)

5.2 Residues, copper leaching (Umicore)



6.1 Ag (spent) electrolyte (KGHM)

6.2 Au (spent) electrolyte (Aurubis)



7. Flue dust, PM refining (Johnson Matthey)

8. Residues, PM cementation & precipitation (Heraeus)



9.1 Materials for reclaim, PM with or without support (Johnson Matthey)

9.2 Materials for reclaim, PM on bricks, crucibles and trays (Johnson Matthey)

9.3 Materials for reclaim, PM production by-products (Johnson Matthey)

10 Lead bullion, PGM rich (Vale)

All but one registered by 1 Dec 2010

Non-scc complex intermediates according to Dec 2010 ECHA guidance on intermediates (and answers to PMC's preliminary survey)



5.5.2 Ref - Dossier update strategy and timeline

- Original strategy approved at 11/12 Jan 2011 meetings
- In the meantime, advocacy strategy put in place by Eurométaux
- CARACAL meeting on 7-10 Jun 2011 - formal outcome yet unknown
 - Launch tiered exposure data collection/generation programme (required anyway)
 - Wait with further effects/testing work until political and technical clarification on test waiving and SCC conditions (Autumn 2011?)



5.5.3 Ref - Project Manager



- At 12 Jan 2011 Assembly meeting a request was put to the PMC secretariat to identify a Project Manager to support the Refinables project



- Job description was prepared and circulated among PMC Belgium-based consultancies
 - Described profile ideal/surreal → → → →



- One CV received from ARCHE
 - Good/long experience in project management
 - Decent technical/ecotox/environmental assessment skills
 - No metal-specific experience but can be facilitated by rest of ARCHE team
 - OK to work on a partial time basis



Green light to proceed?



6. AOB, next meetings and closing remarks



6.2 Next PMC Assembly Meeting

Brussels, Belgium
Metals Conference
Centre

6 December 2011





6.3 Next PMC Plenary Meeting

Belgium (city tbc)
14-16 June 2012
Hosted by Umicore - THANK YOU!

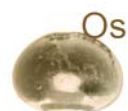
May require re-organisation:

Until now:

- Day 1 am: EPMF Board
- Day 1 pm: EPMF Assembly
- Day 2 full: PMC Assembly
- Day 3 am: Site-visit

In future:

- Day 1 full: PMC Assembly
- Day 2 am: EPMF Board
- Day 2 pm: EPMF Assembly
- Day 3 am: Site-visit



Thank you all for your input today!
Enjoy your summer holidays!