PGM Project Exposure Scenario Meeting

Brussels, 27 June 2012

1. Welcome & Introduction

- Reminder on Confidentiality and Competition Law
- Tour de table and apologies
- Approval of the Agenda

2. Scope of the PGM CSA/CSR + ES Work

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Caroline BRAIBANT
Klaus ROTHENBACHER

Scope

- 7 Pt and 9 Pd substances are currently > 10 t/a and classified for ENV/HH endpoints in the PMC inventory (dd 10 April 2012), hence requiring a CSR
  - declared by a total of 12 PMC Members
  - ranging from 1 to 9 companies per substance
- Depending on the outcome of the on-going testing programme, additional PGM > 10 t/a may require a CSR
- From all the confirmed substances requiring a CSR, only Diamminedichloropalladium (DDP) requires full registration in 2013
  - data collection and assessment will be prioritized for DDP and/or the Pd family (effects from and exposure to Pd ion)

Scope: Pd CSA/CSR + ES work

Name of the substance	Identification numbers CAS	EC	REACH Category	Type of registration dossier prepared by PMC	Total number of registrations	Volunteer Lead Registrant
Dihydrogen tetrachloropalladate(2-) (in solution)	16970-55-1	241-047-9	Mono-constituent	Substance	4	Heraeus
Diamminedichloropalladium	14323-43-4	238-269-3	Mono-constituent	*Substance*	5	Heraeus
Palladium (II) di(4-oxopent-2-en-2-oate) (solid only)	14024-61-4	237-859-8	Mono-constituent	Substance	2	Heraeus
Tetraamminepalladium(2+) dichloride	13815-17-3	237-489-7	Mono-constituent	Substance	6	?
Tetraamminepalladium(2+) diacetate (in solution)	61495-96-3	262-819-1	Mono-constituent	Substance	1	Umicore
Palladium dinitrate (in solution)	10102-05-3	233-265-8	UVCB	Substance	6	Heraeus
Palladium dihydroxide (solid only)	12135-22-7	235-219-2	Mono-constituent	Non-SCC intermediate	1	Umicore
Diammonium hexachloropalladate (solid only)	19168-23-1	242-854-9	Mono-constituent	SCC intermediate	1	Johnson Matthey
				Non-SCC intermediate	1	?
Dipotassium hexachloropalladate (solid only)	16919-73-6	240-974-6	Mono-constituent	Non-SCC intermediate	2	Carl Hafner

Scope: Pd CSA/CSR + ES work

- Pd metal: > 10 t/a but no hazard identified
  - CSR-type of report to document effects + exposure patterns?
- Pd monoxide (1314-08-5; 215-218-3): > 10 t/a but not hazardous
  - TD test: solubility = 0,00 µg/l, unlikely to be ENV hazardous → WCA to confirm?
  - On-going testing programme: Monitor need for CSA/CSR + ES
- Pd dioxide (12036-04-3; 1234-836-4): > 10 t/a and Oxid. Solid 1
  - Need CSA/CSR + ES for physico-chemical properties?
  - On-going testing programme: Monitor need for CSA/CSR + ES
- Currently 9 Pd in scope could become 12!

Scope: Other PGM

- Other registrations due by 2013:
  - SCC intermediates: no need for CSA/CSR + ES
- Other PGM due by 2018:
  - Pt:
    - 7 compounds
    - On-going workplace exposure + data collection and assessment at IPA level
  - Rh:
    - 1 compound > 10 t/a and with physico-chemical hazard
    - On-going testing programme: Monitor need for CSA/CSR + ES
  - Ru:
    - 2 > 10 t/a and with no hazard
    - On-going testing programme: Monitor need for CSA/CSR + ES
  - Ir:
    - All < 10 t/a

Scope: work programme

EBRC and WCA to confirm

- CSA/CSR + ES for each compound:
  - Environment → emissions to environment versus PNEC for env. compartment
  - Man via the environment → exposure via environment/food versus DNEL
  - Workplace → releases/ exposure at workplace versus DNEL for each relevant route of exposure
  - Consumer → emissions from consumer goods versus DNEL
  - Combined exposure → all in one scenario
  - Waste → emissions from waste streams versus PNEC and DNEL?

3. Use Questionnaire

Jutta SCHADE
Ed STUTT

Aim of the use questionnaire (1)

- REACH requires the submission of use information as part of the registration dossier
  - » IUCLID section 3.5 (all tonnage bands)
  - » CSR section 2 (if CSA/CSR required)
  - » CSR section 9 and 10 (if exposure assessment required)
- Use information should cover all the identified uses of registrants and their downstream users
  - » If a use is not identified in the REACH registration dossier the substance cannot be used for that purpose

Aim of the use questionnaire (2)

- Use information needs to cover the entire life cycle of the substance for Industrial, Professional and Consumer uses
- Use information is recorded and communicated using the Use Descriptor System
  - » ECHA (2010) Guidance on information requirements and chemical safety assessment Chapter R.12
  - » Standardised to allow easier communication along supply chains

Aim of the use questionnaire (3)

- Use Descriptor System describes each use based on
  - » Sector of Use (SU)
  - » Product Category (PC)
    - o the types of chemical products the substance is contained in when it is supplied to end uses
  - » Process Category (PROC)
    - o the techniques or process types from the occupational perspective
  - » Environmental Release Category (ERC)
    - o the broad conditions of use from the environmental perspective
  - » Article Category (AC)
    - o the type of article into which the substance has been processed

Aim of the use questionnaire (4)

- An excel template will be circulated to gather information on your uses and those of your downstream users
- Based on the Use Descriptor System
- Pass the blank Excel file to your downstream users for them to complete and return as directed
- Complete a separate questionnaire for each substance you intend to register
- Responses will be treated in strict confidence

Aim of the use questionnaire (5)

- We will use the information you provide in this questionnaire to:
  - » develop generic exposure scenarios
  - » build short titles for the exposure scenarios
  - » group uses with similar potential exposure patterns
- We may need to come back to you for clarification
- Further questionnaires will then be used to collect more detailed emissions data
  - » these will be covered later on the agenda

4. Environmental Emissions Questionnaire

Ed STUTT

Aim of the environmental exposure questionnaire

- To facilitate compilation of sector-wide data for preparation of Generic Exposure Scenario(s) (GES)
  - » GES based on values calculated from compiled dataset and are therefore anonymous
- Provision of initial dataset for site-specific risk assessment
  - » If Tier 1 assessments indicate a pass (i.e. RCR <<1 then this will be all that is required)
  - » Additional data may be required for higher tier modelling; this will only requested if Tier 1 indicates a failure

The questionnaire

- Captures information on:
  - » Tonnage
  - » Potential emissions
    - o *Air (i.e. stack emissions)*
    - o *Water (i.e. waste-water discharge)*
  - » Risk Management Measures (RMMs)
  - » Monitoring data (inc. background concentrations)
  - » Confounding factors (e.g. other sources of exposure of the same metal)

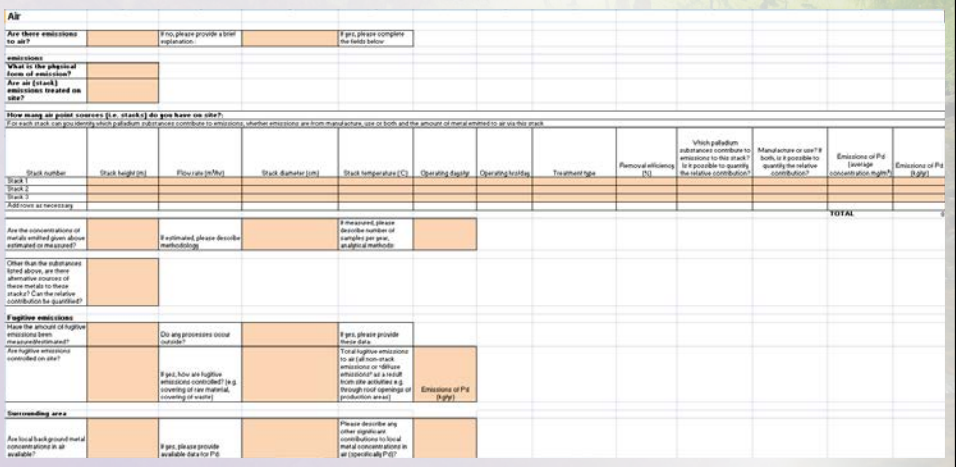
Questionnaire - tonnage

Tonnage			
Total Pd/Pd compounds used at the site (Tonnes metal/year)			
Please indicate annual tonnage for each Pd compound and indicate whether this is for manufacture or use			
Substance name	CAS number	tpa	Manufacture/Use
Add rows as necessary			

Questionnaire - tonnage

- Please provide tonnage data for overall quantity of the metal (Pd in first instance) AND individual Pd compounds
- Provide tonnage data in metal equivalent (tonnes Pd) but clearly indicate if tonnage refers to mass of a compound (we can convert manually but this is time consuming so we prefer metal equivalent)
- Tonnage data are important in environmental context for calculation of the emission fraction (more on this later)

Questionnaire - emissions to air



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Questionnaire - emissions to air

- Stack emissions
  - » How many stacks, how high etc?
  - » Height, temperature, flow rate, diameter used for higher tier assessment .....if required
- RMMs and efficiency
- Total amount discharged
- Emissions days per year
- Concentration of metal in stack emissions and info on background concentration if available
- Info on fugitive emissions (IF relevant or available)

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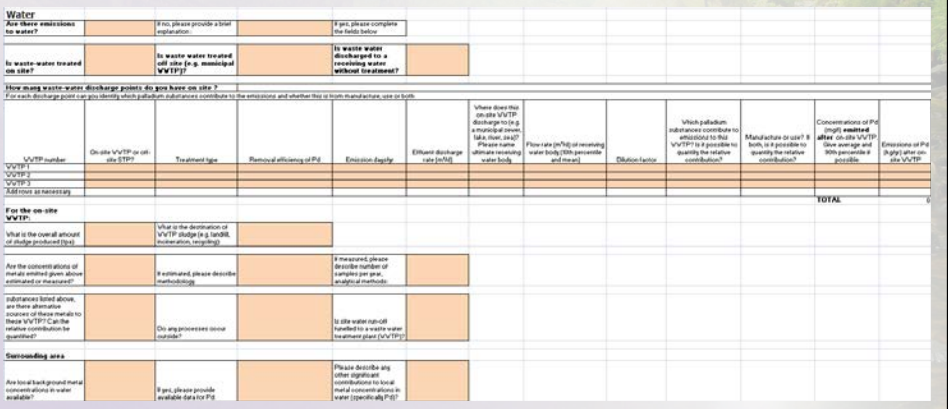
Questionnaire - emissions to water



Water												
Are there emissions to water?		If no, please provide a brief explanation:		If yes, please complete the fields below								
Is waste-water treated on site?		**Is waste water treated off site (e.g. municipal WWTP)?**		**Is waste water discharged to a receiving water without treatment?**								
How many waste-water discharge points do you have on site ?												
For each discharge point can you identify which palladium substances contribute to the emissions and whether this is from manufacture, use or both:												
WWTP number	On-site WWTP or off-site STP?	Treatment type	Removal efficiency of Pd	Emission days/yr	Effluent discharge rate (m³/d)	Where does this on-site WWTP discharge to (e.g. a municipal sewer, lake, river, sea)? Please name ultimate receiving water body	Flow rate (m³/d) of receiving water body (10th percentile and mean)	Dilution factor	Which palladium substances contribute to emissions to this WWTP? Is it possible to quantify the relative contribution?	Manufacture or use? If both, is it possible to quantify the relative contribution?	Concentrations of Pd (mg/l) **emitted after** on-site WWTP Give average and 90th percentile if possible	Emissions of Pd (kg/yr) after on-site WWTP
WWTP 1												
WWTP 2												
WWTP 3											**TOTAL**	0
Add rows as necessary												
For the on-site WWTP:												
What is the overall amount of sludge produced (t/a)		What is the destination of WWTP sludge (e.g. landfill, incineration, recycling)										
Are the concentrations of metals emitted given above estimated or measured?		If estimated, please describe methodology		If measured, please describe number of samples per year, analytical methods								
substances listed above, are there alternative sources of these metals to these WWTP? Can the relative contribution be quantified?		Do any processes occur outside?		Is site water run-off handled in a waste water treatment plant (WWTP)?								
Surrounding area												
Are local background metal concentrations in water available?		If yes, please provide available data for Pd		Please describe any other significant contributions to local metal concentrations in water (specifically Pd)?								

Questionnaire - emissions to water

- Is waste-water treated prior to discharge?
  - » what type of treatment (RMM) is used?
  - » what is its efficiency?
- Flow rate of receiving water body / WWTP

  ↓

  Dilution Factor (for GES & site-specific)
- Total amount discharged
- Emissions days per year
- Concentration of discharged water and info on background concentrations if available

Questionnaire - emissions to soil

Soil		
Surrounding area		
Are measured metal concentrations in soil available (specifically Pd)?		
If yes, please complete the following:		
Location relative to site emission points (e.g. 1 km from site, ...)	Concentration of Pd (mg/kg dry weight)	Specify: average value, ranges, analytical methods & results, year, sampling depth etc.
Please describe any other significant contributions to local metal concentrations in soil (specifically Pd)?		

Questionnaire - emissions to soil

- Discharge of waste to land is NOT permitted
- This information is unlikely to be available but can be useful in assessment of secondary poisoning and to indicate the contribution from site emissions

Questionnaire - emissions to waste

Waste					
Has the amount of solid waste (tonnes metal/year) been estimated?					
If no, please provide an explanation					
Waste Type (description) e.g. form	Amount (tpa)	Percentage of Pd (%)	Destination of waste (recycling, landfill, incineration...)	Waste removal to off-site location?	Recycling for re-use?
Other waste management measures:					
Please provide details:					

Questionnaire - emissions to waste

- How much is produced?
- What forms e.g. solids/sludge or liquid?
- Where does it go and how is it treated?

- Basic information on waste needs to be included for all tonnage bands
- A waste exposure assessment is now required in the CSR for substances >10tpa.

Using the data collected

- Development of generic exposure scenarios (GES) for use in CSA
- Sector-wide approach to exposure assessment (consistent and harmonised approach across the industry)
- Collection of questionnaires into database & subsequent analysis of data
- Values derived from compiled data are used to quantify the GES

Parameter values for GES

Typically

- 90th percentiles values (90P) for:
  - » Tonnage
  - » Emission factor
- Median or 10P values for:
  - » Dilution factor for waste-water
  - » Emission days

Emission factors

- Emission factor to air and water EF is a very important parameter for GES. It is used to replace the extremely conservative default values provided by ERCs
- EF = $\frac{\text{amount discharged (after RMM)}}{\text{amount produced}}$
- Expressed as % or g/T
- Analogous to SpERCs and we will compare those generated here to those calculated by ARCHE for various sectors of the metals industry

Emission factors and exposure modelling

- More data → more statistically robust EF values (reduce effect of outlying values on 90P calc)
- In GES exposure assessment EF is applied to 90P tonnage to derive the amount of substance emitted to environmental compartment
- EUSES model is used to calculated PEC, which is then compared to PNEC to give RCR

KEY DATA

- Tonnage
- Total amount discharged per year to water and air
- Emission days per year
- RMMs and treatment efficiency
- Flow rates for waste-water emissions and receiving water body
- Yes/no for WWTP and STP

Other issues

- Date for submission of questionnaire (**31st July**)
- Where limit values are presented for concentrations and volumes discharged the recommended approach is to use 50% LoD
- Numerical analysis is hampered by text in number fields – please avoid this!

- Any further questions?

5. Workplace Exposure Questionnaire

Daniel VETTER
Jutta SCHADE

EBRC

Exposure scenarios under REACH I/II

- **Exposure scenarios (ESs) are required for:**
  - *Hazardous substances produced and/or imported at ≥10 tons*
- **Definition of ES:**

REGULATION (EC) No 1907/2006 OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL

of 18 December 2006

37. exposure scenario: means the set of conditions, including operational conditions and risk management measures, that describe how the substance is manufactured or used during its life-cycle and how the manufacturer or importer controls, or recommends downstream users to control, exposures of humans and the environment. These exposure scenarios may cover one specific process or use or several processes or uses as appropriate;
38. use and exposure category: means an exposure scenario covering a wide range of processes or uses, where the processes or uses are communicated, as a minimum, in terms of the brief general description of use;

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Exposure scenarios under REACH II/II

- **Types of ESs include:**
  - *Occupational exposure (industrial and professional)*
    - *Inhalation exposure*
    - *Dermal exposure*
  - *Environmental exposure*
  - *Consumer exposure*
- **ESs have to demonstrate safe use of a substance:**

  → *Exposure estimate / relevant DNEL < 1*

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ES format/structure

Table D.2.2.1 Standard format for exposure scenarios related to uses of substances carried out by workers

Exposure Scenario Format (1) addressing uses carried out by workers	
1. Title	
Free short title	*Short free text (in supply chain specific language) describing the scope of the exposure scenario*
Systematic title based on use descriptor	*List of identified uses covered in the exposure scenario*
Processes, tasks activities covered	*Additional free text specification of the activities or tasks covered (if needed)*
Assessment Method*	*Assessment methods applied to create the final exposure scenario (specify the routes if relevant)*
2. Operational conditions and risk management measures	
Brief description of overall operational conditions referring to process categories (PROC) and environmental release categories (ERC)	
Number of sites using the substance (potentially required to demonstrate strictly controlled conditions of use to justify waiving of information according to Annex XI of REACH)	
2.1 Control of workers exposure	
Product characteristic	

Table D.2.2.3: Standard exposure scenario format for uses of substances by workers

Exposure Scenario Format (1) addressing uses carried out by workers
9.x. Title of Exposure Scenario number x: .....
List of all use descriptors related to the life cycle stage and all the uses under it; include market sector (by PC), if relevant;
Name of contributing environmental scenario (1) and corresponding ERC
List of names of contributing worker scenarios (2-n) and corresponding PROCs
Further explanations (if needed)
9.x.1 Exposure Scenario
9.x.1.1 Contributing scenario (1) controlling environmental exposure for ...
Name of contributing scenario
Further specification
Product characteristics
Product related conditions, e.g. the concentration of the substance in a mixture; viscosity of product; package design affecting exposure

- Title description of exposure scenario
- Product characteristics
- Operational conditions and risk management measures
- Exposure estimation
- Guidance for compliance checking (for DU)

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Use descriptors (UDs)

- **What do all of these abbreviations stand for?**
  - *SU: Sector of use category*
    - *Including 3 main groups (**industrial, professional,** consumer)*
  - *PC: Chemical product category*
    - *Type in which the substance is supplied*
    - *Description of market sector (formulating sector) to which the substance is potentially supplied by the manufacturer*
  - ***PROC: Process category***
    - *Task or process type (**occupational perspective**)*
  - *ERC: Environmental release category / SPERC*
    - *Conditions of use (environmental perspective)*
  - *AC: Article category*
    - *Article types in subsequent service and waste life*

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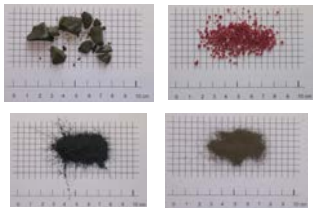
Information requirements

- *Hazard profile?*
- *Level of relevant (inhalation) DNEL?* 0.001 mg/m³ **10 mg/m³**
- *In which physical forms is the substance used?*
- *Is the emission potential (substance/process) low or high?*



- *Are measured data available?*
- *Knowledge about uses? (RARs, free text descriptions, UDs)*

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Core information requirements (R.14)

- Physical state of the substance
- Physical state of the product handled
- Vapour pressure (for liquids)
- Different levels of “dustiness” (for solids)
- The concentration of the substance in the preparation
- The level of containment
- Efficiency of local exhaust ventilation (LEV)
- Duration of activity
- What is done with the substance

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Information requirements in IU questionnaire

- Physical state of the substance
- Physical state of the product handled
- Vapour pressure (for liquids)
- Different levels of “dustiness” (for solids)
- The concentration of the substance in the preparation
- The level of containment
- Efficiency of local exhaust ventilation (LEV)
- Duration of activity
- What is done with the substance

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Occupational exposure questionnaire I/IV

- Physical state of the substance/product during handling
- Physical state of the product handled
- Vapour pressure (for liquids)
- Different levels of “dustiness” (for solids) during handling
- The concentration of the substance in the preparation
- The level of containment
- Efficiency of local exhaust ventilation (LEV)/additional RMMs
- Duration of activity
- What is done with the substance (=activity classes)

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Occupational exposure questionnaire II/IV

- Development of a tailored questionnaire:
  - Kick-off meeting last month
  - ESs required for a number of PGMs
  - Are some/all of these manufactured similarly?
  - Is a grouping of processes/workplaces possible?
    - Similar manufacture of 1 substance at all sites, or even
    - similar manufacture of a group of substances at all sites?
    - Grouping could be used for
      1) a structured development of exposure scenarios, and
      2) to pool measured data available for processes/ workplaces.

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Occupational exposure questionnaire III/IV

→ Development of “activity classes”:

Generic grouping of workplaces for palladium proposed, based on Renner, H. et al., 2005 (Platinum Group Metals and Compounds)

→7 workplaces proposed and send to industry experts of 4 different companies for modification/ confirmation/discussion

→Additional need for 1 further workplace, wording modified to better reflect activities

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Occupational exposure questionnaire IV/IV

Live demonstration of occupational exposure questionnaire

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Occupational exposure estimation

- Preferential hierarchy of assessment basis according to ECHA Guidance R.14:
  1. measurements of exposure in actual workplaces (have to be representative and robust), preferred over
  2. appropriate analogous data, preferred over
  3. exposure models.
- Risk assessment has to result in a safe use:
  → Exposure estimate / relevant DNEL < 1

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Use of measured data I/III

- Quality of measured data is crucial !
  - Basic information is needed on sampling method (e.g. personal sampling, measured fraction) and sampling duration
  - A minimum number of samples is needed (≥6 for one company/ workplace; ≥12 for one industry sector/ workplace), depending on (i) the variability/uncertainty of the data (ii) the RCR → possibly requiring more than 50 values for high RCR/GSD
  - Use of 90th percentile values in most cases

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Use of measured data II/III

- Data to be assigned to the OCs & RMMs present during sampling
- Site-visits can serve as a basis for such an assignment (questionnaires are used given the short deadline)
- High quality data sets enhance the potential to re-use data in a read-across concept
- Low quality data sets can/have to be used as supportive information

→ Data submission form will be provided

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Use of measured data III/III

Live demonstration of data submission form

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6. Next Steps

Caroline BRAIBANT
Klaus ROTHENBACHER

Site-visits?

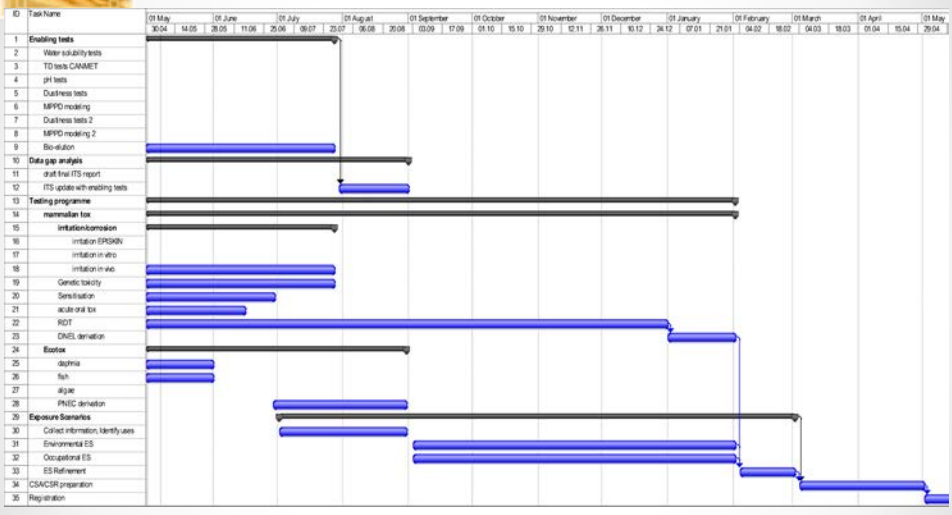
- Are site-visits needed for EBRC and WCA?

Roles and responsibilities

- Dave Boyd (Johnson Matthey): Chairman
- Klaus Rothenbacher (EPMF): Secretariat
- Katrien Arijs (ARCHE):
  - Coordination and secretariat support: circulation of questionnaires, collection of responses, first screening of responses for completeness (not accuracy), conference calls and meetings preparation, minutes, action points follow-up, etc.
- WCA:
  - Overall responsibility for the CSA/CSR and ES preparation, and uploading into IUCLID 5
  - Environmental exposure assessment, exposure of man via the environment and waste exposure
- EBRC:
  - Occupational exposure scenarios and potentially for the consumer and combined exposure
- Members:
  - Experts
  - Data providers
  - Reviewers of tiered CSA/CSR + ES reports

Timeline for 2013 deadline

(status: 14 June 2012)

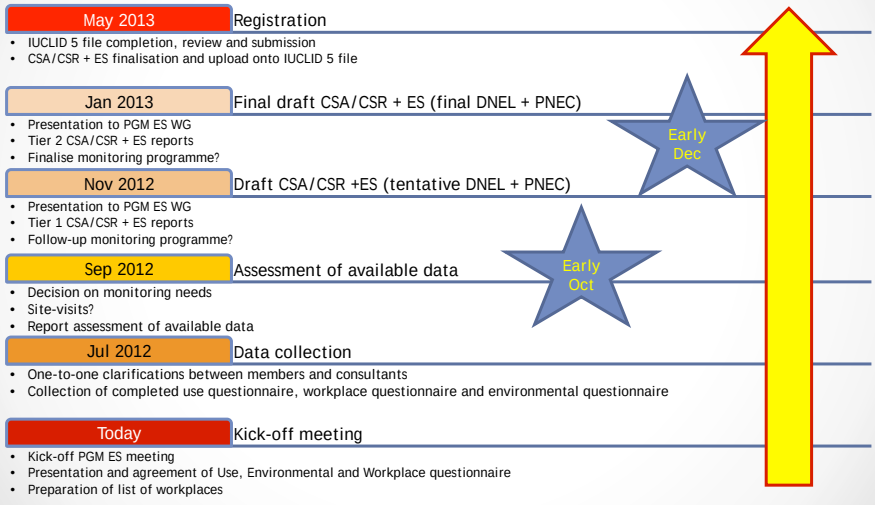


- Our first priority
- Tight schedule, but on track for 2013 registration deadline

Timeline for PNEC/ DNEL

- PNEC
  - On track, studies completed
  - PNEC ready by September
- DNEL
  - Originally planned for Jan 2013, after completion of 28d RDT/repro study (OECD 422)
  - New situation: OECD 422 study needs to be repeated + extensive dose range finding needed = not ready for 2013 deadline
  - Need to work based on available data:
    - Acute oral (just completed)
    - Acute dermal (just started – results in Aug/Sep)
  - High uncertainty in DNEL
  - Alternative OPTIONS →

Timeline for CSA/CSR + ES work



7. AOB, Next Meetings/Calls & Closing Remarks

David BOYD

Thank you!