Precious Metals and Rhenium Consortium

Plenary Meeting

18 June 2010, 9h00 – 17h30
Park Hyatt Hamburg Hotel
Hamburg, Germany

1. Welcome and introduction

Welcome and introduction

- Confidentiality and Competition Law
- Objectives of today's meeting
- Approval of the Agenda

Agenda

1. Welcome and introduction
2. Status and progress of PMC projects:
    1. Key messages from the TAP
    2. Ag
    3. Au
    4. PM CN-
    5. PGM
    6. Re
    7. Refinables

Agenda (cont.)

3. Preparing for Registration and CLP notifications
4. Review of the Consortium Agreement
5. 2007-2020 PMC Budget and Letter of Access
6. 2010 PMC Budget revision, 2011 Budget proposal
7. AOB, next meetings and closing remarks

Actions agreed at the last PMC Assembly meeting

1. Identify the risks involved in not meeting the registration deadline with a complete Dossier – **DONE**
2. Circulate guidance on substance identification to Members as soon as it becomes available - **DONE**
3. Contact potential candidates to identify a potential Lead Registrant for all substances in scope – **DONE**
4. Clarify and strengthen Appendix 5 of the Consortium Agreement – **DONE**

Actions agreed at the last PMC Assembly meeting

5. Circulate an updated list of uses covered by the Ag project – **DONE**

6. Devise a classification notification strategy with EBRC and WCA – **DONE**

7. Add column for budget tracking in all project plans – **DONE**

8. Obtain clarification on the following aspects of the OECD Programme – **DONE** – Cf. report under AOB

9. Clarify any open issue (e.g.: security, IT set-up, etc.) before signing any contract commissioning the implementation of WCA's IUCLID 5 Hosting System – **DONE**

VOTE: Approval of the Minutes of the 3 Dec 2009 meeting

2. Status and projects of PMC

2.1 Key messages from the TAP

M. Raffray, Johnson Matthey
Chairman, TAP

2.1.1 Priority projects: Ag

- Registration and CLP notification in 2010 of:

Ag metal	AgNO3	Ag2O
Substance	Substance	Substance
> 1000 t/a	100-1000 t/a (R50/53)	10-100 t/a

Human Health

- Final HH study data acquisition and test waiving (sensitisation, systemic toxicity, genetic tox etc.)
- HH - DNEL derivation

2.1.1 Priority projects: Ag

ENV – Problematic area of Ag environmental toxicity and narrow margin of safety

- Efforts to improve aquatic PNEC (REACH & also WFD use)
- Environmental monitoring ▸ real-world PEC assessments
- Fallback mitigation via BLM (further feasibility work)

Dossier preparation stage

- Exposure scenario integration and CSA/CSR assembly

Classification

- Effort to differentiate “massive” vs powder Ag (T/D work)
- Initial classification of AgNO3 from Oxidising solid Cat. 2 to Oxidising solid Cat. 1
- Such classifications may impact at company level

2.1.1 Priority projects: PM Refinables

- Minimum of 10 Dossiers subject to 1 Dec 2010 submission
- All intermediates, all UVCB !
- Initial deliverable: characterisation & classification (allowing for UVCB status)
- Further deliverable: Attempt to waive Annex VII (Eco-)Tox tests via modelled classification approach – work in progress

2.1.1 Other projects

- Other PMC projects will be addressed in full detail later today

2.1.2 CLP notifications

- If Registration **by** 1 Dec 2010: CLP notification part of Registration (e.g.: Ag and PM Refinables registrations)
- If Registration **after** 1 Dec 2010: CLP notification via standalone exercise by 3 Jan 2011 – *ad hoc* action in each project involving:

Data gap analysis	→	**Testing or waiver plan**
Select testing house	→	**Id Sample providers (LR)**
Driving physico-chemical tests for classification	→	**Review test results and derive classification**
Review classification proposal at PMC/SIEF level	→	**Submit classification notification to ECHA**

- **Key message**:
  - **Respond to LR / Sample provider requests as quickly as possible**
  - **Provide any information (*tests, papers, rationales/viewpoints*) you may have on physico-chemical parameters**

2.1.3 Strictly controlled conditions (SCC)

- Interpretation of what SCC means in practice
  - View varies from companies & industry sectors vs national authorities (e.g. MS CA) vs EU authorities (ECHA)
- ECHA guidance under review
  - Disagreement re "flexibility" in industry guidance (e.g. CEFIC); revised Guidance not ready before 2010 registration deadline
- Industry sectors invited to provide examples:
  - NFM proposed a metal matte example
  - Defended concept of "adequate control" requirement for well characterised intermediates with known hazards
- Unpredictable!
  - Given implications, metals/chemicals sector may have to fight

2.1.3 Strictly controlled conditions (SCC) (cont.)

- Industry views not supported by some Members States who claim:
  - Strict control = no possible exposure
  - Therefore strict control = no reliance on PPE
- **Key message:**
  - 2010 registrations: properly document steps taken to implement strict control in line with existing (ECHA and Eurométaux) guidance
  - Post 2010 registrations: monitor situation – might need to prepare substance dossiers instead of intermediate ones…

2.1.4 The crucial need for real exposure data

- Ag experience: existing emissions & exposure data surprisingly limited or non-existent
- Reminder: No emission/exposure data = enforced use of modelling ▸ default & over-conservative values ▸ often much tougher to demonstrate safe use
- Ag experience: Must guide us on other projects

Key messages:

- Need data in next projects (e.g. some PGMs)
  - (1) Look ahead - what is your local data availability?
  - (2) Plan data capture resources if needed
  - (3) Respond to data generation requests quickly

2.1.5 Substance identification

- Known as common reason for dossier rejection !
- EM Guidance on substance id & naming – comprehensive
- PMC recommendations added to EM guidance:
  - 1-pager with PM & Re-specific analysis advice
  - Takes into account complex PGM chemistries
  - Includes best advice, e.g. solids PSD not legally required for co-registrants but recommended re "safety sameness
  - More details later….
- Proper identification is each company's responsibility
- Recommendation: ensure id's for 2010 registrations in good shape; prepare next up in steady manner

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2.2 Ag Project

K. Rothenbacher, EPMF
T. Hird, EPMF

2.2.1 Scope

Registration by	Name	Status	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	Disilver (1+) sulphate	Substance	1-10	2	Johnson Matthey
	Silver carbonate	Substance	1-10	3	Johnson Matthey
	Silver chloride	Intermediate	100-1000	7	Umicore
	Silver bromide	Intermediate	1-10	1	Umicore
	Silver sulphide	Intermediate	10-100	1	Umicore

2.2.2 Phase I - III: Remaining data gaps

- Long term toxicity to soil
  - Needed to avoid risk scenario
    - ❑Terrestrial invertebrates (earthworm)
    - ❑Terrestrial plants
    - ❑Nitrogen transformation
  - Testing programme running from Jun till Sep 2010
  - Will also be used to derive a PNECsoil for Ag
- Parameters reducing aquatic toxicity of Ag ions (See BLM scoping study)

2.2.3 Phase IV – Chemical Safety Assessment

Background

- Risk assessment conducted on the basis of:
  - Effects data → obtained through literature search + testing programme
  - Exposure data → obtained through uses, emissions and exposure questionnaire + monitoring programmes + workshops + exchanges with companies
  - Default data vs. measured data
- Effects data is used to derive:

Human Health	Environment
DNEL – for each route of exposure: Oral Inhalation Dermal	**PNEC – for each environmental compartment:** Water Sewage sludge Sediment Soil Air

2.2.3 Phase IV – CSA (cont.)

Background (cont.)

- Exposure data is used to derive:

Human Health	Environment
Reasonable worst-case exposure per manufacture process/use	**PEClocal – for each manufacturing/using scenario** **PECregional – for each region (e.g. country)** **PECcontinental – for EEA**

- Effects and exposure data are then compared to perform a risk assessment:

Human Health	Environment
RCR = Exposure / DNEL	**RCR = PEC / PNEC**
RCR > 1 = Risk **RCR < 1 + sufficient quality exposure data available = No risk**	**RCR > 1 = Risk** **RCR < 1 = No risk**

2.2.3 Phase IV: CSA – DNELs

- **DNELs – Human Health:**
  - **Oral:**
    - Tentative DNEL very conservative (based on Argyria)
    - Currently reviewing additional literature on Argyria + external data-holders data
    - Revised DNEL will be proposed in Aug 2010
    - Limited impact on occupational ES
  - **Inhalation** – based on SCOEL recommendation:
    - 0,1 mg/m³ for Ag and Ag2O
    - 0,01 mg/m³ for AgNO3
  - **Dermal** – exposure route not relevant + no systemic effects = no DNEL needed

2.2.3 Phase IV: CSA – PNECs

- **PNECs - Environment:**
  - **Water:**
    - Current PNECwater of 40 ng/l
    - Improved from 34 ng/l (= 18% improvement, but still very low)
  - **Sewage Treatment Plant (STP)** – 0,025 mg/l sludge
  - **Soil** – pending results of remaining soil tests
  - **Sediment** – 1,2 mg/kg sediment
  - **Air** – exposure route not relevant, no PNEC needed

2.2.3 Phase IV: CSA – Exposure scenario (ES)

Occupational (Human Health)

Approach proposed by EBRC:

- Only inhalation relevant (oral and dermal exposure in workplace unlikely)
- Group similar production processes
  - As per the ECHA PROC codes: high level generic descriptions
  - Advantages in taking this approach:
    - Reduced number of ESs needed (workload & cost)
    - Allows covering uses discovered later
- Have both an Industrial ES & a Professional (DU) ES for each of Silver metal, Disilver Oxide and Silver Nitrate

2.2.3 Phase IV: CSA – ES (cont.)

Occupational (Inhalation) – Human Health

- Hard to come by…
- Data not sufficient to achieve statistical robustness to demonstrate that the OEL is not being exceeded and that RCR is of the correct magnitude
- But following April ES Workshop Members have dug deep and quite a bit more data has become available
  - One or two Members still to complete their monitoring programmes - **Thanks to those who did manage to come up with some data!**
  - Draft example of an industrial occupational ES has been circulated and Ag members were asked to comment

2.2.3 Phase IV: CSA – ES (cont.)

Other ES – Human Health

Type of exposure	Consumer	Man via the environment	Combined
Via	Consumer goods and articles	Air, water and food	Work, consumer, and surrounding environment
Main route of exposure	Oral, dermal	Oral, inhalation	Oral, inhalation, dermal
ES per	Good/use	Environmental compartment and food	Realistic worst case of a Ag worker, eating and drinking Ag-containing food and water and living in a Ag-rich environment

- Work launched in May with an initial teleconference involving EBRC, WCA & PMC, continued with meetings on 17 and 21 June:
  - Tier 1 assessment on Consumer Exposure received: considers applications as jewellery, cutlery, decorative coins, staining pigments, and photographic film
  - Next: Man v Environment and Combined Exposure

2.2.3 Phase IV: CSA – ES (cont.)

Environment

Approach proposed by WCA: one ES per environmental compartment

Water & Sediment

Tier 3 assessment now received from WCA:

- with the additional data submitted after April ES Workshop → vast majority of producers have an RCR <1 (no risk) for:
  - Fresh & marine water
  - Fresh and marine sediment

Soil

Awaiting PNECsoil (Sep 2010)

Air

Air is not at risk

2.2.3 Phase IV: CSA – ES (cont.)

For those wishing to learn more confirm your registration for:

2nd Ag ES workshop

Brussels, 28&29 June 2010

So far only 10 confirmed participants…!

2.2.3 Phase IV: CSA – Environment (Cont.)

- **Additional projects:**
  - Ag ion is hazardous to the aquatic environment:
    - PNECwater very low at 40 ng/l (nanograms!)
    - To prove safe use, need to demonstrate aquatic Ag levels < 40 ng/l, also near production/use sites
  - Two additional projects have been engaged to better describe impact of Ag in the environment:
    - Monitoring Programme – measured data
    - BLM scoping study – potential mitigating environmental effects

2.2.3 Phase IV: CSA – Environment (Cont.)

- **Monitoring Programme:**
  - **Aim:**
    - Use measured data instead of unrealistic modelling data
    - Determine PECregional, PEClocal and removal rates of STP
    - Demonstrate safe use despite very low PNECwater
    - Derive EQS for Ag under Water Framework Directive (WFD)
  - **Scope and duration:**
    - Determine natural background concentrations of Ag in the environment
    - Determine Ag levels downstream of industrial sources and STP
    - From Jan – Jul 2010 → In time to finalise CSA Water before Registration dossier submission
  - **Initial results:**
    - Show surprisingly low levels
      - No risk for background waters
      - No risk for 4/5 point sources

2.2.3 Phase IV: CSA – Environment (Cont.)

- **BLM Scoping study:**
  - **Aim:**
    - Correct PNECwater for factors which may mitigate the solubility/bio-availability and hence, toxicity of Ag (e.g.: sulphide levels, Cl-, DOC, etc.)
    - Focus on key parameters to demonstrate validity of concept
    - Demonstrate safe use despite very low PNECwater
    - Derive EQS for Ag under WFD
    - Overall, improve CSA Water on-time for Registration deadline + prepare further update/improvement of Dossier and possible Evaluation
  - **Scope:**
    - Scoping study combined with additional measurements taken in above Monitoring Programme (extended)
  - **Duration:**
    - Jul – Sep 2010: preliminary results from extended Monitoring Programme used for dossier preparation
    - Oct – Dec 2010: additional results from continued extended Monitoring Programme used for statistical and scientific robustness

2.2.4 Phase IV: Classification

- Physico-chemical hazards:
  - Oxidising properties (AgNO3 and Ag2O)
- Environmental hazards:
  - Transformation/Dissolution (All Ag)
- Human health hazards:
  - Sensitisation (All Ag)
  - Genetic toxicity (All Ag)

2.2.4 Phase IV: Classification – Physico-chemical

- Oxidising properties:
  - AgNO3 already classified as oxidising solid category 2
  - Additional PMC studies
    - AgNO3 → oxidising solid category 1
      - PMC Members currently confirming this test result on own materials
      - PMC will go ahead with classification recommendation as category 1 if no contradicting data becomes available – So far no objections
      - AgNO3 solution not classified for oxidising properties
    - Ag2O → oxidising solid category 1

2.2.4 Phase IV: Classification – Environment

- Transformation/Dissolution (T/D):
  - Before CLP/REACH Ag was not classified
  - New data from T/D tests indicates need to classify Ag metal and all Ag compounds
  - Tentative recommendation to classify all Ag and Ag compounds as acute category 1/ chronic category 1 (corresponds to R50/53)
  - T/D data currently being re-assessed and refined to
    - confirm above data
    - differentiate powder from massive Ag metal
  - Duration: Jun-Sep 2010

2.2.4 Phase IV: Classification – Human health

- Sensitisation:
  - PMC study inconclusive (due to confounding effects)
  - Additional external data holders' data could resolve situation (data-sharing agreement in progress)
- Genetic toxicity:
  - PMC study indicates marginally positive response, but likely due to indirect effects
  - Consulted with genotoxicity expert Prof. Kirkland
    - 4/5 studies indicate no genetic toxicity, 1 study shows marginal effects
    - Weight of evidence thus indicates Ag and Ag compounds are not mutagenic/genotoxic

2.2.5 IUCLID 5.2 and Registration readiness

- WCA and EBRC working on populating three IUCLID 5.2 files
- Meeting scheduled on 24 Aug with LR (Aurubis and Ames Goldsmith) to:
  - Check IUCLID 5.2 progress
  - Identify remaining gaps
  - Prepare steps towards Dossier submission to ECHA by LR
- Expected submission time:
  - LR: end Oct 2010
  - Co-registrants: Nov 2010 and on

2.2.6 Update on nanosilver

Background:

- PMC monitoring developments in RIP-oN1
- RIP-oN1 in charge of discussing whether/how the existing guidance on substance identification applies to nanomaterials
- Nanosilver picked as one of four examples / case-studies

PMC provisional position in Dec 2009:

- Nanosilver not included in Silver dossier in Dec 2010
- CEFIC not in agreement with PMC's approach
- PMC provisional position remains unchanged

Other developments:

- In RIP-oN3 US company developing CSR for nanosilver
- PMC has contacted Nanomaterials Industries Association (NIA) to seek an exchange with US company and make sure Ag CSA and Nanosilver CSA are compatible

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Any question?

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2.3 Au and PM CN- Projects

T. Hird, EPMF

2.3.1 Background

- Au and PM CN- Projects initially placed with DKC in Germany
  - DKC sent PMC updated Phase I reports + collected literature on 22 February 2010
  - Related invoices were paid in May 2010
- Projects effectively placed with WCA since Jan 2010

2.3.2 Scope (Au)

Registration by	Name	Status	Tonnage Band (t/a)	N° of PMC registrants	Lead Registrant
2013	Gold	Substance	10-100	23	Carl Hafner
	Tetrachloroauric acid	Substance	1-10	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	Intermediate	1-10	1	Heraeus
	Gold trihydroxide	Intermediate	1-10	1	

2.3.2 Scope (PM CN-)

Registration by	Name	Status	Tonnage Band (t/a)	N° of PMC registrants	Lead Registrant
2013	Potassium dicyanoargentate	Substance	10-100	5	
	Silver cyanide	Substance	10-100	6	
	Potassium dicyanoaurate	Substance	10-100	8	Umicore
	Potassium tetrakis (cyano-C)aurate	Substance	1-10	2	

2.3.3 Project progress

- Phase I now finalised: literature search reported in a matrix showing data gaps
- Phase II in progress → filling data gaps with intelligent testing strategy recommendations (read-across, waivers, etc.), focus on CLP
  - Info gathered in phases I and II immediately uploaded onto IUCLID 5.2 by WCA to maximise efficiency (Phase V)
- Phase III to be launched soon with CLP physico-chemical tests (including T/D test)
  - Testing scope under preparation
  - Test houses identified
  - LR/Sample providers not identified for all substances and intermediates!
  - Samples will be requested in late June, early July

This is key!

2.3.3 Project progress (cont.)

- Not for 2010:
  - Phase III:
    - "Non-CLP" physico-chemical testing
    - Tox/Eco-tox testing
  - Phase IV:
    - Not sure for which substances CSA/CSR will be required (must be > 10 t/a + hazardous)
    - Recognised that monitoring data is not readily available → need to prepare Phase IV carefully to allow:
      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

Step-wise

2.3.4 2010 Testing programme

- T/D of Au powder at ECTX
- CLP physico-chemical tests at Harlan, e.g.:
  - Melting + boiling point (as surrogates to next tier tests)
  - Water solubility, vapour pressure and flash point
  - Flammability of all powders
  - Self-ignition (depending on melting point)
  - Oxidising properties
- You are still on-time to share any data you may have on the physico-chemical properties of your Au and PM CN- materials!

Reason to ask whether any PMC Member manufactures Au powder Answer is YES!

2.3.5 CLP notification - timeline

- Jul/Aug 2010: Commence tests
- Oct 2010: Reports from testing houses
- Nov 2010: Prepare classification proposals
- Dec 2010: Circulate classification proposals for submission to ECHA prior to deadline
- **3 Jan 2011: Deadline for submission!!**

Any question?

2.4 PGM Project

K. Rothenbacher, EPMF

2.4.1 Scope

Registration by	Family	Status	Highest tonnage Band (t/a)	N° of PMC Members registrations	Lead Registrants*
2013	Platinum	11 substances 4 intermediates	Sub: 10-100 Int: 100-1000	58	**Vale**, JM, Umicore, Heraeus
	Palladium	16 substances 4 intermediates	Sub: 10-100 Int: 100-1000	73	**Umicore**, Heraeus, JM, C. Hafner
	Rhodium	14 substances 4 intermediates	10-100	46	**Anglo**, Heraeus, Umicore, Vale
	Iridium	5 substances 2 intermediates	1-10	20	**JM**, Umicore
	Ruthenium	6 substances 4 intermediates	10-100	27	**Heraeus**, Umicore, Vale

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

2.4.1 Scope (cont.)

Lead Registrants

Members invited to vote on proposed Lead Registrants

(See handouts)

Still 6 Pt, 10 Pd, 4 Ir, 7 Rh and 4 Ru LR-orphans !!

No LR = no sample provider = no testing = no CLP notification ready by 3 Jan 2011 !!

DEADLINE FOR VOLUNTEER LR: 15 July 2010 !!

2.4.2 Project progress

- Phase I finalised: literature search reported in a matrix showing data gaps – changes to PGM inventory have slightly complicated exercise
- Phase II finalised:
  - Intelligent testing strategy recommendations (read-across, waivers, etc.) proposed for all of endpoints – very conservative
  - Focus is on CLP:
    - Recommendations very conservative - Possibility of applying:
      - Expert scientific/handling judgement – need PGM experts' input!
      - Waivers – need to know melting/boiling point (not readily available!)
    - Testing recommendations under revision with WCA and Harlan
      - N.B.: Budget presented today based on first (conservative) proposal

2.4.2 Project progress (cont.)

- **Prioritisation: focus on time-critical work in 2010 (e.g., CLP). Rest of Phase IIII and IV in 2011 onwards**

- **Phase III – testing programme:**
  - Test houses identified
  - LR/Sample providers not identified for all substances and intermediates!
  - Samples will be requested in late June, early July
  - 10 T/D at CANMET: 5 PGM metal powders + 5 PGM oxides and chlorides
  - CLP physico-chemical tests at Harlan, e.g.:
    - Melting + boiling point (as surrogates to next tier tests)
    - Flammability
    - Self-ignition (depending on melting point)
    - Oxidising properties
  - **You are still on-time to share any data you may have on the physico-chemical properties of your PGM materials!**

This is key!

Reason to ask form of PGM materials:
• anhydrous / hydrated solid,
• aqueous solution,
• other
8/11 companies responded – see inventories in handouts

2.4.2 Project progress (cont.)

- **Phase III – testing programme (cont.):**

Solutions may be regarded as mixtures under CLP and do not require a CLP notification before 2014 → Possible tiered approach to CLP preparation !

- PGM manufactured in different forms:
  - Solids: anhydrous and hydrates
  - Liquids: solutions in water, in acid, in organic solvents

- Testing approach proposed by WCA is:
  - If there is only one option → test that
  - If the anhydrous solid exists → test anhydrous solid
  - If the anhydrous solid does not exist but the hydrated solid does → test hydrated solid
  - If both the anhydrous and the hydrated solid exist, and the expectation is that they will have different properties → test both
  - If the substance is available in multiple solutions → test aqueous solution
  - If it doesn't exist as aqueous solution → test one of the alternatives

2.4.3 CLP notification - timeline

- Jul/Aug 2010: Commence tests
- Oct 2010: Reports from testing houses
- Nov 2010: Prepare classification proposals
- Dec 2010: Circulate classification proposal for submission to ECHA prior to deadline
- **3 Jan 2011: Deadline for submission!!**

2.4.4 Next steps (not for 2010)

- Phase III:
  - "Non-CLP" physico-chemical testing
  - Tox/Eco-tox testing
- Phase IV
  - Not sure for which substances CSA/CSR will be required (must be > 10 t/a + hazardous)
  - Recognised that monitoring data is not readily available → need to prepare Phase IV carefully to allow:

Step-wise

1. Proper development of effects data (Phase III),
2. Assessment of effects data to identify hazards,
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2.5 Re Project

C. Braibant, EPMF

2.5.1 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	Intermediate	1-10	1	Heraeus
	Sodium rhenate	Intermediate	1-10	1	Climax Molybdenum
	Dirhenium heptasulphide	Intermediate	1-10	1	Johnson Matthey

2.5.2 Project progress

- Phases I and II finalised:
  - Literature search and data-gap analysis finalised
  - Intelligent testing strategy recommendations (read-across, waivers, etc.) proposed for all of endpoints
- Phase III in progress:
  - Started with UV, pH, water solubility, T/D and eco-tox tests
    - UV, pH and T/D moved to other testing house:
      - Preliminary indications show that ReO4 is species formed in solutions
    - Eco-tox test results received:
      - No toxicity shown to Sludge Micro-organisms, Daphnia, Fish or Algae (EC50 > 100 mg/l)
  - Will continue with CLP:
    - Testing recommendations under revision with WCA and Harlan
      - N.B.: Budget presented today based on first (conservative) proposal

2.5.2 Project progress (cont.)

CLP notification - timeline

- Jul/Aug 2010: Commence tests
- Oct 2010: Reports from testing houses
- Nov 2010: Prepare classification proposals
- Dec 2010: Circulate classification proposal for submission to ECHA prior to deadline
- **3 Jan 2011: Deadline for submission!!**

2.5.2 Project progress (cont.)

- Not for 2010:
  - **Phase III:**
    - Tox/Eco-tox testing
  - **Phase IV:**
    - Not sure for which substances CSA/CSR will be required, must be:
      - > 10 t/a: only *APR*
      - And hazardous: *APR does not seem to be so far*
- Phase V: work in progress (in parallel with data collection and generation)

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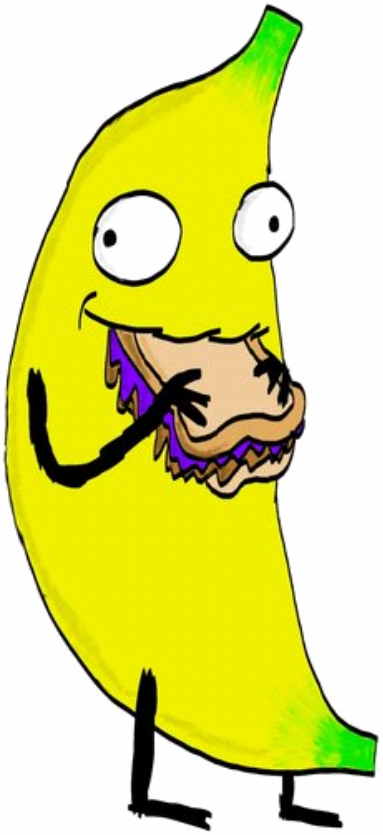
LUNCH BREAK



2.6 PM Refinables Project

C. Braibant, EPMF

2.6.1 Scope

14 Dossiers in total: **6 as Trans > 1000 t/a**

8 as other (Trans < 1000 t/a or on-site)

Registration by	Name	Status	Tonnage Band (t/a)	N° of PMC registrants	Lead Registrant
2010	1. Doré	Transported	> 1000	11	Aurubis
	2. PM matte	Transported	> 1000	4	Umicore
	3. PM slags	Transported	> 1000	10	Umicore
	4. PM slimes and sludges	Transported	> 1000	12	Aurubis
	5.1 Matte leaching residue	Transported	> 1000	4	Umicore
	5.2 Speiss leaching residue	Transported	100-1000	1	Umicore
	6.1 Ag electrolyte	On-site	> 1000	2	KGHM
	6.2 Au electrolyte	On-site	100-1000	1	Aurubis

2.6.1 Scope (cont.)

Registration by	Name	Status	Tonnage Band (t/a)	N° of PMC registrants	Lead Registrant
2010	7. PM flue dust	Transported	100-1000	7	Johnson Matthey
	8. Residues cementation and reduction	Transported	100-1000	10	Heraeus
	9.1 Materials for reclaim, PM with or without support	Transported	> 1000	5	Johnson Matthey
	9.2 Materials for reclaim, PM in bricks, crucibles and trays	Transported	10-100	5	Johnson Matthey
	9.3 Materials for reclaim, PM production by-products	Transported	100-1000	4	Johnson Matthey
	10. Pb bullion, PGM rich	On-site	10-100	1	Vale Inco

2.6.2 Project progress

- Phasing approach of this project is different than other PMC projects
- Focus is not on “gap filling” but on:
  - Proper identification/characterisation and grouping
  - Proper (CLP) classification (cf. interpretation of REACH regulation recital 45 !)
- Although intermediates, UVCB complex intermediates → gathering “any existing available information” does not allow robust id and classification

2.6.2 Project progress (cont.)

Thus, main tasks are (with support/guidance of Hugo Waeterschoot):

- **Members + Outotec:**
  - Ensure strict control
  - Obtain elemental composition
  - Obtain mineralogical composition (not always)
- **Harlan:** perform CLP tests, unless:
  - Expert judgement (Members), and/or
  - Waivers (WCA)
- **ARCHE:** Derive tox/eco-tox classification from:
  - Constituents - ERV, TRV (collected by WCA)
  - T/D data (ECTX)
- **WCA:** Prepare IUCLID 5.2 file for:
  - Registration, and
  - CLP notification

  in Nov 2010 !!!!

Team work !!

Due to time constraints, most tasks are ran in parallel !

2.6.2 Project progress (cont.)

- Annex VII (Eco-)Tox testing:

FACTS

- Required for Transported > 1000 t/a intermediates (i.e. 6/14 Refinables)
- Necessary to identify (eco-)tox hazards of materials
- (Eco-)Tox hazards of Refinables influenced by constituents and their leaching/release potential from the Refinable
- Classification of Refinables derived from data on constituents and release rates
- Refinables (eco-)tox hazards properly addressed and communicated through classification

→ No added value in performing additional (eco-)tox tests
→ No Annex VII (eco-)tox tests foreseen

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Any question?

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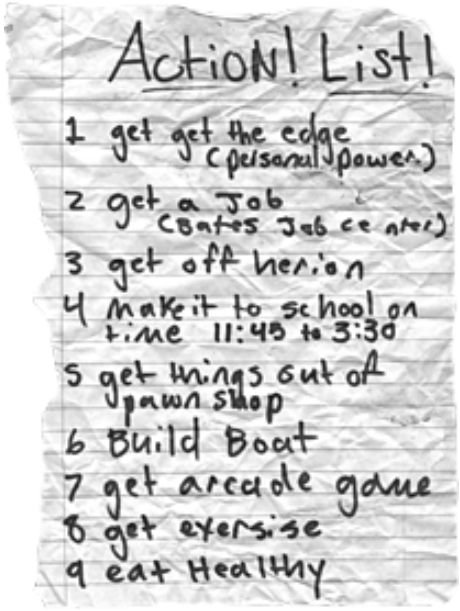
3. Preparing for Registration and CLP Notifications

C. Braibant, EPMF

3.1 PMC Plan for Jun-Dec 2010

C. Braibant, EPMF



3.1.1 Important deadlines - reminder

- **1 Dec 2010:** first REACH deadline for all pre-registered substances and intermediates manufactured/imported in volumes:
  - > 1000 t/a
  - > 100 t/a and R50/53
  - > 1 t/a and classified as CMR
- **3 Jan 2011:** deadline to submit CLP notification of harmonised classification for all substances and intermediates placed on the market, no matter their volume of production!

3.1.2 PMC Plan Jun-Dec 2010

- Jun:
  - ✓ Plenary Meeting (18-19 June)
  - ✓ Ag ES workshop (28-29 June)
  - ✓ First 2010 Invoices (end Jun/early Jul)
  - ✓ Finalise IUCLID 5 Guidance
- Jul - Aug:
  - ✓ Meetings with WCA and EBRC to progress Ag and Refinables projects
  - ✓ Ag and Refinables projects follow-up calls with Members
  - ✓ Circulate IUCLID 5 Guidance to Members
  - ✓ Circulate LoA Agreement to non-Members
  - ✓ Meeting with Ag LRs to prepare Registration
  - ✓ Generate joint submission objects on REACH-IT
  - ✓ Some holidays…

3.1.2 PMC Plan Jun-Dec 2010 (cont.)

- Sep - Oct:
  - ✓ Assess Ag and PM Refinables outstanding testing results
  - ✓ Assess CLP testing results
  - ✓ Finalise Ag and PM Refinables dossiers with consultants and LR
  - ✓ Finalise CLP notifications (first batch) – where LR identified and test results received
  - ✓ Submit dossiers and notifications for approval to Members
- Nov - Dec:
  - ✓ Finalise CLP notifications (second batch) and submit to Members for approval
  - ✓ Submit registration dossiers
  - ✓ Submit CLP notifications

3.1.3 Duties of LR

- Create joint submission object as per name recommended by PMC **
- Provide name and token number to PMC
- Install IUCLID 5 and plug-ins (at least TCC)
- Properly identify and characterise the reference substance
- Meet with PMC Secretariat & Consultants to check IUCLID 5 content, complete with LR-specific information **
- Submit Registration Dossier to ECHA and pass TCC **
- Inform PMC Secretariat on Registration success to allow joint registrants to co-register **

** With support of PMC Secretariat

3.1.4 Duties of co-registrants

- Obtain name and token number of joint submission object from PMC **
- Log-on onto REACH-IT and sign-up to the joint submission
- Install IUCLID 5 and plug-ins (at least TCC)
- Properly identify and characterise their substances and intermediates
- Check (and approve) content of Registration dossiers and CLP notifications as presented/described by PMC and Consultant **
- Submit Co-Registration Dossier to ECHA when indicated by PMC Secretariat and pass TCC

** With support of PMC Secretariat

3.1.5 Other duties

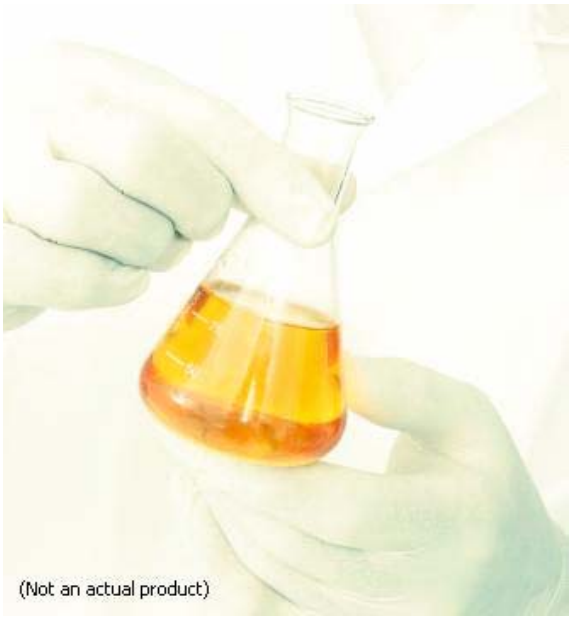
Registrants should in general:

- Carefully document strictly controlled conditions for each on-site and transported intermediate!
- Update SDS to include newly identified hazards, classification, and recommended safety measures when needed + communicate up and down the supply chain!

3.1.6 Progress tracking by the Mgmt Cttee

- Proposed to hold monthly calls with MC to follow track of main actions (see slide 3.1.1)
- Any other recommendations?

3.2 Substance identification



C. Braibant, EPMF

3.2 Substance identification

- Proper substance identification is essential to:
  - Provide sufficient information to properly describe a registered substance or intermediate, and
  - Ensure sameness of all materials registered under same EINECS entry
    - LR ← → Co-registrant
    - Co-registrant ← → Co-registrant

3.2 Substance identification (cont.)

- Eurométaux recently released a paper to assist Registrants of NFM metals, compounds and alloys to properly identify and characterise their substances and intermediates

- PMC has applied existing guidance to PM-specificities and produced the following guidance:
  - PM in metallic form:
    1. ICP-MS or XRF
    2. XRD
    3. Particle size by laser diffraction
    4. N-BET

3.2 Substance identification (cont.)

- Solid PM compounds:
  1. ICP-MS
  2. XRF
  3. IR spectroscopy
  4. XRD
  5. Particle size
  6. N-BET

- Solution/liquid PM compounds:
  1. ICP-MS
  2. XRF
  3. Raman spectroscopy

- UVCB Complex PM Refinables:
  1. ICP-MS
  2. XRF
  3. Particle size by laser diffraction
  4. N-BET

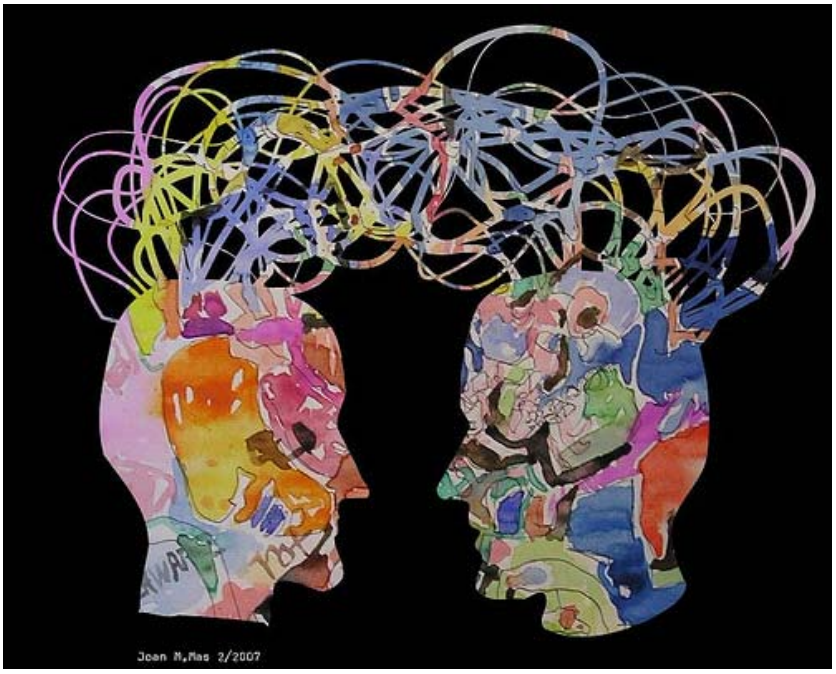
3.2 Substance identification (cont.)

- XRD: although only for crystalline material, this remains unknown until the analysis is performed
- Particle size and N-BET: although not absolutely required, useful to show applicability of recommendations laid down in Guidance on Safe Use (exposure and safety may depend on particle size and actual surface area)

→ PMC Members to obtain and document above information in-house in due course but in time for Registration!

3.3 SIEF Communication

C. Braibant, EPMF



3.3 SIEF Communication

- Obligation to communicate:
  - LR proposal
  - Classification recommendation

  to SIEF

- Originally foreseen to take place in Q1-Q2 2010 – will take place in Q3 instead…

3.4 Registration check-list and guidance

C. Braibant,
EPMF

3.4 PMC support to Members

- Guidance for REACH and CLP under preparation:
  - Grouped submission: one Lead company submits for others
    - REACH: PMC Members + LoA
    - CLP: PMC Members (+ LoA ?)
  - Format: PMC Secretariat & Consultants will have gone as far as possible in preparing IUCLID files to:
    - Minimise LR's and co-registrants efforts
    - Maximise uniformity and harmonisation of submissions

3.4. Files to be submitted

- REACH
  - One by Lead Registrant → joint submission dossier
  - One by each co-registrant having a legitimate right to refer to the LR's file → legal entity-specific dossier
    - PMC Members other than LR
    - Non-Members having purchased a LoA
- CLP
  - One by volunteer company (listing all companies who have contributed and agree with the CLP notification)
  - Other companies manufacturing or importing substance subject to notification can agree with proposed classification on REACH-IT (as simple as ticking an "I agree" box)

4. Review of the Consortium Agreement

4.1 Background

- PM Consortium was formed in 2007
  - Consortium Agreement version 1, 6 Jul 2007
- PM & Re Consortium followed in 2008
  - Consortium Agreement version 2, 6 May 2008
- Since:
  - Addendum: 6 May 2008
  - Clarification signature folio: 1 Sep 2008
  - Notice to Members with higher tonnage bands: 29 Oct 2008
- Today:
  - Integration of addendum, clarification and notice
  - Adjustments in light of REACH progress and next steps

4.2 Changes already approved by Members

- These are part of addendum, clarification and notice – already approved, no need to vote again
- For information, they are "labelled" with an *ad hoc* comment in the draft Consortium Agreement, e.g.:
  - Article 3.4.1.1 on transfer of membership
  - Article 4.2.1.2 on quick decisions by MC
  - Article 7.1.2(e) on reimbursement of sample costs
  - Appendix 1 on changes to Signature folio
  - Appendix 2 on updates of Substance and tonnage band declaration

4.3 New changes to the Consortium Agreement

- Wording: corrections and updates (e.g. EC Treaty replaced by TFEU)
- Purpose and scope:
  - Preamble and Article 2(l): extension to include update of Registration Dossiers, Evaluation and Authorisation
  - Scope: addition of PM Refinables (definition, cost-sharing formula, work group, etc.)
- Consequences of withdrawal and exclusion:
  - Article 3.5.3: withdrawing and excluded Members have no rights on data generated and Registration Dossier

4.3 New changes to the Consortium Agreement

- Duration of the Consortium:
  - Articles 4.1.2(m) and 9.2: Until purpose (Article 2) has been achieved
- Decision modalities:
  - Article 4.1.6.1: Changes to Consortium Agreement by 2/3 of Members (instead of unanimity)
  - Appendix 5: Clarification of role and decision power of Work Groups and at each organisational level
- Lead Registrant:
  - Article 4.7.1 and Appendix 10: LR's Declaration of Commitment

4.4 Change to cost-sharing formula

- Inclusion of all intermediates to cost-sharing
  - Weight:
    - Transported > 1000 t/a → weight of 5
    - Transported < 1000 t/a and On-site (any tonnage) → weight of 1
  - Background:
    - Transported > 1000 t/a and Substance 1-10 same requirements (CLP + Annex VII) → same weight
    - Other intermediates:
      - Until now, no work done
      - Now, CLP testing needed
      - Sometimes, intermediate is best read-across case (ideal testing material)
      - However, remains "reduced" REACH case → weight of 1

4.4 Change to cost-sharing formula (cont.)

- *Ad hoc* cost-sharing formula for PM Refinables Project
  - No matter tonnage band or status (transported or on-site) → same weight (5)
  - Background:
    - With the exception of Annex VII tests, work on Refinables is all the same → Classification
    - Instead of 5:1 weight, consider "fairer" weighted approach: 1:1
    - If Annex VII were required, 1:1 no longer "fair"

4.5 Other comments on the Consortium Agreement?

Members invited to indicate other items requiring clarification / correction / completion / update

4.6 Approval of Version 3 of the Consortium Agreement

Members invited to vote on proposed Consortium Agreement

5. 2007-2020 PMC Budget and Letters of Access

5.1 Background

- Letter of Access (LoA) = right to refer to a Registration Dossier prepared by the Consortium
- LoA = legal agreement + fee
  - Template circulated
  - Fee must be calculated in a fair, transparent and non-discriminatory manner
  - Fee must not be calculated with the aim of generating profit
- Hence, LoA fee/conditions must be as close as possible to PM Consortium membership costs/conditions
- Overall, Consortium remains open to new Members

5.2 Approach to calculate LoA fee

- LoA should be regarded as virtual Members of the Consortium:
  - Apply PMC cost-sharing formula on total costs
  - Predict PMC expenses and allocate a proportionate share of these to LoA purchasers
- Timeline of PMC expenses (REACH = Registration, Evaluation and Autorisation):
  - Start in 2007: creation of Consortium
  - "End" in 2020: 2018 + 2 years
- Prediction of PMC expenses (REACH full of unknowns):
  - Timeline: 2 extra years after last registration deadline
  - Generic costs: permanence for minimum maintenance, communication and LoA service
  - Metal-specific costs: realistic worst case considering probabiliy of being subject to Evaluation and Authorisation (Ag > PGM > others)
  - 20% contingency
  - 3% annual inflation

5.3 Proposed LoA costs

Members invited to vote on proposed LoA costs

Project/Dossier	Band	Min	Max
Generic	N/A	32.000,00 €	38.500 €
Ag	Intermediate	100,00 €	125 €
	1-10	5.500,00 €	6.500 €
	10-100	7.000,00 €	8.500 €
	100-1000	15.000,00 €	18.000 €
	➢1000	103.500,00 €	124.500 €
Au	Intermediate	1.500,00 €	1.500 €
	1-10	19.000,00 €	23.000 €
	10-100	37.500,00 €	45.000 €
PM CN-	Intermediate	1.500,00 €	1.500 €
	1-10	16.500,00 €	20.000 €
	10-100	34.000,00 €	41.000 €
PGM	Intermediate	2.000,00 €	2.500 €
	1-10	23.000,00 €	30.000 €
	10-100	46.000,00 €	60.000 €
Re	Intermediate	1.500,00 €	2.000 €
	1-10	15.500,00 €	20.000 €
	10-100	34.500,00 €	41.000 €
Refinables	Intermediate	9.000,00 €	10.500 €

5.4 Difference between Member and LoA

	PMC Member	PMC LoA
Payment/Cost	Twice per year, based on agreed annual budget	Unique, based on PMC predictions (subject to annual review)
Reimbursements	Eligible	Not eligible
Participation to PMC activities	Required	Not required
Vote, ownership rights	Yes	No

6. 2010 PMC Budget review, 2011 PMC Budget proposal

6.1 Metal-specific budgets

- Metal-specific budgets are not allocated to Members having no interest in concerned substances and intermediates
- Metal-specific budgets include:
  - Consultants' time (deliverables + meeting participation)
  - Literature cost
  - Testing programme and samples cost
  - IUCLID 5.2 dossier preparation (IT and consultants' time)
  - Contingency for unknowns:
    - Currency fluctuations
    - Number and data available to external data holders
    - Number and type of tests required
    - Number and type of tests requiring repetition
    - Need for external peer reviewers where uncertainty
    - Consultants' time associated to above fluctuations
    - Other unknowns…
- Nothing in metal-specific budget goes beyond the preparation of a quality and successful REACH Dossier and/or CLP notification!

6.2 Original vs. Revised 2010 budget

	Dec 2009	Jun 2010	Difference	Justification
Generic	585 000 €	480 000 €	- 105 000 €	• Allocation of consultants' time to *ad hoc* projects
Ag	380 000 €	570 000 €	+ 190 000 €	• BLM scoping study (~ 40 000 €) • Extended monitoring programme (~ 40 000 €) • Refinement of T/D test (~ 50 000 €) • Place-holder for data purchase (50% of ~ 535000 €)
Au	150 000 €	345 000 €	+ 195 000 €	• CLP testing programme (~ 50 000 €) • T/D test (~ 20 000 €) • Cost of samples (~ 150 000 €)
PM CN-	140 000 €	140 000 €	None	• Predictions match CLP needs and cost of samples

6.2 Original vs. Revised 2010 budget

	Dec 2009	Jun 2010	Difference	Justification
PGM	550 000 €	2 000 000 €	+ 1 450 000 €	• CLP testing programme (~ 50 000 €) • T/D test (~ 20 000 €) • Cost of samples (~ 1 000 000 €) → **very conservative estimate**
Re	195 000 €	180 000 €	- 15 000 €	• Confirmation of testing scope
Refinables	0 €	640 000 €	+ 640 000 €	• New budget item, no cost before 2010 • Focus on proper characterisation and classification

6.3 2010 budget description (e.g.)

- Generally follows a + 33% increase compared to 2007-2009 expenses but for figures in blue
  - Ag:
    - No samples but purchase to external data-holders possible (~ 50% of 535 000 €)
    - Refinement of T/D test results (and environmental classification) at ECTX (~ 65 000 €)
    - Monitoring programme, BLM scoping study and extended monitoring programme (~ 100 000 € + 75 000 € + 10% based on quotes + WCA's analysis time + subject to currency fluctuation)
    - IUCLID 5 Hosting – accepted in Dec 2009

6.3 2010 budget description (e.g.) (cont.)

- Refinables
  - New project, new budget
  - As indicated in technical segment, team work → budget foreseen to feed and implement sound characterisation, classification (several expertises required)

6.4 2010 Invoices

- Three options:
  - As revised (keep reserves)
  - Revised – reserves (spend reserves)
  - Revised – 50% reserves (keep/spend 50% reserves per project)
- Amounts sent in advance of meeting for consideration
- 2010 Invoices:
  - 1st Jul 2010
  - 2nd Dec 2010

Members invited to select best option
and agree on invoicing period

6.5 2011 Budget proposal for information

- Will be reviewed for next Assembly meeting

7. AOB, next meetings and closing remarks

7.1.1 OECD programme - background

The OECD-HPVC program:

- **Is about:** hazard assessments of chemicals (organics & inorganics),
- **Most important benefit:** approved data sets are summarised in a SIAR (SIDS Initial Assessment Report), and become a worldwide reference for all OECD countries + those which have signed the MAD agreement (Mutual Acceptance of Data agreement).
- I.e. **Information in REACH dossiers could become globally accepted/recognised reference data set**

The programme is looking to establish:-

- Harmonised standards for Mutual Acceptance of Data (TGs, GLP, compliance monitoring procedures)
- Tools and guidance for assessment
- Streamlined chemical management practices
- Co-operative, internationally agreed hazard assessments
- Dissemination of products and increased use beyond member countries

At last PMC Assembly meeting, several questions were raised on this program before a formal "green light" could be provided… see next slides

7.1.2 OECD programme - questions

Q: How would confidentiality and ownership rights apply in the event a Commodity shares (part of the content of) its Registration Dossiers with the OECD countries?

A: There is a difference between Confidentiality and Ownership issues:

- No issue of Confidentiality involved in OECD SIAP-SIAR files → OECD only reviews the effects section and the Risk Characterisation in very generic terms (e.g.: there is no environmental risk for the Ag producer sector)
- SIAR's summarise effects data but DO NOT allow industry or countries to claim ownership on summaries. Industry would however remain owner of information in Registration dossier

Q: Will extracts of the Registration Dossier be required or a full version of it?

A: Only effects sections will be summarised under SIAP/SIAR format.

7.1.2 OECD programme – questions (cont.)

Q: Are all Dossiers concerned or only the Ag metal one (only High Production Volume)?

A: All substances but given timeframe of OECD project (2012-2014), focus on > 1000 t for the moment (i.e. Ag, AgNO3 and Ag2O).

Q: Are Intermediates Dossiers of interest to the OECD Programme?

A: In principle NO, unless these materials are OUTSIDE the EU produced and used as a substance and not as an intermediate. Given their limited data sets, it is suggested by Eurometaux to leave them aside and to focus on substances in the EU

7.1.2 OECD programme – questions (cont.)

Q: When are Commodities expected to provide the required information?

A: Agreement just reached with the OECD secretariat to organise FIRST a workshop in 2011 Q1-Q2 to familiarise the non EU OECD countries and MAD countries with metals effects assessment principles. I.e., not before late 2011/early 2012

Q: What is the timeline to confirm interest in this programme?

A: Generic expression of interest → before the end of the 2010

Members invited to signal any additional question and/or provide generic expression of interest for PMC to participate in this initiative

7.2 Next PMC Assembly Meeting

- Originally: 2 December 2010
  - This is one day after 2010 registrations
  - This is before all CLP notifications have been submitted
- Proposed:
  - Hold Assembly Meeting on 2 Dec but focus on budget and general management issues rather than detailed technical programmes
  - Move meeting date to early Jan 2010 (w/c 10 Jan?)

7.3 Next PMC Plenary Meeting

Johnson Matthey proposes to host the 2011 EPMF Plenary Meeting

- **In Cambridge, UK**
- **On 17-18 June 2011**

Thank you for today's fruitful discussions!

See you at our next Assembly Meeting