Precious Metals & Rhenium Consortium

GENERAL ASSEMBLY MEETING

Brussels, 5 December 2012

1. Welcome & Introduction

Guy ETHIER
Umicore

1.1. Reminder on confidentiality and Competition Law

1.2. Tour de table & Apologies

1.3. Approval of the agenda

1.4. Status of actions agreed at and approval of minutes of the last meeting (Antwerp, 14 June 2012)

	What?	Who?	Status
1.	Identify Lead Registrants for remaining PM CN- and PGM	PMC Members	On-going
2.	Assess resources and mechanism to perform regular literature reviews for all projects at PMC Secretariat and/or with external consultant	Mgmt Cttee	Done
3.	Send sample management protocol to all consultants coordinating testing programmes for PMC so they are used by all test houses	Secretariat	Done
4.	Keep track of LoA versus PMC membership costs and reserves for transparency (e.g. Re)	Secretariat	Done, cf. item 2.2
5.	Send SIEF communication for confirmed LR and 2013 registrations	Secretariat	On-going
6.	Send 2nd 2012 invoices for Hydrazine project costs (after RPA's revised proposal has been received, discussed and agreed) to concerned PMC Members	Secretariat	Done
7.	Prepare proposal to strengthen PM sector resources available to PMC and EPMF as part of a 2013 budget proposal to be presented to PMC Members at the Dec 2012 Assembly meeting	Secretariat + MC	Done, cf. item 6
8.	Illustrate application of simplified invoicing approach on the basis of the confirmed 2013 budget	CB	Postponed
9.	Prepare and circulate SCC survey for completion by all PMC Members having declared intermediates to PMC before Dec 2012	CB	Done, starting with Ref
10.	Send information supporting organisation of Plenary Meeting to Boliden colleagues hosting the 2013 Plenary Meeting	Secretariat	Done

	What?	Who?	Status
11.	Draft formal PMC resolution properly documenting the terms under which PMC Assembly has approved the collaboration of PMC and the photographic sector for the three silver halide dossiers	AP+CB	In progress
12.	Prepare LoA Agreement for photographic sector including specific clauses addressing: • Deviation from the Consortium Agreement as regards the non-member nature of the LR; • Safety net would additional (testing) work be required for the three silver halides dossiers after submission to ECHA; Responsibilities related to Dossier preparation, submission, follow-up, update, communication with SIEF and ECHA, etc.	CB	Done
13.	Circulate a dedicated bulletin to PMC Members as soon as more information becomes available on the on-going T/D testing	KR	Done
14.	Submit PMC position and strategy on the preparation to Evaluation to legal compliance check in order to prepare eventual exchanges with NL	KR+CB+AP	Postponed
15.	NanoAg: Include manufacturing process as criteria for deciding whether nanoAg and Ag belong to the same Dossier in pros and cons document	CB	Done
16.	NanoAg: Find out more about the exact sizes and forms of nanoAg with Ag acetate in the NTP study	KR	Done, on-going
17.	NanoAg: Re-launch contacts with EU Ag TF (Biocides), NIA and OECD; liaise with relevant representatives participating in GAARN, SiO2 Evaluation, etc.; and consider possibility of involving additional consultancy experienced with risk assessing nanomaterials in other contexts, e.g. biocides	EBRC & WCA	Done
18.	NanoAg: Find out more about the expectations from NL on nanoAg	KR+CB	Postponed
19.	NanoAg: Assess endpoints which are at risk of being challenged by regulators	EBRC & WCA	Done
20.	NanoAg: If high tier/cost nanoAg-specific testing requirements are needed for nanoAg, review PMC cost-sharing formula in order to arrive at a fair and proportionate cost-sharing and data-access solution	CB	Done, cf. item 5.1
21.	NanoAg: Decide and argument whether nanoAg and Ag need to be registered in one same or two separate dossiers under REACH once the work by EBRC and WCA is progressed/finalised	PMC Members	Action for today, cf. item 5.1

	What?	Who?	Status
22.	Send comments on data-sharing agreement template between EPMF & IPA	PMC Members	Done, no comments received
23.	Finalise data-sharing agreement with IPA	CB	Done
24.	Request a revised proposal from RPA for hydrazine project	CB	Done

2. Membership News

Caroline BRAIBANT - EPMF

2.1. New members: BASF in 2013?

2.2. Various:

- LoA:
  - LoA Agreements for Ag, Re and 2013 registration substances now/soon available on LoA e-shop
  - Each LoA refers to ID Card of substance (LoA progress at pace of ID Card preparation and SIEF communication)
  - Confirmed LoA purchase interests to date for 2013 include:
    - 5 Ag substances 100-100 t/a (5*22.000 € + generic costs)
    - 1 refinable substances 100-1000 t/a (1*12.500 € + generic costs)
  - Comparison of LoA with PMC membership cost shows PMC higher than LoA (cf. next slide)
    - Propose to review in particular cost of Re LoA after 2013 registration deadline
    - PMC membership cost not fully spent – reserves
    - N.B.: Valid comparison can only be made after 2018 registration deadline where all LoA purchases can be compared with all PMC invoices
- SIEF communication status:
  - Ag halides: Nov 2012
  - Re compounds: Jan 2013
  - Other 2013 registrations: Jan 2013

LoA vs. PMC membership

Provisional calculation, for information

2007-2012 costs*	PMC	LoA	PMC s or non-SCC i 1-10 or SCC ti > 1000	LoA s or non-SCC i 1-10	PMC s or non-SCC i 10-100	LoA s or non-SCC i 10-100	PMC s or non-SCC i 100-1000	LoA s or non-SCC i 100-1000	PMC s > 1000	LoA s > 1000	PMC SCC i any tonnage	LoA SCC i any tonnage	Overall comparison
Ag			19.410 €	8.000 €	21.948 €	10.500 €	35.481 €	22.000 €	159.144 €	152.000 €	86 €	145 €	LoA < PMC
Au			15.485 €	35.500 €	28.379 €	69.000 €					590 €	2.500 €	PMC < LoA
PM CN-			14.298 €	28.500 €	29.278 €	59.000 €							PMC < LoA
PGM			18.040 €	34.000 €	38.205 €	71.500 €					1.021 €	2.500 €	PMC < LoA
Re			35.793 €	22.000 €	85.091 €	49.500 €					1.947 €	2.000 €	LoA < PMC
Refinables											11.511 €	12.000 €	PMC < LoA
Hydrazine													No LoA
Generic	46.652 €	38.500 €											LoA < PMC

- Data-sharing with IPA: finalised and signed
- TSCA 8(e) notifications :
  - To allow collective notification of PMC generated data to US EPA via IPMI
  - SOP + model letter + example text developed and under legal review by B&C
  - Agreed PMC/EPMF will prepare technical content and IPMI submit on behalf of all members of all (tbc) PM associations' members

2.3. Feedback on bi-monthly updates:

- Do Members find the updates useful?
- Is format and frequency adequate?

2.4. Others

- Handy & Harman unpaid dues are being resolved, commitment to revert by Mar 2013 (~ 24.000 € due since 2009; confusion caused by change of responsibilities)

3. Eurométaux' REACH Budget, Challenges & Achievements in 2011 and 2012

Violaine VEROUGSTRAETE, Eurométaux

Eurometaux & REACH : main activities, challenges, resources and budgets

PMC Assembly,

December 5 2012

Outline

- Brief overview of the main REACH activities and main challenges
- What is Eurometaux's role in REACH?
- How can EM ensure its roles?
- Eurometaux REACH budget 2012 and 2013/2014: what does it include, how does it work?
- Eurometaux REACH achievements in 2011- 2012?

Brief overview of the main REACH activities and main challenges

REACH activities

ECHA activities (Helsinki)	*REACH activities (Brussels)*	*EM (Brussels)*
Registration: • 2013-2018 • Updates .	**CARACAL** • REACH and CLP	**REACH Forum meetings**
Evaluation • Dossier Evaluation • Testing proposals evaluation • Substance Evaluation	**Contacts/networking Commission** • Autorisation and restriction • SVHC listing	**Taskforces meetings:** UVCB, autorisation, ES …
Restrictions and Authorisation	**REACH Review** (January 13)	**Communication: REACH metals gateway and REACH news**
Harmonised classification	**Nanos** • CASG nanos	**Link with REACH outside EU:** e.g.OECD
Communication		**Technical support projects**
Nanos • GAARN • NMWG		**Screening emerging issues:** e.g. use of REACH data for other purposes

Main challenges (1)

- **Learn** quickly how the different REACH 'processes' work + rules of the game
  - Dos and Don'ts
  - Timing?
  - How?
  - Which type of knowledge to acquire?
  - Which type of knowledge to feed in?
- Be recognised as valid, credible, visible, representative **interlocutor**
- ***Speed***

Main challenges (2)

- Fight for **consistency**
  - between process and registration data
  - between different metals
  - between different industry sectors on specific issues
  - REACH political implementation
- Fight for **proportionality** and **pragmatism**
- Identify areas of **precedent-setting or learning** for other metals
- Find/generate **technical knowledge** where needed (projects, taskforces)
- **Communicate** efficiently!! (authorities, consortia, downstream uses)

What are EM's main roles in REACH?

Eurometaux's main roles

Ensure consistency in:

- Industry's representation at ECHA meetings (> 45 days/year) and at CARACAL
- Providing a clearing house for best practice transfer and cost-effective development of methodologies and scientific responses
- Advocacy on pragmatic/proportionate interpretation
- Proactive contribution to REACH's "political" implementation

Via REACH Forum and taskforces, provide exchange platforms for metals Consortia and generate technical knowledge

Maintain links between EHS and REACH activities

- Overlapping legislations water/waste, GEHS technical/scientific aspects

How can EM ensure its roles in REACH?

« Basic » tools

- Overview on REACH authorities' (ECHA, Commission, Member States) intentions, work plans and timings
- Network

- Capacity to follow-up of technical/administrative issues that may cause precedents
- Clearing house best practice transfer and cost-effective development of methodologies and scientific responses
- Build upon experience
- Exchange and communication platform

Analysis of ECHA activities for 2013 and >2013 + impact on workload

based on the detailed review of…

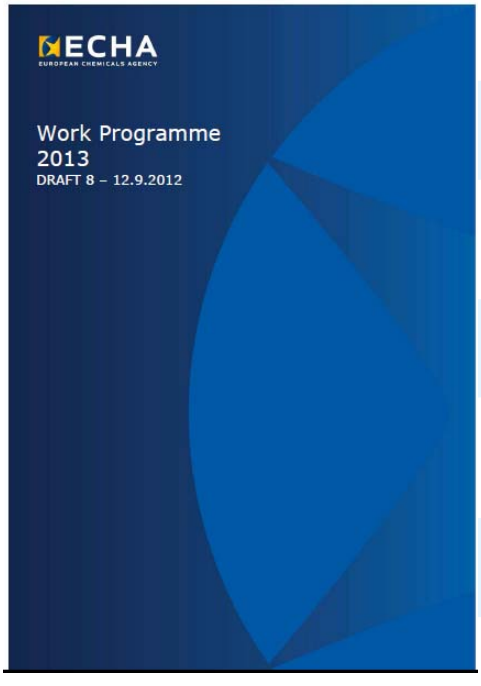
- ECHA's « *2013* » and « *longer term* » work plans
- REACH agenda and timing
- EM' s experience with the ECHA Committees
- Metal dossiers appearance in REACH processes

How does ECHA plan its work?

- ECHA currently works with a **rolling 3 Year plan** (2013-2015)
  - Identification of challenges
  - Definition of priorities
  - Quantified objectives
  - Report system (to Management Board)

- ECHA wants to move to a **5 years planning** : 2014-2018
  - As REACH is now in a 'more mature' phase
  - There are more longer term vision/objectives

1) ECHA work plan 2013: main objectives



- Ensure succes ***second registration deadline (2013)***
- Finalise ***Testing Proposal (TPE)*** reviews of the first registration deadline in 2013
- Increase number of ***Compliance Checks (CC)*** and scan > 5 % by end of 2013
- Handle ***first Authorisation Application (AA)*** effectively and efficiently and increase SVHC/prioritisation
- Launch ***Substance Evaluation***
- Provide input for ***REACH review***
- Launch ***Biocides assessments***
- Maintain ***Restriction and Harmonised Cl&L*** activity at high level

ECHA workplan 2013: impact on workload (1)

- Activity will **never be as high as in 2013** with significant demand from:
  - **ECHA staff** : preparation and handling
  - **Member States Committee (MSC)** : identification and prioritisation of Substances of Very High Concern (SVHC)/ Substance evaluation / Dossier assessment : workload estimate x 2 or 3
  - **Socio-economic Committee (SEAC)**: Authorisation Applications (AA) for SEA route + continuation of restriction: workload depending on number of AAs but may be x 2
  - **Risk Assessment Committees (RAC)**: AA's for Risk route (none in 2013) + continuation of restriction and harmonised Classification: significant workload increase
  - **Appeal Board** : expected increase in contested Compliance Checks and TPE decisions

ECHA workplan 2013: impact on workload (2)

ECHA meetings: *require preparation, attendance, reporting and follow-up from EM REACH Team*

	2013 compared to 2012
- RAC (4x5 days)	Raising slightly
- SEAC (4x3 days)	Raising slightly (Authorisation)
- MSC (6x4 days)	Raising (SVHC, Testing Proposals, Substance/ Dossiers Evaluation,...)
- ECHA Forum (1 x 2days)	Stable
- Workshops	Raising (4? x 2days)

2) ECHA Strategic review 2014-2018

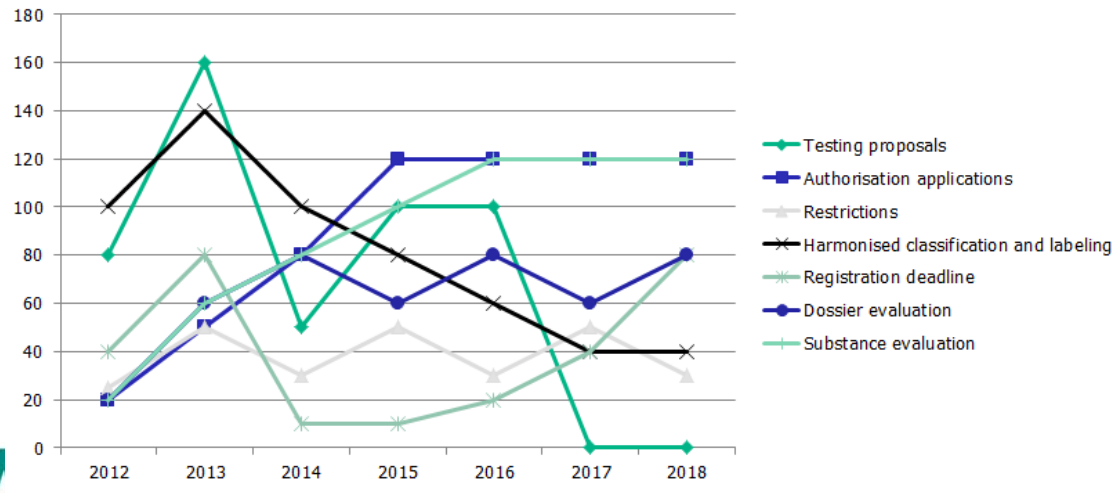
Basis:

- REACH, CLP and Biocides regulation legal requirements
- Strategic approach along the 4 strategic drivers/objectives:

1. Maximising the availability of high quality information to enable the safe manufacturing and use of chemicals
2. Mobilising authorities to use information intelligently in order to identify and address chemicals of concern
3. Addressing scientific challenges by serving as a hub for building the scientific and regulatory capacity of Member States, European institutions and other actors
4. Embracing current and new legislative tasks efficiently and effectively, while adapting to upcoming resource constraints

ECHA program development overview

	2012	2013	2014	2015	2016	2017	2018
Testing proposals	80	160	50	100	100	0	0
Authorisation applications	20	50	80	120	120	120	120
Restrictions	25	50	30	50	30	50	30
Harmonised classification	100	140	100	80	60	40	40
Registration deadline	40	80	10	10	20	40	80
Dossier evaluation	20	60	80	60	80	60	80
Substance evaluation	20	60	80	100	120	120	120



To summarise...

In general

- **2012** was the first full year of REACH implementation and SVHC identification
- **2013:** ramping up of Substance Evaluation and full scope of Testing proposals, high number of C&L
- **2014:** start of metal authorisation applications and C&L
- **2015:** evaluation outcomes Testing proposals and Substance Evaluations
- 2016 ...

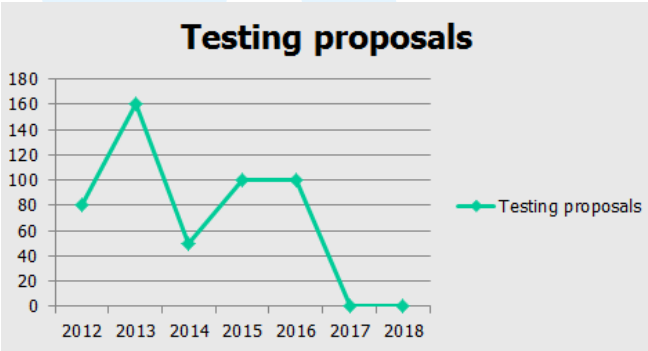
The different activities are detailed in the following slides

in more detail: Testing proposals

All 2010 registrations by mid 2013

All 2013 registrations by 2015

- Concept development in 2012
- High workload for 2013 and 2015
- Resulting in follow-ups (every) 2 years later
- Focus on metals in 2013-2015

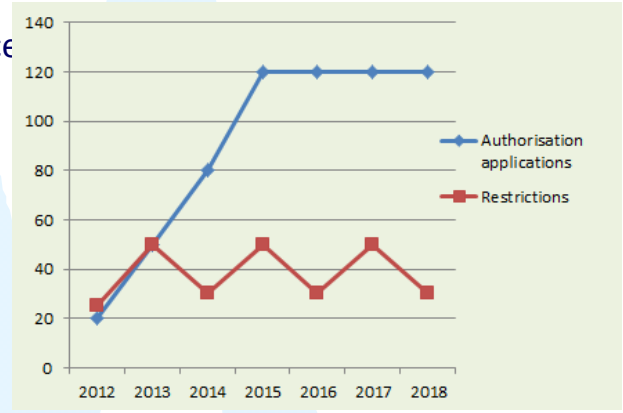


in more detail: Authorisation and Restriction

Restrictions : 4-8 /year

- Up and down depending on Member States initiatives
- May be stimulated by outcome Substance Evaluations (> 2015)

Metal cases planned : Pb metal (2013), Cd metal ('13-'14), Co plating ('13-'14)



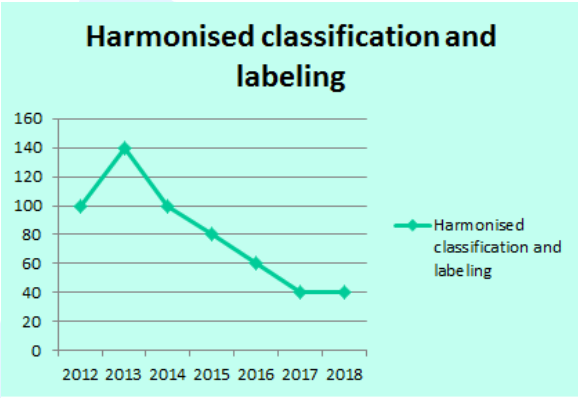
Authorisations:

- Ramping up by 2013
- On full steam from 2014
- SVHC identification to increase in 2012 and doubling towards 2020
- RMO development increasing from 2013 !

Metal cases planned : Cr6+ metal (2013), SVHC on Pb compounds (2012-2014), B(2013-2015), other metals in 2014-2018

in more detail: Harmonised Classification and Labelling

- On average 50 /year
- Mostly CMR focussed but not all
- High level until 2015
- Industry initiative (reclassification) from 2013 on



METAL cases already planned:

- 2013 : Pb metal, Cu and Cu compounds,..

in more detail: Dossier Evaluation (DE) and Substance Evaluation (SE)

SE : aiming at 50 per year by 2015

- CoRAP starting in 2013
- Substance doubling towards 2015

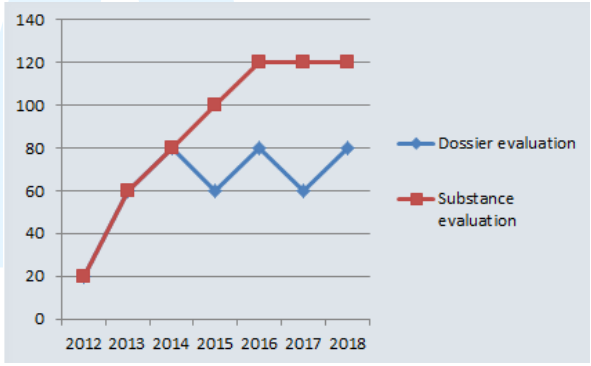
Metal cases planned :

2012: SiO_2, ...
Ag,GaAs,TiO_2

2013 : Be, Zn...2014:
2015 : Al, Sn, ...

DE : aim 5 % reviewed by 2013/14

- Balancing workload Testing Proposals
- Doubling by 2014
- Thereafter cruising speed



+ Emerging issues requiring review

- **Waste assessment**
  - 2011: Development concepts
  - 2012: Data gathering and registration
- **Intermediates updates/upgrades:**
  - 2012: Concept-methodology-negotiation with ECHA
  - 2013: Implementation
- **Combined exposure assessment:**
  - 2013: Concept-methods-guidance?
  - 2014-:... Implementation

Member States' and Commission's intentions

- Visible through the Registry of Intentions…
- Some selection bias
- 'weaknesses' in REACH : Intermediates, nanos
- Political move from Commission to meet 136 SVHC target by end 2012
- Commitment from Commission to put all relevant CMRs, PBTs, EQs on SVHC list by 2020

« Basic » tools

- Overview on REACH authorities' (ECHA, Commission, Member States) intentions, work plans and timings
- Network
- Capacity to follow-up of technical/administrative issues that may cause precedents
- Clearing house best practice transfer and cost-effective development of methodologies and scientific responses
- Build upon experience
- Exchange and communication platform

REACH Forum

Eurometaux budget for 2012 , 2013 and 2014

Overview REACH activities

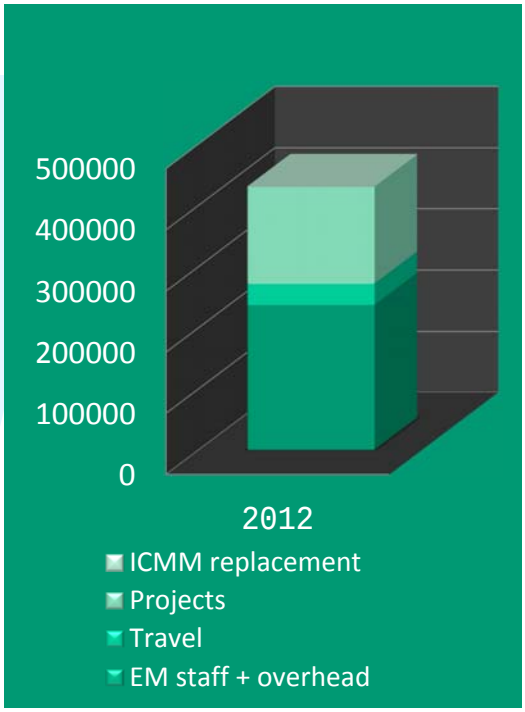
- The Workload for REACH in Eurometaux entails:
  - ECHA meetings/preparations
  - ECHA program development
  - Metals included in different ECHA programs
  - Communication aspects
  - Emerging issues requiring review

- Eurometaux REACH Forum aspects:
  - Monthly newsletter
  - Members questions
  - REACH Forum meetings (4/year)

2012 REACH funding exercise

- REACH budgeted 430 k€ to cover the first full year of REACH **implementation (best estimate)**
- Two levels of funding (35 k€/ 15 k€)*, for same service
- Total budget: 240 k€
  - **1.8 FTEs (consultancy)**,
  - travel / meetings and
  - **agreed project portfolio** (158 K€)
- Consultancy: Hugo (0.75), Federica (0.5 FTE)

- Separate **generic REACH policy activities** (e.g. REACH review) covered by EM EHS budget



2012 REACH funding exercise: learning lessons

Increasing workload: actual workload exceeds 1.8 FTE

- ***Huge*** *preparatory and representation resources for metal dossiers and* ***many more*** *metals involved in Authorisation and Restrictions*
- *ECHA Committees are* ***"decreasing access by experts", requiring more work from Stakeholders Observers like EM***

- *Some ECHA workshops were not accounted for (not expected):*
  - *UVCB workshop May 2012*
  - *Read-across workshop October 1 2012 and October 3*

- ***Changes in legal text and guidance*** *(e.g. Intermediates) : unplanned, additional technical work and tools to develop (guidance on UVCB assessment, RICOG tool...)*

2012 REACH funding exercise: learning lessons

Budget did not cover EM staff work on REACH (about 0,8 FTE)

Changes in Belgian VAT rules

ICMM is decreasing its chmical management activities

2013 REACH funding exercise

The budget 2013

- should cover 'true costs' (costs EM staff involved in REACH)
- should consider the increasing workload (including support ICMM at OECD/UN)
- structure should fit in with new VAT rules (service structure)
- be 'stabilised'

2013 REACH funding exercise

- Proposal: Total budget to fund **2.6 FTEs,** travel / meetings and projects: 510 k€ for 2013. Same amount estimated for 2014
  - 1.9 FTE consultancy
  - 0.7 FTE: Eurometaux staff covering EHS experts, accounting, admin support and a small part of the Director-General: total human resource cost is estimated at 400 K€
  - Travel & meetings: 40 K€
  - Proposed projects: 70 K€
- **Proposal sent out to consortia on 24 October**

2013 REACH funding exercise

- Confirmed

Funding for 2013*	**Fee/category**
Category 1: Metals in the 2013-2014 spotlight for evaluation/authorisation/restriction/classification Pb, **Co, Ni, PM, Cu, Zn group**	**50 K€**
Category 2: Larger consortia who should not be in the spotlight for 2013-2014 **Al, As,** Fe-	35 K€
Category 3: Smaller consortia who should not be in the spotlight for 2013 Be, **Mo**, Mn, **Sb**, Sn, **Se/Ge**, **ferro-alloys**, MaREC, B-P and V, *borates, chromates*	20 K€
TOTAL	

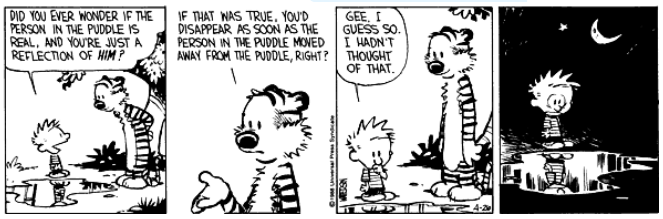
What will Eurometaux deliver?

- Act as a Stakeholder Observer (STO) at all ECHA RAC-SEAC and MSC meetings and relevant ECHA workshops, including preparation and reporting
- Support the preparation of/defend metal dossiers and ensure consistency
- Active involvement during the development of arguments and advocacy planning, and representation at relevant ECHA meetings
- Communicate on/document learnings and facilitate exchanges on experiences with the various processes
- Advocacy on pragmatic/proportionate interpretation
- Proactive contribution to REACH's "political" implementation
- Support knowledge workshops for ECHA and Member States to address recurring critical issues

What will Eurometaux deliver? (2)

- Provide a clearing house for best practice transfer and cost-effective development of methodologies and scientific responses
- Organise platform exchange meetings with Consortia (SEA, Authorisation, Testing proposals, …)
- Be timely in internal meeting preparations, issuing clear minutes, maintaining a manual of decisions and publishing a monthly Metals REACH Newsletter
- Execute, with Consortia support, the portfolio of technical projects

Does it work?



2012 Achievements

Internally:

- Secured consultancy and project funding for a single REACH Forum
- Efficient, quality support to metals in the REACH spotlight
- Built expertise in e.g. socio-economic and impact assessment
- Strengthened communications with Consortia (REACH News)

Externally:

- Increased recognition of EM expertise and value as a fully-fledged partner by ECHA, Commission and Member States
- Technical expertise acknowledged and solicited on key issues, such as intermediates and read-across
- Training of ECHA experts
- Informal and formal communication channels well-established

2012 Achievements

Examples

- Development of tools like SPERCs, MEASE, DU Scaling tool, MECLAS tool acknowledged by authorities
- Existence of metal-specific guidance (part or appendices of ECHA guidance)
- 'Metal platform' in ECHA
- STO status confirmed
- Possibility to discuss and find more pragmatic solutions: intermediates, specific concentration limit on Pb with ECHA and Commission
- Growing interlocutor on autorisation…

Questions?

Please contact the EM REACH team:

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Abbreviations and short explanation

CCs: Compliance checks (as part of the Dossier Evaluation process)

C&L : Classification and labeling (to harmonise and review new hazard profiles by RAC)

DE : Dossier Evaluation (quality control check of Registration dossiers)

MS : Member State

MSC : Member State Committee (ECHA Committee responsible for all Autorisation steps, Testing Proposal reviews and Substance Evaluations)

RAC : Risk Assessment Committee (ECHA Committee responsible for C&L and involved in Restrictions and Authorisations)

RMO : Risk Management Option (non REACH requirement that allows choosing the best Risk Management route)

SEAC : Socio Economic Committee (ECHA Committee responsible for SEA and Assessment of Alternatives evaluations and coordinates Restrictions and Authorisations)

SE : Substance evaluation (Evaluation by a Member State of the combined registration files for a given substance)

SVHC : Substance of Very High Concern (PBT, CMR or substance of equivalent concern)

TPs : Testing proposals (TPs included in the Registration files for assessment by MSC)

4. Preparation for Authorisation

Aggie KOTZE, International Lead Association (ILA)

Preparing for Authorisation

Aggie Kotze
5 Dec 2012

Content

- Overview of authorisation process
- Who will this affect?
- Authorisation process
- Authorisation timeline
- Authorisation process – Candidate listing
- Authorisation Process-Prioritisation for inclusion in Annex XIV
- Authorisation process-Applying for authorisation
- Education and Advocacy
- Complexity of supply chain
- Impact of Pb authorisation on other metal substances

Overview of Authorisation

- **Authorisaton procedure aims to**
  - Ensure that risk resulting from certain substances are **properly controlled**
  - Ensure these substances are **replaced by suitable alternatives** where **economically and technically viable**

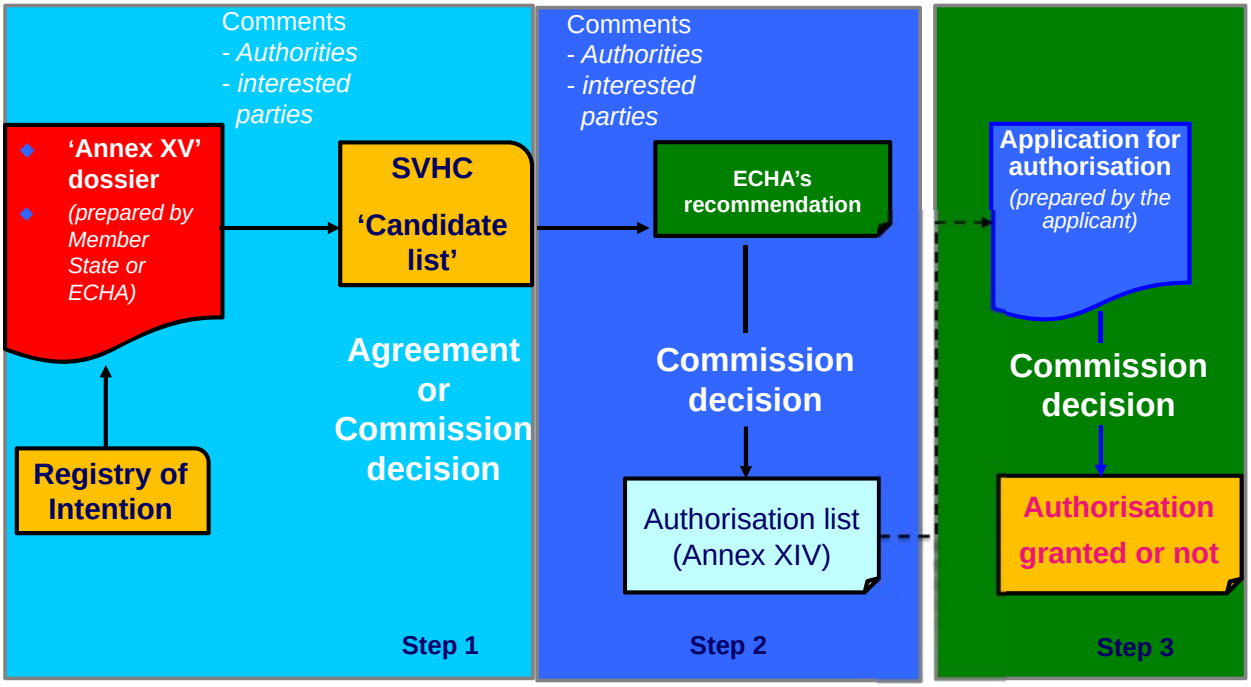
- Applies only to “substances of very high concern”, including, **PBTs,CMR cat 1A or B, endocrine disruptors and substances of similar concern**

Who will this affect?

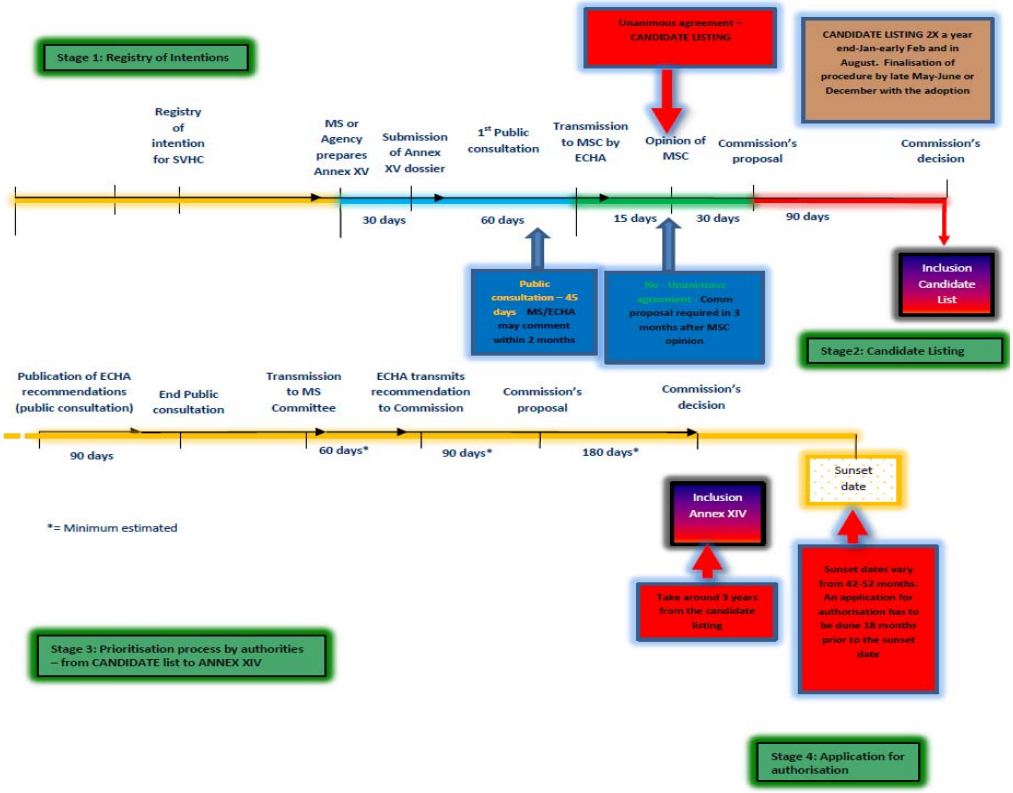
- **MANUFACTURERS, IMPORTERS OR DOWNSTREAM USERS**
- **IMPLICATIONS:** A substance **may not be placed on the market** for **a use or be used by itself** if that substance is included in **Authorisation list (Annex XIV),** unless:
  - ✓ The **use** has been **EXEMPTED**
    - ✓ **Isolated intermediates**
    - ✓ **Specific use exemptions**
  - ✓ The **use** has been **AUTHORISED**

Authorisation does not affect
- **EXPORT** of Annex XIV substance **manufactured** in the EU
- **IMPORTED ARTICLES** containing the Annex XIV substance

Authorisation process



Authorisation timeline



Description of the Authorisation process
Application for Authorisation

- If an application for authorisation is made at least 18 months before the sunset date, then, unless already rejected, the **applicant can continue using the substance after the sunset date has passed**, until a decision on the application is taken.
- Each authorisation will be **reviewed after a specified time** (**will vary in each case**) and may be **amended** or **withdrawn** as a result of the review.
- Holders of an authorisation will have to submit a **review report at least 18 months** before the review is carried out for use to continue.
- The Commission can also decide to review an authorisation **at any time** if circumstances change.
- Confidential business information
- Anticompetative behaviour

Description of the Authorisation process
Application for Authorisation

- **2 routes**

1. Adequate control route - applicant can demonstrate **adequate control** of risks arising from the use of SVHC

2. Socio - economic route - applicant must demonstrate that:

- There are **no suitable alternatives to SVHC**

Availability of alternatives (technology / process) and consider their risks, and the **technical and economic feasibility of substitution**.

- **AND** the **socio-economic benefits outweigh the risks** to the environment and human health

Art 60(4) : .... Authorisation may only be granted if it is shown that socio-economic benefits outweigh the risk and if there are no suitable alternative substances or technologies....

Description of the Authorisation process
Application for Authorisation

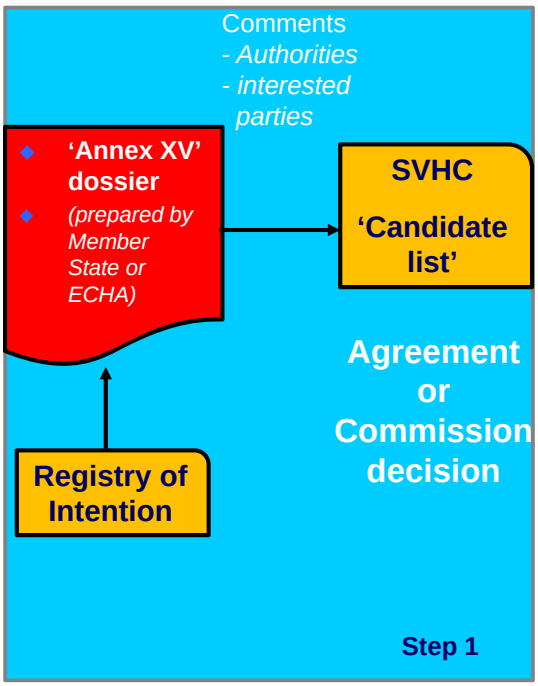
Applications can be made:

- **Individually** by a company (Manufacturer, Importer or Downstream user)
- **Jointly** (manufacturer(s) and/or importer(s) and/or downstream user(s)
  - For a specific use
  - A group of uses
  - Group of substances

Description of the Authorisation process
Application for Authorisation

- **1st application submission will be in 2013** – No industry experience to date
- **No experience** on follow-ups, updates or resubmissions on authorisation to date
- **Important to note** – Authorisation applications can be reviewed by the Commission at anytime.

Authorisation Process-Candidate Listing



What can you do following inclusion in ROI

Work required for an authorisation

Immediate

- **Engage with stakeholders early**
  - Make **contact with consultants** and **originator** of the Annex XV dossier development (Member State or Commission)
  - **Identify all downstream users sectors** and co-develop map of all uses including volumes e.g. manufacture, import/export etc
  - **Identifying all potential cases for exemption** and develop documented arguments and justifications
  - **Provide consultants with above information in time** for inclusion in the draft Annex XV dossier as this will be used by ECHA/Member States and Commission for prioritising SVHCs to enter the authorisation process
- **Legal challenge to candidate listing is difficult**
  - Beware of **time limitations** (2 months after listing)
  - Producers & importers may have **better chance of success in challenging candidate listing**

Work required for an authorisation
Immediate

- Gather information required for a risk management option analysis
  - **Occupational releases and exposure**
  - **Trends in environmental levels**
  - **Voluntary industry initiatives**
  - **Recycling & resource availability**
  - **Contribution to sustainable development**
  - **Alternatives**

Work required for an authorisation
Immediate

Extensive EU wide Community legislation

- Map out all the existing **Extensive EU wide Community legislation**
  - Which has already successfully implemented to control exposure throughout the lifecycle of these substances, from manufacturing to end of life and recycling.
- Existing Community legislation (e.g. 2000/53/EC) already imposes minimum requirements relating to the protection of human health or the environment, design requirements, end of life principles and review schedules.

Work required for an authorisation
Immediate

Intermediate cases

- **Identify** intermediate cases
- Very difficult to convince Sector Associations that **position papers are not accepted as arguments** for intermediate cases.
- The information must be **technically well founded** and available **supporting documentation** must be provided (8-14 pages).
- Will only know if accepted by regulators in 2nd Public consultation (2 ½ to prepare authorisation application if necessary)

1st Public Consultation-Candidate Listing

During the PC regulators only look at the classification criteria (Focus on trying to DE-PRIORITISE the substance in the next phase of authorisation)

Emphasising on key messages for each substance

- **Volume flow diagram –** mass flow on volumes for manufacture, imports, exports **and intermediate volumes.**
- **Description of uses and function of substances**
- What **existing risk management legislation** is already in place?
- Gathering **number of manufacturing sites and locations** in the EU
- **Potential for exposure** during manufacturing and use (to be demonstrated per use).
- **Release from manufacture** (workplace and environment)
- Making a plea for **threshold versus non-threshold**
- Potential **intermediate exemptions**

1st Public Consultation-Candidate Listing

Key messages delivered.

- Emphasising on **Voluntary Phase out initiatives**
- **What is already accepted as exemptions**
- **Current knowledge of alternative uses**
- **Potential economic impact** of a refused Authorisation, countries mostly affected
- EU manufacturing sector would be replaced by article imports
- Can these substances be **substituted**
- Alternative materials may have **own challenges**
- Wide-dispersive use
- Interchangeability
- Recycling

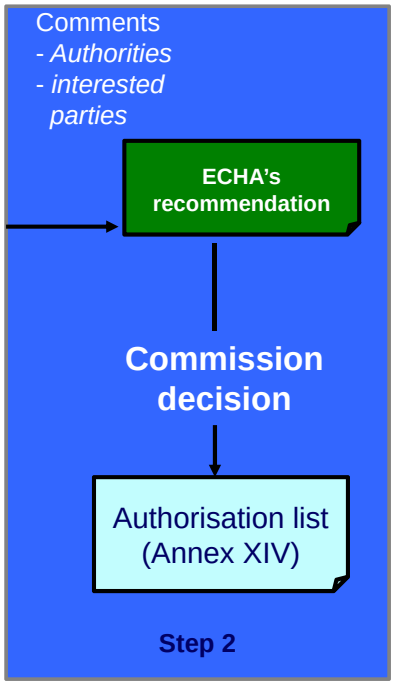
Education and Advocacy

- Regulators knowledge on uses are very limited
- It is critical to educate the regulators about the uses
  - **Commission**
  - **Member States**
  - **ECHA indirectly**
- Advocating – critical
  - Members States have a **big say** NOT only Comm (one needs to advocate
  - Need to target key MSs (also non-key)
  - Technical arguments
  - Socio-economic arguments (individual MSs)
  - **Need to assist Sector Associations on their briefing documents and support Sector Associations with their advocacy strategies.**

Education and Advocacy

- **Gather learning's** from **other metal commodities** subject to candidate listing.
- **Identify public relations support** to facilitate development of key messages/position paper in order to arrange meetings with influential stakeholders if required.
- **Arrange meetings with Member States** who may play key role in the informal committee who will help the Commission identify priority compounds for next public consultation on candidate listing
- **Co-ordinate proactive advocacy** at MS level with consortia member companies and/or key downstream user sectors

Authorisation Process-Prioritisation for inclusion in Annex XIV



How are candidate listed substances prioritized for Annex XIV?

- **Since third Candidate List (2011)** : in parallel :
  - Priority score approach
  - Regulatory effectiveness consideration/ Verbal approach

- **TIER 1** : scoring approach :
  - Intrinsic
  - Volume
  - Wide-dispersive use

→ X

- **TIER 2**: regulatory effectiveness considerations

  - "all available information that is relevant for drawing a conclusion in the prioritisation process" *

→ 

* From RMO analysis, Annex XV dossiers and Public Consultation

What can be done to prevent progression?

- **Prevent Candidate listing** :
  - Possible : NO !!!
  - MSC unanimity required BUT on Q : "criteria or not?"

- **Prevent Prioritisation** :
  - YES !
  - WHEN After "Candidate Listing"

  - **Confirm Exemptions**:
  - YES !
  - WHEN : during RMO and before ECHA starts prioritisation

  - **Improve RMO** :
  - In theory YES
    - Opinion on Article 58(2) argument
    - Update Registration dossiers (intermediate arguments, CSRs, exposure data etc)
  - WHEN : After "Candidate Listing" [unless MS or ECHA already developed]

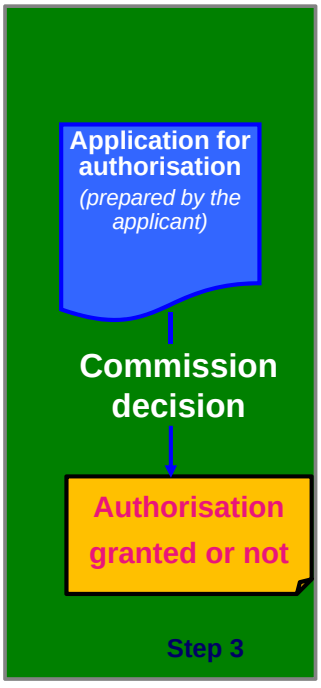
  - **Initiate Advocay with Member States:**
  - YES (Ultimately ECHA's recommendation must be approved Parliament (by majority) or the Council (by qualified majority)
  - WHEN: Now but iterative process peaking before any vote

Additional Activities to Consider During this Phase

- Continuously **learn from best practices**
- Work on the **SEA and analysis of alternatives**
- **Update registration dossiers** to include new scientific and use data (eg intermediate status, updated occupational blood lead data etc.)
- **Continue development of scientific information and arguments** to support adequate control route (eg threshold vs non-threshold)

Be prepared - Timelines are not always as they should be. Do not underestimate the amount of work to be carried out.

Authorisation process-Applying for authorisation



Authorisation – Cost to companies

STANDARD FEES	
Base fee	€ 50 000
Additional fee per substance	€ 10 000
Additional fee per use	€ 10 000
Additional fee per applicant	Additional applicant is not an SME: € 37 500
	Additional applicant is a medium enterprise: € 30 000
	Additional applicant is a small enterprise: € 18 750
	Additional applicant is a medium enterprise: € 5 625

Base fee covers the application for an authorisation for **one substance, one use, and one applicant**

The Agency shall levy an **additional fee** for

- **each additional use**
- **each additional substance** meeting definition of a group of substances
- **each additional applicant** that is party to the application

e.g. **1 use = 10 registrants (non-SMEs) = 377, 500 Euro**
7 uses = 10 registrants (non-SMEs) = 437,500 Euro

Authorisation – Cost to companies

Chromium trioxide estimated total cost of developing information to support authorisation application for **7 uses is Euro 1.5 million…….**

- **IMPORTANT** – Work normally takes 1.5 years **PER USE**
- Estimated cost **45,000 Euro PER USE (Just consultancy fees)**

Complexity of supply chain



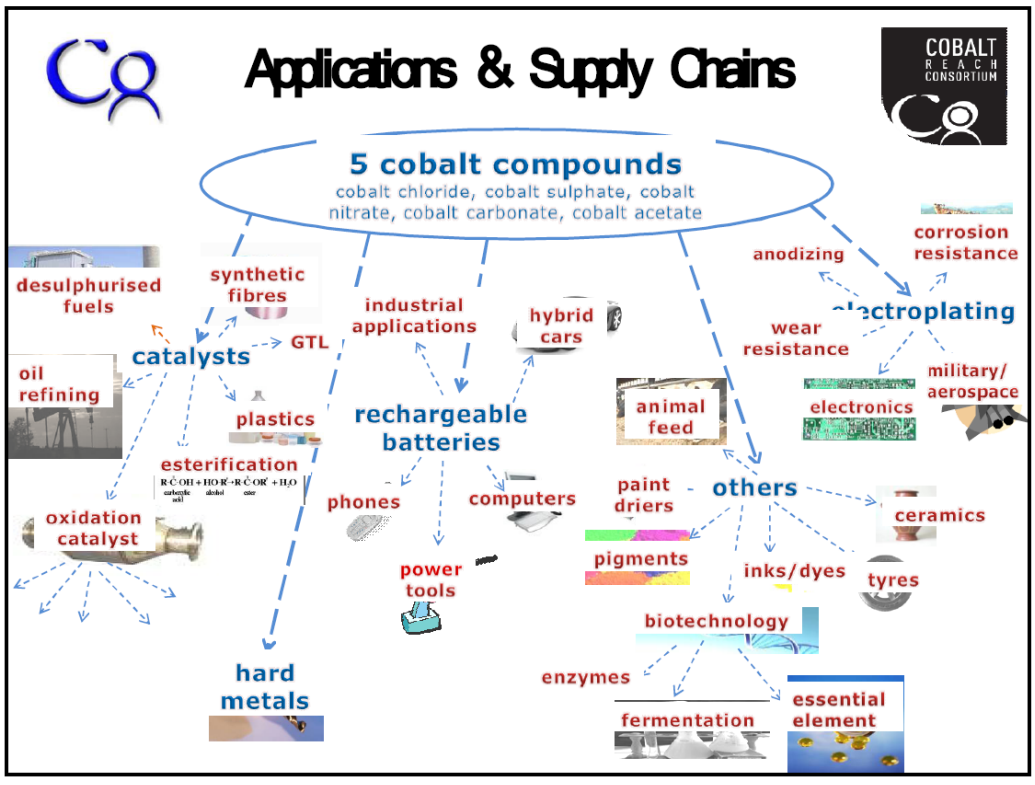

Lead Oxides








Complexity of supply chain



Impact of Pb authorisation on other metal substances

If Pb is a non-intentional impurity

Candidate listing

- Will result in **additional communication burden** for downstream users (REACH Article 33)
  - if >0.1% in substance/mixture or article need to provide Information immediately to downstream users within 45 days of request and to be sent updated SDS.

Impact of Pb authorisation on other metal substances

If Pb is a constituent

Candidate listing

- **Seen as stigma** and will potentially result in downstream users
  - Reducing R&D spending on innovation
  - Switching to lead free alternatives
- Will result in **additional communication burden** for downstream users (REACH Article 33)
  - if >0.1% in substance/mixture or article need to provide Information immediately to downstream users within 45 days of request and to be sent updated SDS.
- Will **require increased funding** to develop information required to support potential future authorisation application

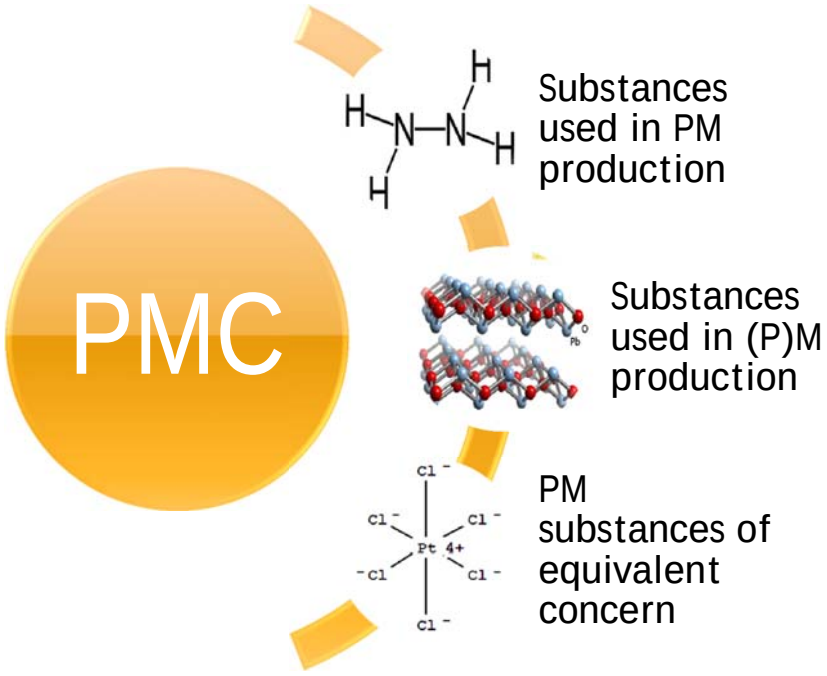
Impact of Pb authorisation on other metal substances

Authorisation

- **Significant cost implications** of a decision to apply for authorisation
- Downstream users will **no longer be allowed to use SVHC** after the sunset date unless they are **covered by an authorisation** (**or uses are exempt**).
- **Time limits** apply to granting of authorisation and reviews of original decision required creating increased uncertainty (and cost…)
- Suppliers must **update safety data sheets** with details of authorisation
- Holders of authorisation and downstream users must include **authorisation number on labels**
- Downstream users must **notify ECHA within 3 months** of first supply and a database of such users will be maintained by ECHA

Lead REACH CONSORTIUM

PMC & AUTHORISATION: POSSIBLE SCOPE AND CHALLENGES



5. PMC's REACH Challenges from 2013 onwards

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5.1. Short update per project and key topic (C. Braibant & K. Rothenbacher, EPMF)

Ag project

- Testing proposals:
  - Agreement reached with ECHA on eco-toxicity testing programme
  - Informal green light given to CSIRO, results expected in Q3 2013
- Ag halides: AgCl, AgBr and AgI
  - All files likely to be ready for submission in Feb 2013
  - Except for skin and eye irritation, all endpoints fulfilled and safe use demonstrated
  - Cooperation with I&P continues to be very good
- Ag2O:
  - PMC Member + potential LoA purchasers have indicated 100-1000 t/a applicable to Ag2O (current dossier only 10-100 t/a)
  - EBRC & WCA upgrading dossier to allow update before May 2013 deadline

Ag project

- Preparing for Evaluation *et al.*
  - Evaluation start now postponed to Feb 2014
  - PMC will remain in contact with NL to establish early contact
  - PMC also following all (regulatory + guidance) nano developments + comparable Evaluations (e.g. SAS)
  - Deferred start will allow complete dataset (soil, nanoAg) and latest literature search results (summer 2013) to be available before Evaluation commences
  - Literature search covering 2008-2012 completed and relevant studies being summarised in IUCLID 5
  - Repeated T/D test massive Ag completed: demonstrates no release of Ag → massive Ag non-classification confirmed

Ag project

- NanoAg:
  - Following recommendation from PMC Assembly, full literature review and effects assessment of nanoAg compared to Ag performed (and finalised in Nov 2012)
    - Assessment of effects indicate ionic Ag generally drives (eco-)toxicity of all sizes of Ag
    - Effects data (> 80 studies) assessed for quality and relevance, now being prepared into RSS in IUCLID 5
    - Except for one endpoint (*), data available for all endpoints either on form, read-across from another form, or waived
    - Awaiting outcome of on-going CSIRO and NTP work + (*) OECD 209 test to clarify more precise relative toxicity of nanoAg and ionic Ag to STP micro-organisms
    - CSR can be generated as soon as IUCLID 5 completed
    - NanoAg specific ES not needed because of same supporting effects dataset, same uses, and lower volumes
    - Approach to completing nanoAg risk assessment validated against recent recommendations from various experts under COM and ECHA nanomaterial discussion groups
  - M-factors: worst case or additional T/D testing?
    → For discussion by Ag WG, depends on use of nanoAg in mixtures
  - Nano TF recommends one dossier for all Ag forms
    → PMC **DECISION POINT 1**
  - When to submit the nanoAg content to ECHA now that Evaluation postponed?
    → PMC **DECISION POINT 2**

Ag project

- Proposed schedule for dossier submissions and updates:

	Q1 2013	Q4 2013	< Feb 2014
Submissions	AgCl (100-1000 t/a) AgBr (100-1000 t/a) AgI (1-10 t/a)	-	-
Updates	Ag2O (100-1000 t/a)	Ag (> 1000 t/a) AgNO3 (100-1000 t/a) Ag2O (100-1000 t/a) AgCl (100-1000 t/a) AgBr (100-1000 t/a) AgI (1-10 t/a) Ag2CO3 (1-10 t/a) Ag2SO4 (1-10 t/a)	Ag (> 1000 t/a)
Content	Substance- and tonnage-band-specific dataset (effect, exposure and CSR+ES demonstrating safe use) Indirect exposure Waste ES Latest C&L + M-factors	Soil toxicity updated dataset and CSR+ES including indirect exposure and waste ES Complete nanoAg dataset (incl. NTP and OECD 209 data) Latest Ag and nanoAg information Latest C&L + M-factors	'Cosmetic' update to comply with latest guidance and recommendations in preparation for Evaluation
Pending	Skin & eye irritation dataset for AgBr and AgI Soil toxicity dataset	Nothing?	Nothing?

Au project

- All enabling tests finalised
- Testing programme well progressed, slowed down with genotoxicity testing programme on TCA:
  - Negative Ames test
  - Positive *In vitro* micronucleus
  - FISH confirmes clastogenic response
  - Now need to conduct an *in vivo* assay to evaluate clastogenicity
- TCA has annex VIII requirements and proposed as reference Au substance to read-across to Au3+ or 1+ compounds
  - Genotoxicity read-acrossable?
  - Next *in vivo* steps:
    - Cannot administer acid, need surrogate substance
    - Possibility of integrating three tests in one adding *in vivo* genotox assay to OECD 422 (? ECHA)
- Once surrogate substance identified and testing programme re-launched, Au project can continue
- Start collection of exposure and emission data – tbd
- Registration not before late 2013/early 2014

PM CN- project

- All enabling tests finalised
- Read-across from HCN data not appropriate, data gap fill via testing and modelling:
  - Eco-tox: testing programme complete, awaiting reports
  - Tox: testing to commence soon on KAuCN and AgCN-, for Kag(CN)2 (decomposes fully) proposed to read-across from HCN
- Start collection of exposure and emission data – tbd
- Registration not before late 2013/early 2014

PGM project

- Sameness
  - Substance ID cards
  - Further discussion required on PGM nitrates; expert meeting 11 Dec
- Enabling Tests completed
  - Bio-elution, dustiness, water solubility, oxidising properties, irritation/corrosion
  - Summary report in preparation
- Full testing programme started
  - Genotoxicity and sensitisation tests started (nitrates are on hold)
  - Ecotoxicity: ready to start
  - Feeding studies
    - Scope based on final results enabling tests
    - Expert meeting planned for Jan 2013
- Exposure Scenarios (ES)
  - Jun 2012: kick-off meeting, prepared questionnaires (uses, emissions, exposure)
  - 9 Oct 2012: identified uses, tier 1 ES
    - Potential risk for sediment compartment
  - 12 Dec 2012: refined ES

PGM project

- Diamminedichloropalladium (DDP)
  - Environment part
    - Scheduled ecotox tests completed
    - Env classification Acute1/Chronic1 (M-factor 10/10) required
    - Need to refine PNEC sediment (new test), currently under discussion by PGM WG
  - Mammalian toxicity
    - All tests completed, except repeated dose study
    - Eye irritant 1, acute tox 4, not a sensitiser
  - Repeated dose test
    - Study at Charles River had to be terminated
    - Need to repeat study + extensive range finder (new CRO: CiToxLAB)
    - Study will not be completed in time for 2013 registration = had to develop tentative DNELs based on other ammine Pd compound data

Re project

- All tests completed
- No extended CSR (with ES) needed
- Meeting on 4 Dec to agree on last steps before dossier submission
- Submission anticipated towards end Q1 2013
- LoA cost revised after dossier submission

Refinables project

- 14 Registration Dossiers submitted in 2010 - not 100% in line with latest ECHA Guidance on intermediates
- Since Jan 2011 PMC following and supporting metals' industry initiatives:
  - Challenge/re-open ECHA Guidance: not advisable
  - Provide examples of SCC in inorganics sector
  - Develop RiCoG and decisive DNEL tools with EBRC
  - Understand registration fees for 'full' intermediate dossiers
  - Clarify substance identification and applicability of PROCs
  - Agree and develop non-testing approach
  - Agree on schedule for updates/upgrades
  - Update MeClas and make it freely available to maximise validation
- Also supporting PMC-specific activities:
  - Meeting with ECHA directly, confirming the above
  - Collection of emissions and exposure data to demonstrate RiCo
  - Circulation of survey to define update/upgrade scope as from Jan 2013
- Next meeting on 13 Dec 2012, hoping to agree on scope and finalise upgrades in summer 2013

Hydrazine project

- RPA's updated proposal approved, second 2012 invoices sent to concerned companies for Hydrazine project only:
  - Task 1 – Start up meeting
    - Agree approach, identify information needs, agree schedule of work, launch data collection via dedicated questionnaire
  - Task 2 – Scoping the key issues
    - Based on input from questionnaires – need input from Marketing, Production, R&D, EHS, and Sustainability experts
    - To determine further data needs and complexity of exercise
  - Task 3 – Analysis of Alternatives
  - Task 4 – Assessment of Socio-economic Issues
- Task 5 (preparation of Authorisation Applications) not foreseen unless hydrazine added to Candidate List
  - Meanwhile outcome may serve as input into (in)formal advocacy
- Next meeting/workshop on AofA towards end Feb 2013
- Schedule anticipates task 4 completed by end 2013

5.2. Strategic challenges including Evaluation & Authorisation (M. Raffray, Johnson Matthey)

PMC's Registration challenges

Each step is a challenge on its own:

- ✓ Follow-up guidance and regulation reviews, participate in webinars and other events
- ✓ Scope of each project
- ✓ Ensure confidentiality and Competition Law rules are respected
- ✓ Regular literature searches

- ✓ Development of iterative integrated testing approaches
- ✓ Identifying reference substances (for testing and read-across) for each (type/family of) test
- ✓ Agree on sample management
- ✓ Consult dedicated experts to refine testing approach/protocol
- ✓ Agree on testing protocol: testing vehicle, integration of tests, minimuse use of animals, etc.
- ✓ Obtain ECHA's greenlight where relevant
- ✓ Launch (and repeat/correct) tests
- ✓ Monitor tests and interpret/implement these results: repeat, next test, impact on DNEL or PNEC, impact on classification, etc.

- ✓ Document and justify read-across strategy in general and for each endpoints

- ✓ Monitor IUCLID 5 completion
- ✓ Review CSR

PMC's Registration challenges

- ✓ Monitor collection of uses, emission and exposure data + iterative preparation and review of ES

- ✓ Monitor and review budget and human resources agreed for the task versus expenses and obtain Assembly's approval where relevant
- ✓ Support relevant PMC WG as secretariat
- ✓ Regularly update/involve concerned PMC WG, Mgmt Cttee, or Members: circulate updates, dedicated requests, and follow-up on feed-back
- ✓ Make available relevant dataset via online database (sharepoint)
- ✓ Coordinate SIEF communication

- ✓ Submit registrations
- ✓ Liaise with LoA purchasers

- ✓ Address and resolve ECHA questions and requests
- ✓ Update registrations and notifications

Above is to be multiplied by the number and complexity of substances in scope of the project…
PMC has > 100 individual registrations in scope!

PMC preparing for Evaluation

Means:

- ✓ Follow-up guidance and regulation reviews, participate in webinars and other events
- ✓ Capture key concerns/items of interest to evaluating Member State
- ✓ Share learning lessons with other sectors undergoing Evaluation (with the same evaluating MS)
- ✓ Meet as regularly as possible with evaluating MS before and during Evaluation process
- ✓ Ensure confidentiality and Competition Law rules are respected

- ✓ Monitor most recent scientific publications of relevance
- ✓ Assess and address potential weaknesses of dossier: latest IUCLID 5 version and requirements, latest regulatory or scientific developments
- ✓ Launch necessary research, reviews, etc. with dedicated experts
- ✓ Monitor tests and interpret/implement these results: repeat, next test, impact on DNEL or PNEC, impact on classification, etc.

PMC preparing for Evaluation

- ✓ Monitor and review budget and human resources agreed for the task versus expenses and obtain Assembly's approval where relevant
- ✓ Support relevant PMC WG as secretariat
- ✓ Regularly update/involve concerned PMC WG, Mgmt Cttee, or Members: circulate updates, dedicated requests, and follow-up on feed-back
- ✓ Make available relevant dataset via online database (sharepoint)
- ✓ Coordinate SIEF communication

- ✓ Submit dossier updates
- ✓ Address and resolve ECHA (RAC, MSC) questions and requests

- ✓ Agree on final IUCLID 5 file
- ✓ Launch OECD HPV initiative to promote worldwide recognition of agreed dataset

In the case of PMC, currently only applicable to Silver

PMC preparing for Authorisation

Means:

- ✓ Follow-up guidance and regulation reviews, participate in webinars and other events
- ✓ Capture key concerns/items of interest to originator of SVHC or Candidate listings proposal
- ✓ Share learning lessons with other sectors preparing for Authorisation
- ✓ Ensure confidentiality and Competition Law rules are respected

- ✓ Exchange views with (other) sectors manufacturing, importing and/or using the substance subject to Authorisation
- ✓ Identify suitable Authorisation expert consultant and agree on scope, schedule and costing
- ✓ Agree on cost-sharing amongst Members

PMC preparing for Authorisation

- ✓ Monitor and review budget and human resources agreed for the task versus expenses and obtain Assembly's approval where relevant
- ✓ Support relevant PMC WG as secretariat
- ✓ Regularly update/involve concerned PMC WG, Mgmt Cttee, or Members: circulate updates, dedicated requests, and follow-up on feed-back
- ✓ Make available relevant dataset via online database (sharepoint)

- ✓ Support (in-)formal advocacy
- ✓ Prepare Authorisation Application
- ✓ Address and resolve ECHA (RAC, SEAC, MSC) questions and requests
- ✓ Follow-up Authorisation update requirements
- ✓ Monitor sunset date related-obligations and Authorisation expiries

In the case of PMC, potentially relevant for hydrazine, and possibly to other substances used in PM refining and to compounds resulting from PM production and potentially fulfilling SVHC criteria

Strenghts and weaknesses of PMC

Strengths

- Informed and involved membership
- Expert consultants contracted
- Available dedicated experts
- Formal connections to ECHA's committees via Eurométaux
- Secretariat following both regulatory and scientific developments under REACH
- Sufficient and transparent financial resources available

Weaknesses

- Multi-project, multi-priority entity diverging from key risks for sector
- Staff expected to follow all developments under REACH & easily overloaded/dissipated
- Insufficient officers to effectively follow Registration, Evaluation and Authorisation projects in the most sustainable manner
- If overload, risk of burn out, demotivation, and mistakes…

6. Reinforcement of EPMF/PMC Resources

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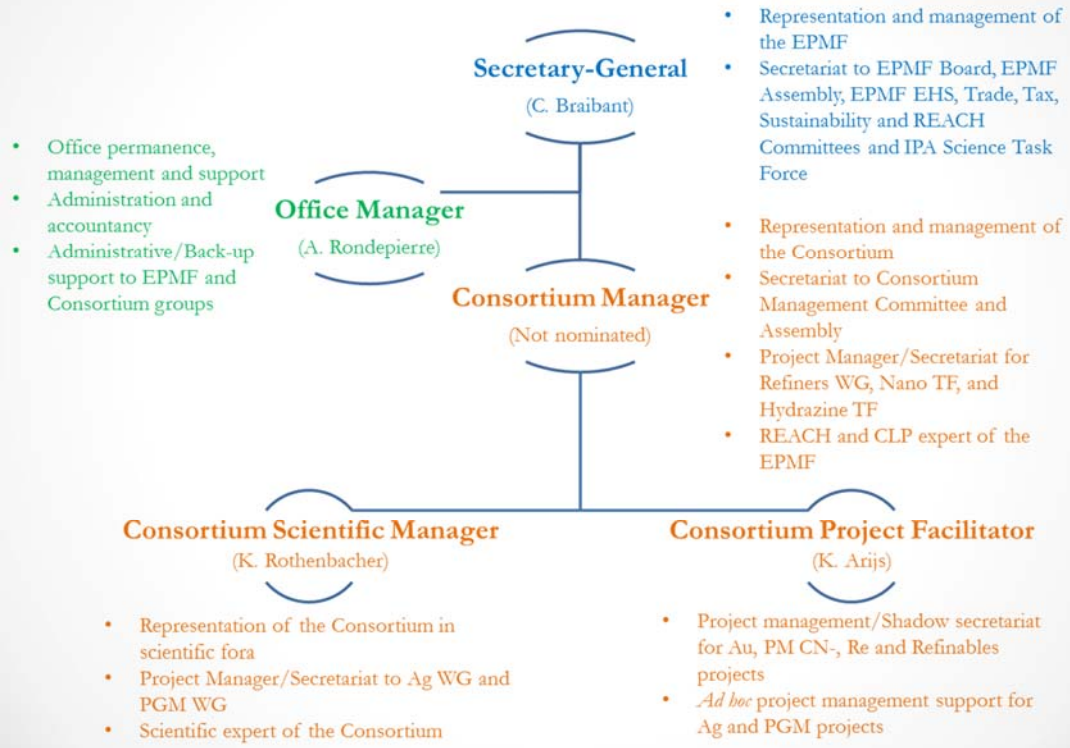
Guy ETHIER, Umicore

6.1 Background

- Insufficient resources for the EPMF
  - Secretary-General (CB) not available & "frozen agenda" for EPMF since 2009
  - CB transitionally addressing non-REACH items
- Insufficient resources for the Consortium
  - Tight/insufficient since 2010: success relies on officers' personal time
  - Increasing agenda: Huge scope, first Registration, then Registration updates too, soon more Registrations, Evaluation and Authorisation
  - CB transitionally moving out REACH management
- Security risk
  - All high-level mgmt/knowledge of both EPMF and PMC with one person…
  - Risk of burn out, demotivation and/or mistakes…

6.2 Proposed structure of EPMF/PMC resources



6.3 Proposal from the PMC Mgmt Cttee

- PMC Members to raise questions, comments and remarks on proposed work programme and associated human and financial resources
  - During meeting
  - Between Dec 2012 and Jun 2013
- 2014 budget based on expanded resources to be presented at Jun 2013 Plenary Meeting for vote/decision

7. Proposed 2013 & 2014 Budget

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Caroline BRAIBANT - EPMF

7.1 PMC 2013 Budget proposal

- UWM+T/D
- EU Water Directive et al.
- Terrestrial testing
- NanoAg IUCLID 5 + CSR&ES work
- Substance Evaluation of Ag (Evaluation + Update)
- Other *ad hoc* tasks

Budget item	Budget
Generic costs	601.278 €
Ag-specific costs	444.641 €
Au-specific costs	148.950 €
PM CN- -specific costs	361.105 €
PGM-specific costs	1.636.208 €
Re-specific costs	50.950 €
Refinables-specific costs	612.150 €
Hydrazine-specific costs	38.220 €
TOTAL	**3.893.502 €**

- 1 FTE Sec-Gen, 0,8 FTE Office Manager, 1 FTE Scientific Manager, and 0,8 FTE PMC Project Facilitator
- 20% Sec-Gen and 10% Off Mgr's times allocated to EPMF, remaining to PMC
- 15% of general office and meeting costs allocated to EPMF, remaining to PMC
- 50 000 € Eurométaux REACH project
- Annual inflation rate of 3% for 2013

- Next steps of testing programmes

- Core of testing programme
- Samples
- Gradual collection of emission and exposure data & ES drafting
- 2013 submissions

- Dossier finalisation and submission

- Analysis of alternatives
- Socio-economic analysis

- Assumes 14 upgrades

7.2 PMC 2013 invoices

- 2013 invoices calculated with following assumptions
  - 50% of new Member's generic costs credited, 50% kept in house
  - 50% of generic LoA incomes credited, 50% kept in house
  - 100% of metal-specific LoA incomes kept in house
  - 50% of reserves credited, 50% kept in house
- Proposal is to invoice:
  - Totality of 2013 invoice in spring 2013
  - Cost of PMC Manager as second 2013 invoice if EPMF/PMC Members approve EPMF Board & PMC Mgmt Cttee's proposal to hire PMC Manager and move C. Braibant to non-REACH items

7.2 PMC 2013 invoices (cont.)

ID Code	2013 Generic cost-share per Member	2013 Ag-specific cost-share per Member	2013 Au-specific cost-share per Member	2013 PM CN- -specific cost-share per Member	2013 PGM-specific cost-share per Member	2013 Re-specific cost-share per Member	2013 Ref-specific cost-share per Member	2013 Hz-specific cost-share per Member	Amount to be invoiced in 2013
1	8.471,66 €	0,00 €	0,00 €	0,00 €	0,00 €	0,00 €	0,00 €	0,00 €	8.471,66 €
2	8.471,66 €	0,00 €	186,41 €	0,00 €	15.918,34 €	0,00 €	5.841,24 €	4.777,50 €	35.195,15 €
3	8.471,66 €	4.649,02 €	360,15 €	0,00 €	3.412,00 €	0,00 €	0,00 €	0,00 €	16.892,83 €
4	8.471,66 €	7.557,13 €	360,15 €	0,00 €	0,00 €	0,00 €	0,00 €	0,00 €	16.388,94 €
5	8.471,66 €	40.309,76 €	360,15 €	0,00 €	0,00 €	0,00 €	40.888,67 €	0,00 €	90.030,24 €
6	8.471,66 €	12.856,50 €	0,00 €	50.354,25 €	8.530,00 €	0,00 €	5.841,24 €	0,00 €	86.053,67 €
7	8.471,66 €	7.593,48 €	186,41 €	40.491,05 €	0,00 €	0,00 €	0,00 €	0,00 €	56.742,60 €
8	8.471,66 €	0,00 €	0,00 €	10.209,28 €	0,00 €	0,00 €	0,00 €	0,00 €	18.680,94 €
9	8.471,66 €	12.856,50 €	720,30 €	0,00 €	13.648,01 €	0,00 €	0,00 €	4.777,50 €	40.473,97 €
10	8.471,66 €	4.103,74 €	186,41 €	20.418,56 €	3.412,00 €	0,00 €	0,00 €	0,00 €	36.592,38 €
11	8.471,66 €	52.479,55 €	546,56 €	50.354,25 €	100.782,14 €	0,00 €	52.571,15 €	4.777,50 €	269.982,82 €
12	8.471,66 €	7.557,13 €	360,15 €	0,00 €	3.412,00 €	0,00 €	0,00 €	0,00 €	19.800,94 €
13	8.471,66 €	40.309,76 €	186,41 €	0,00 €	0,00 €	0,00 €	35.047,44 €	0,00 €	84.015,26 €
14	8.471,66 €	16.855,16 €	0,00 €	0,00 €	0,00 €	0,00 €	0,00 €	0,00 €	25.326,82 €
15	8.471,66 €	12.206,14 €	732,97 €	30.627,85 €	106.041,22 €	-4.352,34 €	29.206,20 €	4.777,50 €	187.711,20 €
16	8.471,66 €	4.140,10 €	186,41 €	0,00 €	32.978,35 €	0,00 €	46.729,91 €	0,00 €	92.506,43 €
17	8.471,66 €	20.413,63 €	360,15 €	40.491,05 €	5.118,00 €	0,00 €	0,00 €	4.777,50 €	79.632,00 €
18	8.471,66 €	4.649,02 €	0,00 €	0,00 €	0,00 €	0,00 €	5.841,24 €	0,00 €	18.961,92 €
19	8.471,66 €	4.649,02 €	0,00 €	0,00 €	0,00 €	0,00 €	0,00 €	0,00 €	13.120,68 €
20	8.471,66 €	7.557,13 €	360,15 €	0,00 €	1.706,00 €	0,00 €	17.523,72 €	0,00 €	35.618,66 €
21	8.471,66 €	7.557,13 €	360,15 €	0,00 €	3.412,00 €	0,00 €	0,00 €	0,00 €	19.800,94 €
23	8.471,66 €	4.103,74 €	186,41 €	0,00 €	0,00 €	0,00 €	0,00 €	0,00 €	12.761,82 €
24	8.471,66 €	4.103,74 €	186,41 €	0,00 €	3.412,00 €	0,00 €	0,00 €	4.777,50 €	20.951,32 €
25	8.471,66 €	25.062,65 €	559,23 €	0,00 €	49.443,08 €	-2.434,36 €	52.571,15 €	4.777,50 €	138.450,92 €

7.2 PMC 2013 invoices (cont.)

ID Code	2013 Generic cost-share per Member	2013 Ag-specific cost-share per Member	2013 Au-specific cost-share per Member	2013 PM CN- -specific cost-share per Member	2013 PGM-specific cost-share per Member	2013 Re-specific cost-share per Member	2013 Ref-specific cost-share per Member	2013 Hz-specific cost-share per Member	Amount to be invoiced in 2013
26	8.471,66 €	12.206,14 €	186,41 €	0,00 €	5.259,09 €	0,00 €	23.364,96 €	0,00 €	49.488,26 €
27	8.471,66 €	4.649,02 €	0,00 €	0,00 €	0,00 €	0,00 €	0,00 €	0,00 €	13.120,68 €
28	8.471,66 €	0,00 €	0,00 €	0,00 €	0,00 €	-1.622,91 €	0,00 €	0,00 €	6.848,76 €
29	8.471,66 €	0,00 €	186,41 €	0,00 €	0,00 €	0,00 €	0,00 €	0,00 €	8.658,07 €
30	8.471,66 €	0,00 €	0,00 €	0,00 €	0,00 €	-1.622,91 €	0,00 €	0,00 €	6.848,76 €
31	8.471,66 €	0,00 €	0,00 €	0,00 €	0,00 €	-73,77 €	0,00 €	0,00 €	8.397,89 €
32	8.471,66 €	4.649,02 €	0,00 €	0,00 €	0,00 €	0,00 €	5.841,24 €	0,00 €	18.961,92 €
33	8.471,66 €	4.649,02 €	0,00 €	0,00 €	0,00 €	0,00 €	0,00 €	0,00 €	13.120,68 €
34	8.471,66 €	0,00 €	0,00 €	0,00 €	0,00 €	0,00 €	5.841,24 €	0,00 €	14.312,90 €
35	8.471,66 €	0,00 €	0,00 €	0,00 €	0,00 €	-1.622,91 €	0,00 €	0,00 €	6.848,76 €
36	8.471,66 €	4.649,02 €	186,41 €	0,00 €	3.412,00 €	0,00 €	0,00 €	0,00 €	16.719,09 €
37	8.471,66 €	4.649,02 €	0,00 €	0,00 €	0,00 €	0,00 €	0,00 €	0,00 €	13.120,68 €
39	8.471,66 €	4.649,02 €	360,15 €	0,00 €	3.412,00 €	0,00 €	29.206,20 €	0,00 €	46.099,03 €
40	8.471,66 €	16.309,89 €	360,15 €	20.072,49 €	10.641,31 €	0,00 €	58.412,39 €	0,00 €	114.267,89 €
41	8.471,66 €	4.649,02 €	0,00 €	0,00 €	0,00 €	0,00 €	0,00 €	0,00 €	13.120,68 €
42	8.471,66 €	0,00 €	186,41 €	0,00 €	1.706,00 €	0,00 €	0,00 €	0,00 €	10.364,07 €
43	8.471,66 €	40.273,40 €	0,00 €	0,00 €	0,00 €	0,00 €	0,00 €	0,00 €	48.745,07 €
44	8.471,66 €	0,00 €	0,00 €	0,00 €	11.942,01 €	0,00 €	0,00 €	0,00 €	20.413,67 €
45	8.471,66 €	4.649,02 €	186,41 €	0,00 €	22.460,18 €	0,00 €	0,00 €	0,00 €	35.767,27 €
46	8.471,66 €	7.557,13 €	0,00 €	0,00 €	0,00 €	0,00 €	0,00 €	0,00 €	16.028,79 €
47	8.471,66 €	4.649,02 €	186,41 €	0,00 €	8.530,00 €	-1.622,91 €	0,00 €	0,00 €	20.214,18 €
48	8.471,66 €	11.660,87 €	0,00 €	0,00 €	3.412,00 €	0,00 €	0,00 €	4.777,50 €	28.322,04 €
49	8.471,66 €	0,00 €	0,00 €	0,00 €	11.942,01 €	0,00 €	0,00 €	0,00 €	20.413,67 €
TPR 1	TPR 1					-1.696,68 €			-1.696,68 €
TOTAL	398.168,16 €	431.418,62 €	8.223,72 €	263.018,79 €	433.941,76 €	-15.048,78 €	414.727,99 €	38.220,00 €	1.972.670,25 €

7.3 2014 budget

- Draft budget based on current knowledge
- Will be circulated for discussion and approval at 2013 Plenary Meeting
- Below figures are indicative and should not be deemed final:

Generic costs	632.643 €
Ag-specific costs	181.900 €
Au-specific costs	148.800 €
PM CN- -specific costs	202.050 €
PGM-specific costs	683.400 €
Re-specific costs	24.450 €
Refinables-specific costs	885.150 €
Hydrazine-specific costs	60.000 €
TOTAL	2.818.393 €

8. AOB, Next Meetings & Closing Remarks

• • •

Guy Ethier, Umicore

8.1. Satisfactory survey

Cf. handouts

Please complete and return before leaving

Basis to measure quality/evolution of PMC's work

8.2. AOB

- Pb SCL of 0,03 %: PMC Members' feed-back sent to Eurométaux
- Action Members:
  - C&L notification updates reflecting 2nd ATP to CLP now due
- Action PMC:
  - Revisit skin corrosive 1A classifications derived on the basis of pH to prevent unreasonable impact on transport of PM compounds

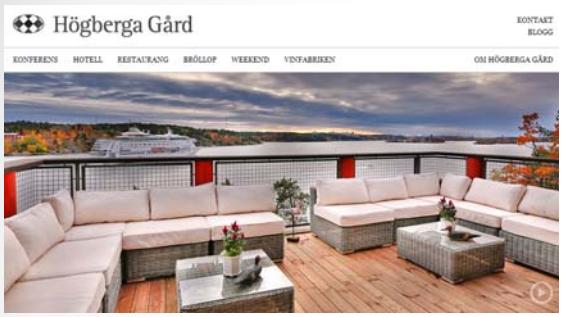
8.3. Next meetings:

Stockholm, 13 Jun 2013 (next slide)

Brussels, 4 Dec 2013 (unless date not suitable?)

Save the date!

Stockholm, 13 Jun 2013



- Hotel Högberga Gård proposed
- Located nicely by the water but outside the city center (20-30 minutes bus ride).
- Taxi from airport takes normally less than 1 hour and cost ~EUR 50.
- Please visit: http://hogberga.se/
- Formal invitation and proposed programme will be circulated in Spring 2013

Thank you!