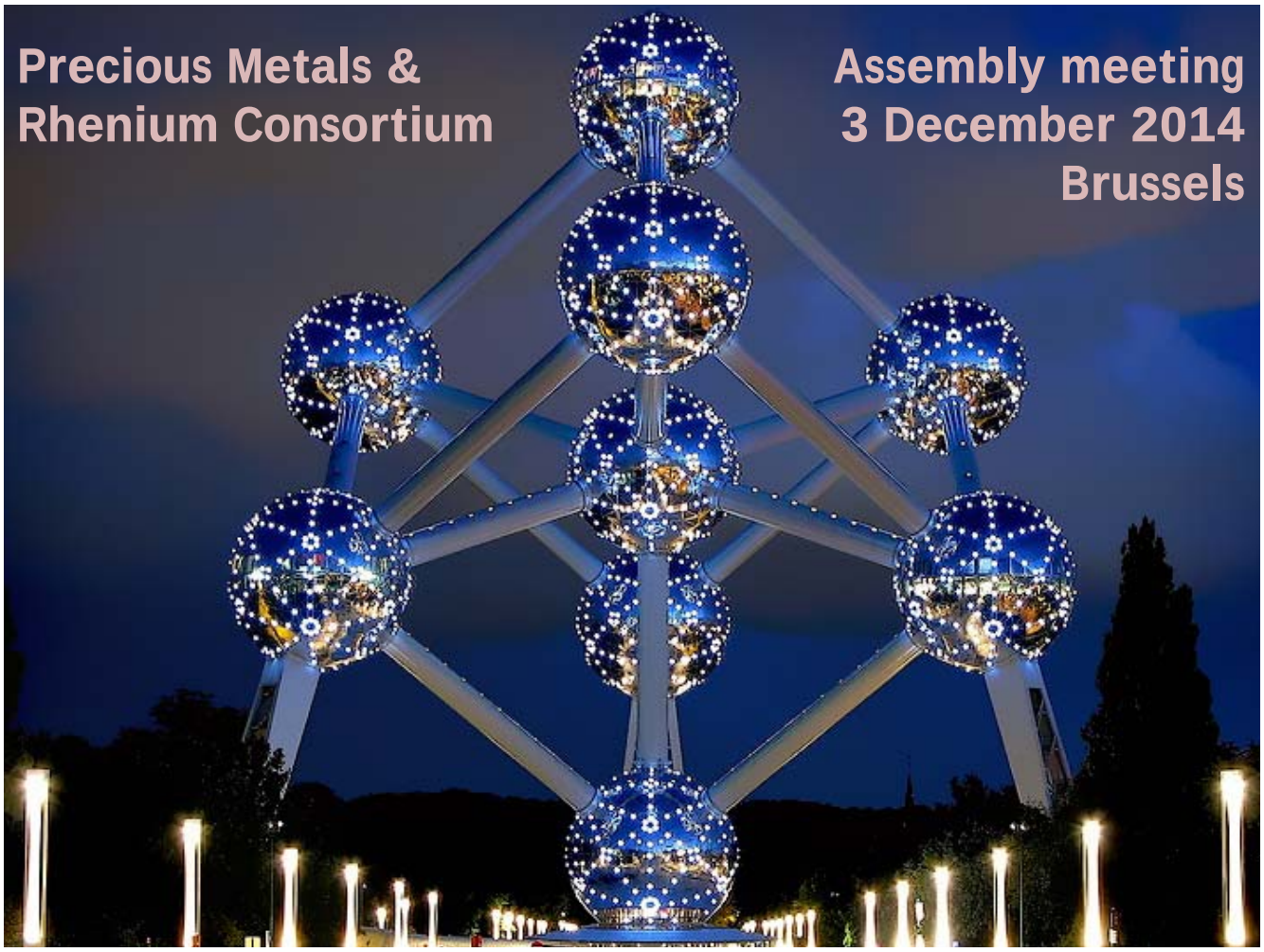




1. Welcome and introduction

1.1. Reminder on confidentiality and Competition Law

1.2. Tour de table, apologies, and quorum

1.3. Approval of the Agenda

1.4. Status of actions agreed at the last Plenary meeting (cf. next slide)

1.5. Approval of the minutes of the last Plenary meeting



1.2. Tour de table, apologies, and quorum

- Cf. Participants list in handouts
- 31 PMC Members present or represented out of 45
- Quorum of 68 %; meeting quorated for all decisions



1.3. Approval of the Agenda

1. Welcome and introduction
2. PMC Membership news
3. Update on PMC Registration Projects
4. Authorisation
5. PMC Finances
6. Next meetings, AOB and closing remarks



1.4. Status of actions agreed at the last Assembly meeting (1)

What?	Who?	When?	Status by 18 Nov 2014
Nominate Mgmt Cttee representatives to take on board (Co-)Chairmanship of PMC for 2016-2018 mandate	Mgmt Cttee	Q2 2015	Advance proposals from companies welcomed
Prepare tentative project plans for Ag, Refinables and Authorisation projects of PMC	R. Nicolay with relevant managers	Dec 2014	Done for Ag and Ref, to do for "Authorisation" project Hydrazine
Include high-level project plan (in .pdf) of each project in bi-monthly updates circulations	A. Rondepierre	On-going	Postponed
Confirm realistic (versus optimistic) registration submission windows for Au, PM CN-, and PGM projects	R. Nicolay + K. Rothenbacher	Dec 2014	Done, current project plans are realistic
Produce ID Cards for all PMC substances and intermediates in the order of registration, using Members' input and expertise	K. Arijs	On-going	On-going
Submit PMC response to public consultation on a possible EU inventory of nanomaterials	C. Braibant	Jul 2014	Done
Compare effects datasets and anticipate/collaborate on a response to the possible release of a CLH proposal from KEMI with Ag Biocides TF	C. Braibant + K. Rothenbacher	Q3 2014	On-going
Include place-holder for research work in 2016 budget, as discussed and agreed with the Ag WG and Mgmt Cttee	C. Braibant	Q1 2015	For next Sec-Gen
Confirm scope of Au registration dossier: nano in or out? (Consult WGC if needed)	R. Nicolay	Q3 2014	Survey completed but update may be needed
Document decision-making re genotoxicity testing of TCA	R. Nicolay	Q3 2014	To update based on revised TG
Identify LR for remaining PM CN-	R. Nicolay	end 2015	Done, Saxonia Holding GmbH



1.4. Status of actions agreed at the last Assembly meeting (2)

Confirm scope of PGM registration dossiers: nanos in or out? (Consult IPA if needed)	K. Rothenbacher	Q3 2014	On-going (questionnaire under development)
Update Mgmt Cttee on SID/Sameness discussions around diammonium hexachlororuthenate, progress of Ru testing programme, and overall impact on registration submission window for Ru and Ru compounds	K. Rothenbacher	Q3 2014	On-going
Settle proper Memorandum of Understanding with Reconsile, in order to set legal framework to allow technical cooperation and dossier preparation	C. Braibant + A. Palmers	Q3 2014	MoU principles agreed verbally, MoU proposal received from Reconsile and under discussion
Contact and mobilise registrants of hydrazine and major user groups of hydrazine to identify and recommend an alternative to Authorisation (RMO), and prepare a collective response to the upcoming public consultation on the 6th recommendation list	R. Nicolay	Q3 2014	Postponed, Hydrazine withdrawn from 6th recommendation
Inform PMC Secretariat on the SVHC which are used/essential in the PM refining and production processes, and which require some level of monitoring and participation in collective initiatives and public consultations by PMC secretariat	PMC Members	On-going	Done
Chase missing payments of 2014 invoices and inform Mgmt Cttee of late payers	A. Rondepierre	Q3 2014	Done
Develop and implement a better budget management system from consultancy proposal generation to P&L tracking with Mgmt Cttee	C. Braibant + A. Rondepierre	Q3 2014	Done
Circulate *ad hoc* mail to PMC Members informing them about likely 2015 invoice, including: 2014 Ag, and 2015	C. Braibant	Q3 2014	Done
Prepare budget projection for Ag, Au, PM CN-, and PGM projects	C. Braibant, R. Nicolay + K. Rothenbacher	Dec 2014	Done
Update LoA e-shop with 2014 LoA prices	A. Rondepierre	Q3 2014	Done for Ag
Prepare letter to let past LoA purchasers know about the increase of LoA price for generic costs, and inform them that the LoA price difference will not be charged retroactively yet, but in 2020, if when comparing the exact LoA price vs PMC Membership cost, a cost difference remains	C. Braibant	Q3 2014	Done



2. PMC Membership news

Guy Ethier

This item will be addressed verbally



3. Update on PMC Registration Projects

Katrien Arijs
Renaud Nicolay
Klaus Rothenbacher
Mark Raffray



3.1. Project phases overview

- **All projects but Ref**

I. Literature search and data gap analysis
II. Integrated Testing Strategy
III. Testing programme
IV. CSA/CSR
V. IUCLID 5
VI. Post-registration work
    1. SID and phys-chem
    2. Human Health
    3. Environment
    4. Admin
    5. Other

- **Ref project (post-registration)**

I. Scoping
II. Substance identification
III. Effects assessment and classification
IV. Exposure and risk assessment
V. IUCLID 5
VI. Post-registration work
    1. Scoping
    2. Substance identification
    3. Effects assessment and classification
    4. Exposure and risk assessment
    5. Compilation of IUCLID 5 file & Registration Dossiers
    6. Admin/other





3.2. Ag project

Katrien Arijs
Klaus Rothenbacher
Mark Raffray



3.2.1. Ag Expenses 2014



Phase	Expenses budgeted	Expenses estimated end 2014	Comment
I.	€ 26.250	€ 67.557	More resources required due to unexpected high number of relevant publications
V.	€ 3.150	€ 3.150	IUCLID hosting
VI.2-4	€ 128.385	€ 156.860	Preparation for Evaluation
VI.5	€ 52.500	€ 28.965	Dossier update
TOTAL	**€ 210.285**	**€ 253.383**	



3.2.2. Ag Budget 2015



Phase	Expenses budgeted	Assumptions
I.	€ 83.786	Increase due to continuing high number of new publications
V.2	€ 3.150	Unchanged from June assumptions
VI.2-4	€ 119.972	Increase due to inclusion costs for already committed experimental studies (not included in June predictions)
VI.5	€ 34.507	Increase based on most recent proposals
TOTAL	**€ 241.415**	**Total increase of 129.065 € over June assumptions** Additional expenses possible depending on evaluation results – at the moment not predictable (will be explained later)



3.2.3. Summary of Ag technical items



a. Ag literature searches

b. Ag Evaluation

c. Ag Biocides

d. Ag Dossier updates

e. Ag Roadmap



3.2.3. a) Ag literature searches

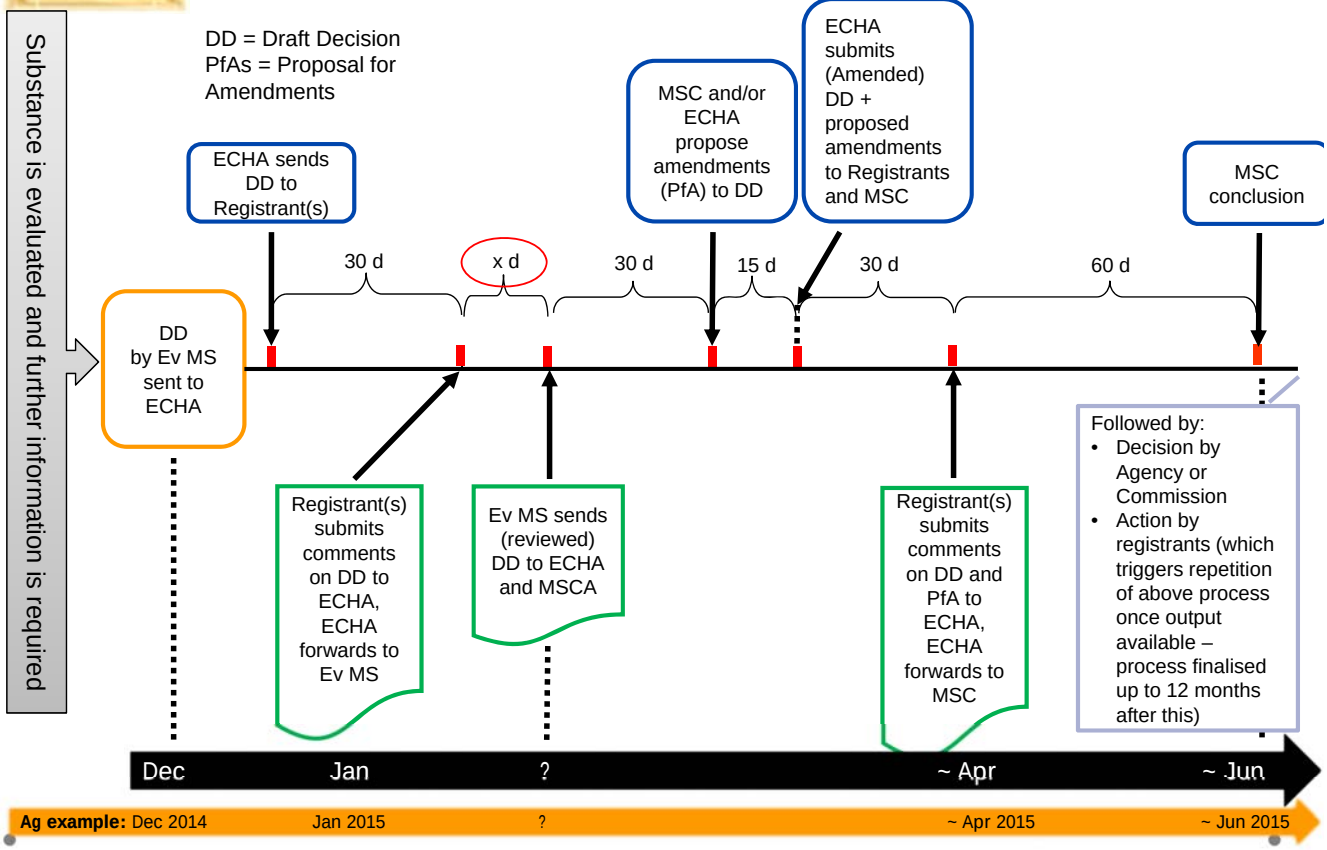


- Silver (nano) is a popular research subject
  - Several big research programmes on-going & researchers keen on publishing
  - REACH: need to consider all reliable & relevant information
  - PMC overwhelmed with Ag literature
  - For 2015 expected to spend > 80.000 € for reviewing literature
- How to make literature searches more efficient?
  - Reduce search frequency (now 2/a), or refine search terms -> no significant effect (literature pre-screened, main time needed to review really relevant papers + nr of relevant papers not depending on search frequency)
  - Combine review of papers with IUCLID input: ca. 20% less time required
  - Other?

3.2.3.
b) Ag Evaluation (1)

- Update
  - RIVM to finalise their opinion by Dec. 2014, then forward to ECHA
  - RIVM offered to share draft evaluation sent to ECHA = expect feedback still in Dec.
  - Timing: cf. next slide

3.2.3. b) Ag Evaluation (2): Timing after Evaluation by Ev MS is done





3.2.3. b) Ag Evaluation (3): Additional study requests

- Financial risk – not in current budget prediction

  Disclaimer: speculation at this stage, will depend on final decision by ECHA

Additional work	Cost (€)	Probability	Comment
Environment			
Reasonable worst case scenario WCA	± 1 million	low	Possible, but only if RIVM dismisses our read-across approach
Doomsday scenario WCA	1 - 1,5 million	negligible	Possible, but only if RIVM dismisses our read-across approach
Mamm. tox			RIVM not interested in mamm. tox but other MS have possibility to request studies too
Reproductive 2-generation study	0,5 million	moderate	Formal data gap, proposed CLH Repro Cat 1B for biocides
Reproductive developmental tox study	100.000	moderate	Formal data gap, currently proposed waiving
Carcinogenicity study	> 1 million	negligible	Proposed CLH Car. Cat 2 biocides
Substance ID			
	limited	high	Further characterisation work? / dossier update Likely to be covered by member companies



3.2.3. c) Ag Biocides



- Background
  - Proposed CLH by KEMI for silver zinc zeolite of Carc. Cat 2 and Repro Cat 1B
  - All effects attributed to Ag ion – need to avoid domino effect
  - 5 Sep. 2014: technical meeting PMC/ silver task force (STF) to review data and discuss next steps
  - CLH expected to be published end Dec.
  - 45-day commenting period once CLH published on registry of intentions (ROI)

- Next steps (decision points for near future)
  - PMC (EBRC) currently drafting comments
  - STF agreed to share underlying data for review (only with consultants)
  - Coordinate PMC response with STF
  - Submit comments once commenting window is open



3.2.3. d) Ag Dossier updates

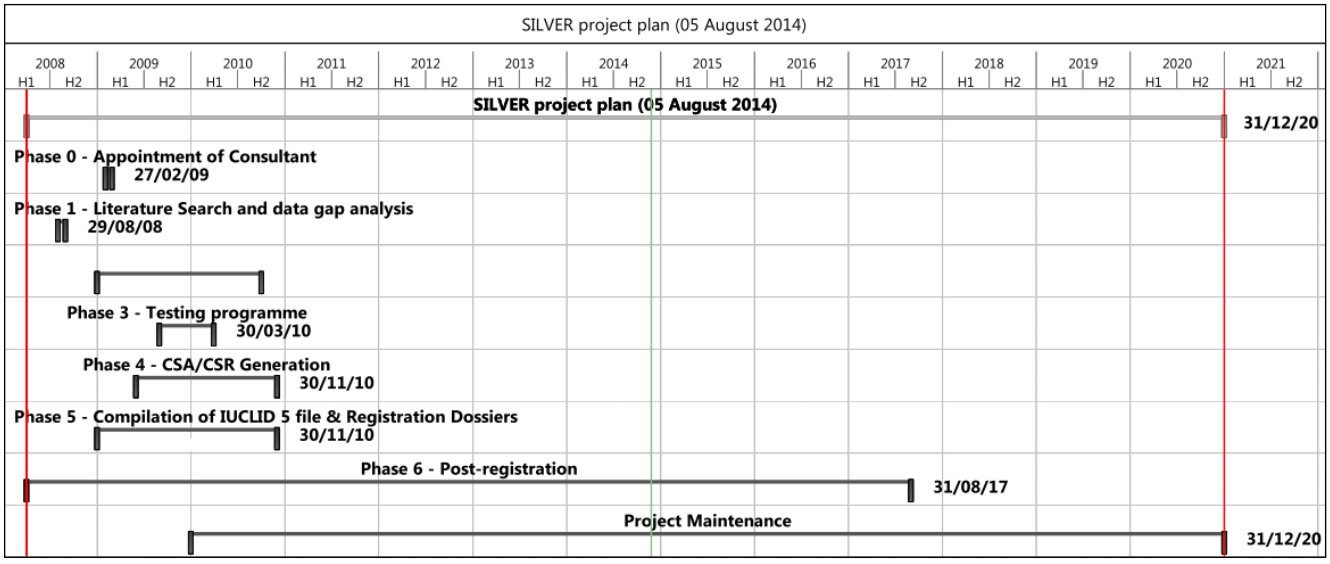


- Scope
  - Bring dossiers in line with Ag metal dossier
  - Include new soil data, adapt dossiers to latest ECHA requirements
- Ag_2O and $AgNO_3$
  - Updates submitted in Nov.
  - Put dossier updates forward to meet ECHA deadline on testing proposals (not required for other Ag compounds b/c lower tonnage band)
- Other Ag compounds
  - Currently being processed
  - Update expected end Dec. 2014 / Jan. 2015



3.2.4. Ag Roadmap









3.3. Au project

Renaud Nicolay



3.3.1. Gold Expenses 2014



Phase	Expenses budgeted	Expenses estimated end 2014	Comment
I.	€ 8.400	€ 10.500	Average based on experience (minimum cost is 2.000eur)
II.	€ 0	€ 5.000	adsorption/desorption test on TCA and others ITS addendum
III.	€ 69.000	€ 171.193	Based on actual proposals and OECD474 & ads/des test on TCA
IV.	€ 31.500	€ 19.000	based on actual proposals (30% invoiced)
V.	€ 8.400	€ 8.400	based on proposal (33% invoiced) (incl. hosting system)
TOTAL	**€ 117.300**	**€ 214.093**	



3.3.2. Gold Budget 2015

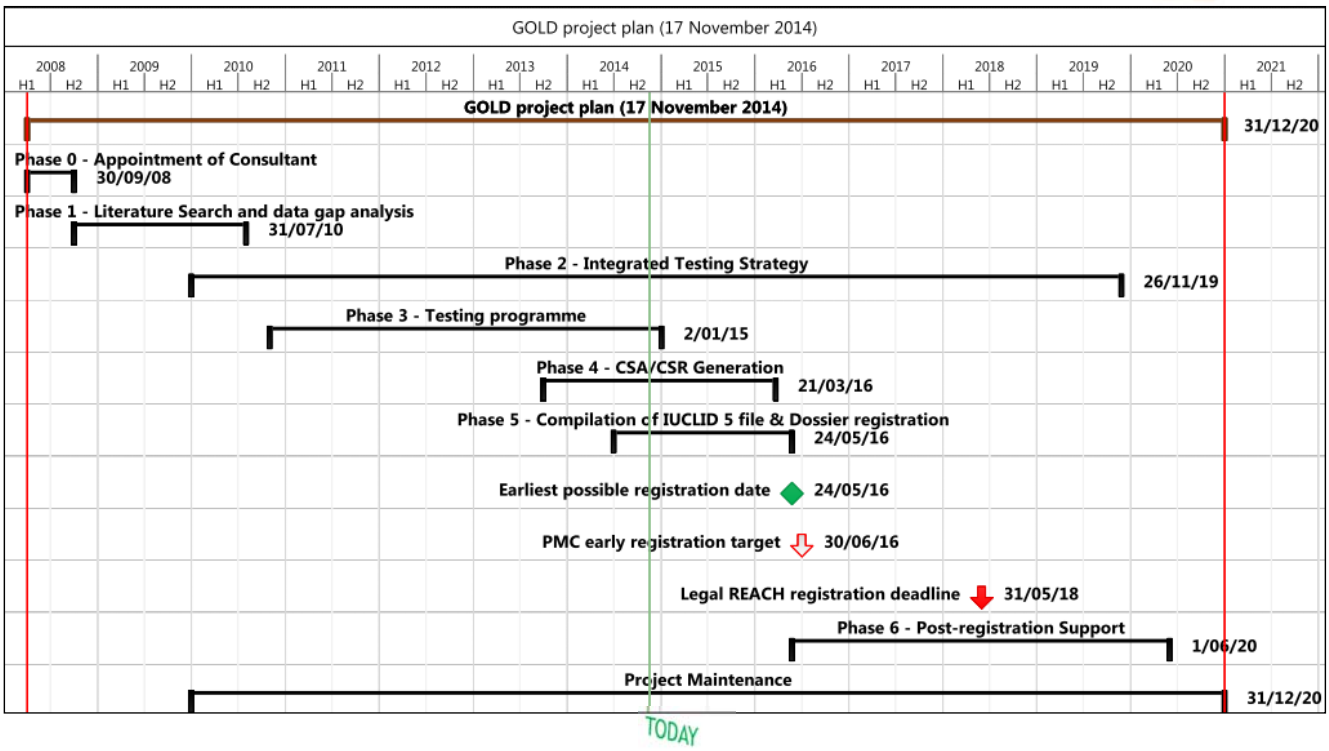


Phase	Expenses budgeted	Assumptions
I.	€ 10.500	Average based on experience (minimum cost is 2.000eur)
II.	€ 0	If not reported from 2014
III.	€ 0	study programme should be completed in 2014
IV.	€ 38.000	based on actual proposals (70% invoiced)
V.	€ 8.150	based on proposal (33% invoiced) (incl. hosting system)
TOTAL	**€ 56.650**	**Budget is stable (+4%) compared to June assumptions**



3.3.3. Gold Roadmap





3.4. PM CN- project

Renaud Nicolay

3.4.1. PM CN Expenses 2014

Phase	Expenses budgeted	Expenses estimated end 2014	Comment
I.	€ 8.400	€ 12.000	Average based on experience (minimum cost is 2.000eur)
II.	€ 0	€ 6.000	adsorption/desorption test on KAu(CN)2 and KAg(CN)2 new tests
III.	€ 138.000	€ 241.090	Based on actual proposals and tests postponed from 2013
IV.	€ 10.500	€ 43.000	based on actual proposals (30% invoiced)
V.	€ 8.400	€ 10.700	based on proposal (33% invoiced) (incl. hosting system)
TOTAL	**€ 165.300**	**€ 312.790**	Uncertainty of +70k eur

⚠ In its 08 Oct 2014 meeting, the Gold Working Group agreed to invalidate the read-across from KAu(CN)2 to KAg(CN) 2 and to initiate a testing programme on the substance. The presented Ph.3 cost is assuming a "light" testing programme on KAg(CN)2, which may not be sufficient to fulfil REACH requirements: 70.000 eur more may be needed in 2014.

3.4.2. PM CN Budget 2015

Phase	Expenses budgeted	Assumptions
I.	€ 10.500	Average based on experience (minimum cost is 2.000eur)
II.	€ 5.250	ITS addendum for additional KAgCN2 testing programme
III.	€ 90.000	Finalise study programme KAu(CN)2 & AgCN + continue KAg(CN)2
IV.	€ 80.000	based on actual proposals (70% invoiced)
V.	€ 8.150	based on proposal (33% invoiced) (incl. hosting system)
TOTAL	**€ 193.900**	Budget increased of 132.550 € compared to June assumptions. Uncertainty of +180k eur

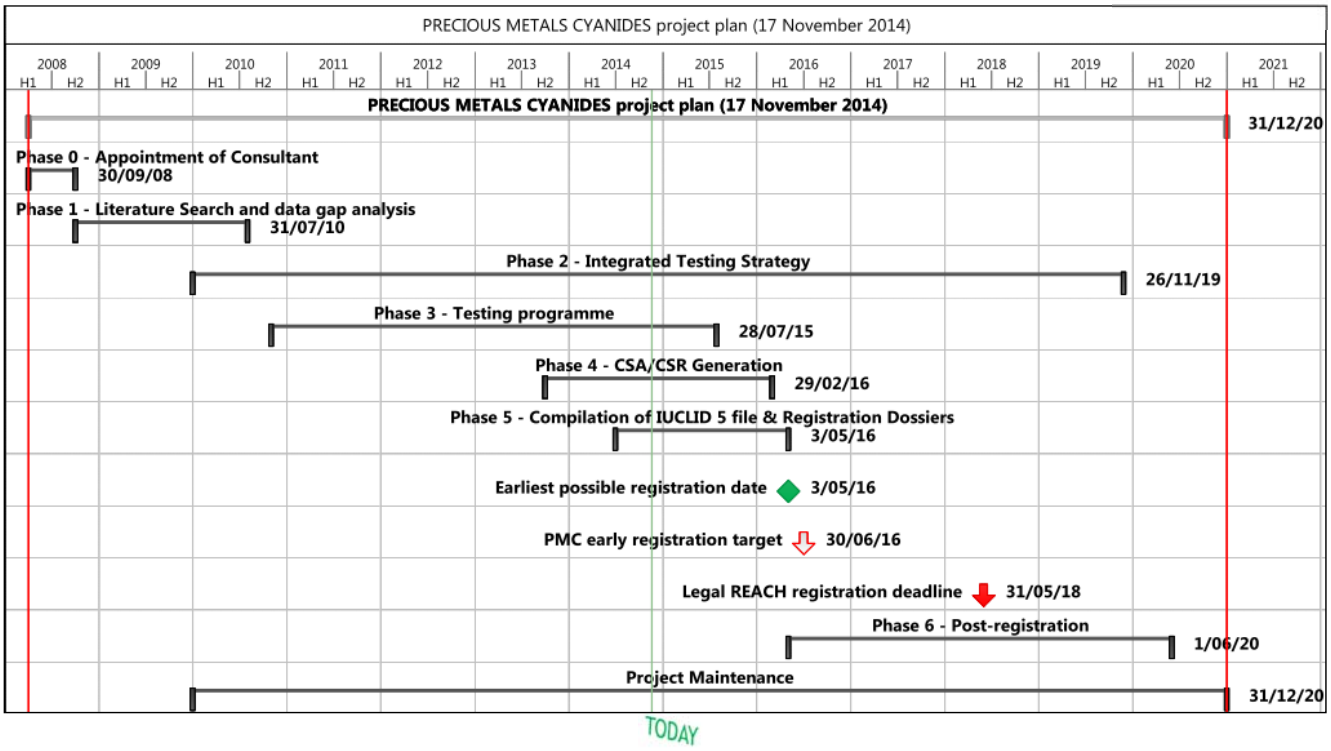
⚠ In its 08 Oct 2014 meeting, the Gold Working Group agreed to invalidate the read-across from KAu(CN)2 to KAg(CN) 2 and to initiate a testing programme on the substance. The ⚠ presented Ph.3 cost is assuming a "light" testing programme on KAg(CN)2, which may not be sufficient to fulfil REACH requirements: 180.000 eur more may be needed in 2015.

3.4.3 Classification

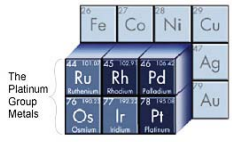
- Ph.3: LLNA (OECD 429) and enhanced LLNA (OECD 442b) confirmed the new classification of KAu(CN)2 as skin sensitiser of category 1
  - TSCA(8e): ✔ (pending update)
  - CLP: To do with LR

- Ph.3: Dermal acute tests on KAu(CN)2 and AgCN were negative:
  ➔ Substance should be declassified as *Acute tox. 1 (H310: Fatal in contact with skin)*

3.4.4. PM CN Roadmap



KAg(CN)2 "light" testing programme



3.5. PGM project

Katrien Arijs

Klaus Rothenbacher

3.5.1. PGM Expenses 2014

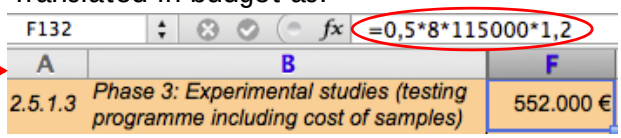
Phase	Expenses budgeted	Expenses estimated end 2014	Comment
I.	€ 15.750	€ 17.096	
II.	€ 10.500	€ 6.000	
III.	€ 552.000	€ 1.119.985	Calculation error in original budget
IV.	€ 215.250	€ 158.599	
V.	€ 24.500	€ 85.385	Balanced by lower expenses phase IV. Includes IUCLID hosting.
TOTAL	**€ 817.650**	**€ 1.387.065**	**Increase due to revised Phase III cost**

Budget assumptions:

50% of (4 Pt + ~ 8 Pd + 1 Rh + 1 Ru + 2 repeat Combined repeat[3] dose + repro/dev screen) = 8*115000 €[5]

50% of 16 tests = 8 tests

Translated in budget as:



50% of 8 tests

-> underestimation of 2014 budget by 552.000 €

3.5.2. PGM Budget 2015

Phase	Expenses budgeted	Assumptions
I.	€ 15.750	Unchanged from June assumptions
II.	€ 2.625	Unchanged from June assumptions
III.	€ 762.109	Increase due to inclusion study monitoring costs in updated budget / calculation error in original budget. Higher ecotox study costs (Ru test postponed to 2015) offset by lower tox study costs (part of RDT tests moved to 2016/2017)
IV.	€ 242.032	Increase based on most recent proposals
V.	€ 145.493	Increase based on most recent proposals. Includes IUCLID hosting.
TOTAL	**€ 1.168.010**	**Total increase of 179.110 € over June assumptions**



3.5.3. Summary of PGM technical items

a. PGM Substance identity / scope

b. Testing programme

c. Hazard assessment

d. Exposure assessment

e. Registration dossiers & timing



3.5.3. a) PGM Substance identity / scope

Sameness

- 'Diammonium hexachlororuthenate'
  - Expert discussions finalised: 'Diammonium hexachlororuthenate' (CAS 18746-63-9, UVCB) is in fact 'Tetraammonium decachloro-mu-oxodiruthenate' (CAS 85392-65-0, mono-const. subst.)
  - Ru portion of PGM testing programme will start now
- Karstedt concentrate
  - MoU under discussion with Reconsile consortium (LR)
  - Need to reach agreement on some key points before work can commence; not urgent

Scope

- Several changes to scope indicated by members (increased tonnage band = more tests required, substances not supported any longer) -> Waiting for official tonnage declaration forms before changing scope
- Further work on PGM blacks needed (nano materials?)



3.5.3. b) PGM Testing programme (1)

General Points

- Programme ongoing and proceeding as planned
- Most time- and cost-intensive tests to be finalised by end 2014
- Monthly updates provided on testing programme + Gantt charts for overall testing programme + detailed charts for RDT work
- No new TSCA 8(e) notifications

Phys.-chem. testing

- Outstanding tests have started



3.5.3. b) PGM Testing programme (2)

Human Health

- Programme on schedule, except for 'diammonium hexachlororuthenate': situation now clarified, testing due to start in Q1 2015
- 2014 study programme:
  - Genotoxicity, sensitisation, irritancy/corrosivity → most completed
  - Repeated dose toxicity (RDT) testing
    - Main batch of studies to be completed by end 2014, incl. DDP study
    - Peer review of histopathology data CitoxLAB in Dec. 2014
    - Test on Ru-compound will be completed in 2015
    - Need to review results in Q1 2015 and decide on way forward

Ecotoxicology

- Programme on schedule, to be completed in 2014
- Next steps:
  - Tests Ru-compound: 2015
  - Additional test on 1 Rh substance required: 2015



3.5.3. c) PGM hazard assessment

PNEC/ DNEL derivation

- Once final data from testing programme available
  - Q1 2015 (Pd, Pt)
  - Q3 2015 (Ru and Rh)
- Mamm. tox. tests completed by end 2015
  - DNELs by Q1 2016
  - If all tests for a metal completed, will start with DNEL derivation (i.e., before 2016 if possible)



3.5.3. d) PGM exposure assessment

- Work paused in Q1-2 2014 = data collection delayed by 6 months
- Work has recommenced in June 2014
  - Conducting most time-consuming work now
  - Questionnaires (uses, occ./env. exposure) sent, currently being evaluated
  - Emission monitoring programme (site-specific+STPs, all PGMs) started in Jul. 2014
- Definitive ES once robust PNECs/ DNELs available (2015/16)

3.5.3. e) PGM registration dossiers & timing

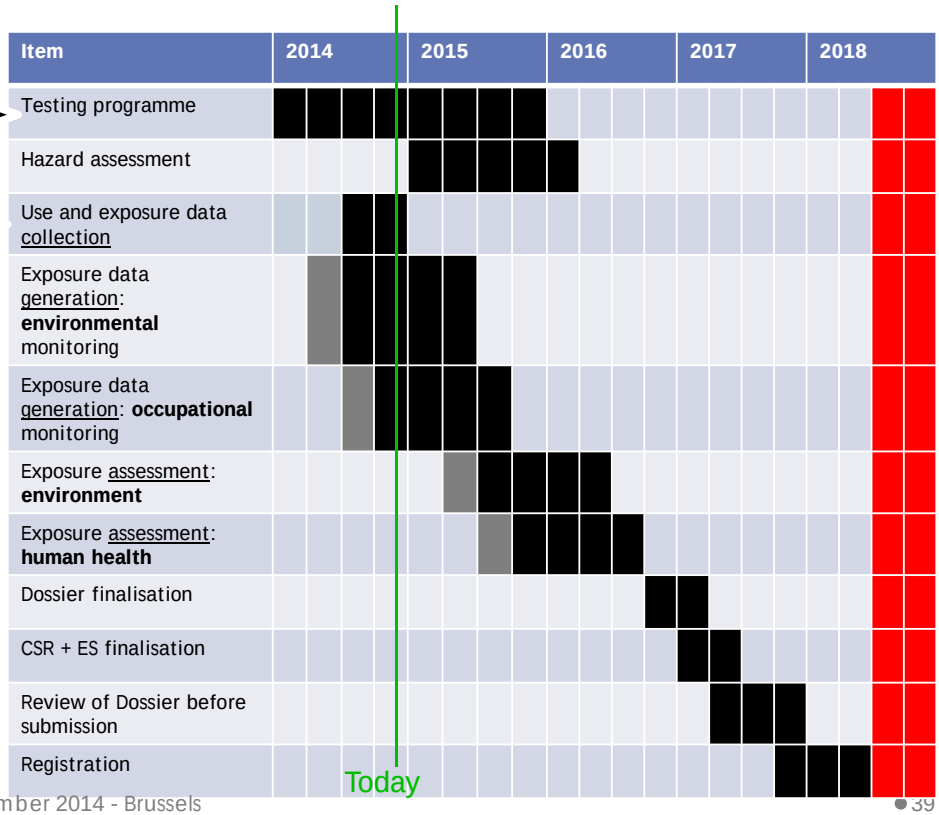
Registration approach/timing unchanged:

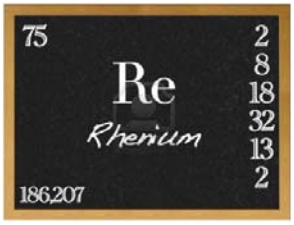
- Phased registrations (Pd first)
- May need fast-track plan if tonnage changes confirmed
- In window 2016-2017
  - **Well in time for 2018 if momentum is kept**
  - Time contingency for 'unexpected' events (study repeats, additional monitoring, etc.) considered

3.5.4. PGM Roadmap

Testing programme on track (exc. Ru)

Data collection delayed by 6 months





3.6. Rhenium project

Katrien Arijs



3.6.1. Re Expenses 2014

Phase	Expenses budgeted	Expenses estimated end 2014	Comment
I.	€ 6.300	€ 1.070	Literature search
II.-IV.	€ 0	€ 0	
V.	€ 3.150	€ 2.368	IUCLID hosting
VI.	€ 0	€ 3.830	Update compositions, generation SDS
TOTAL	**€ 9.450**	**€ 7.268**	



3.6.2. Re Budget 2015

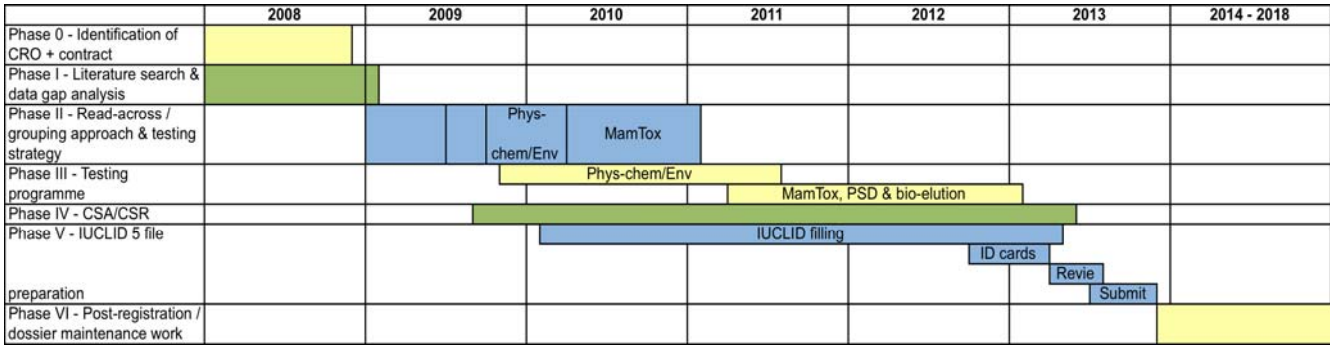
Phase	Expenses budgeted	Assumptions
I.	€ 6.300	Literature search and CLP update
II.-IV.	€ 0	
V.	€ 3.150	IUCLID hosting
VI.	€ 0	
TOTAL	**€ 9.450**	

Payment holiday!

3.6.3. Re project status

- Scope
  - 5/6 dossiers (sodium rhenate, ammonium perrhenate, perrhenic acid, potassium perrhenate and rhenium) completed and submitted
  - 1 remaining dossier (dirhenium heptasulphide) on hold / not a priority for the relevant company
- PMC Registration project completed well before 2018 registration deadline
- 2014 work programme
  - MSDS content for each Re compound has been prepared to harmonise communication in the supply chain – currently being finalised
  - Spontaneous update of all dossiers done to improve SID (information letter from ECHA received for perrhenic acid) and to update Use section
  - Literature search updates carried out by WCA & bibra: no relevant results returned for env/HH that require an update
- **Next**: except for some light dossier maintenance work, no further work anticipated

3.6.4 Re Roadmap





3.7. Refinables project

Katrien Arijs

3.7.1. Ref Expenses 2014

Phase	Expenses budgeted	Expenses estimated end 2014	Comment
I.	€ 0	€ 0	
II.	€ 0	- € 4.051	Credit notes for already paid phys-chem tests (booked in 2013) that were replaced by company data / waivers for the dossier upgrades
III.	€ 5.250	€ 0	CLP update - covered by generic costs
IV.	€ 0	€ 0	
V.	€ 3.150	€ 2.368	IUCLID hosting
VI.	€ 603.664	€ 331.497	Reserves used to upgrade dossiers
TOTAL	**€ 612.064**	**€ 329.814**	



3.7.2. Ref Budget 2015

	Phase	Expenses budgeted	Assumptions
	I.-V.	€ 3.150	IUCLID hosting
Post-registration work (>2014)	VI.1.	€ 5.360	ECHA advocacy (not in original budget)
	VI.2.	€ 0	
	VI.3.	€ 176.250	C&L update, TD & phys-chem testing for splitting dossiers (not in original budget), validation testing
	VI.4.	€ 78.266	Update of exposure & risk assessment, MSDS (not in original budget)
	VI.5.	€ 97.438	Update of IUCLID files & registration dossiers
	VI.6.	€ 5.360	Contingency
	TOTAL	**€ 365.824**	**Almost unchanged from June prediction**

Originally budgeted 255 k€ reduced to 66 k€, to be used together with remaining reserves in case validation testing turns out to be needed in 2015 (will not be done before requested by ECHA)

Reserves:

- Estimated end 2014 = 282.250 €
- Minimum to be retained in-house (7,5% of total costs) = 112.587 €
- Available for use in 2015 = 282.250 € - 112.587 € = 169.663 €

=> ± 235 k€ for validation testing (**placeholder**!)



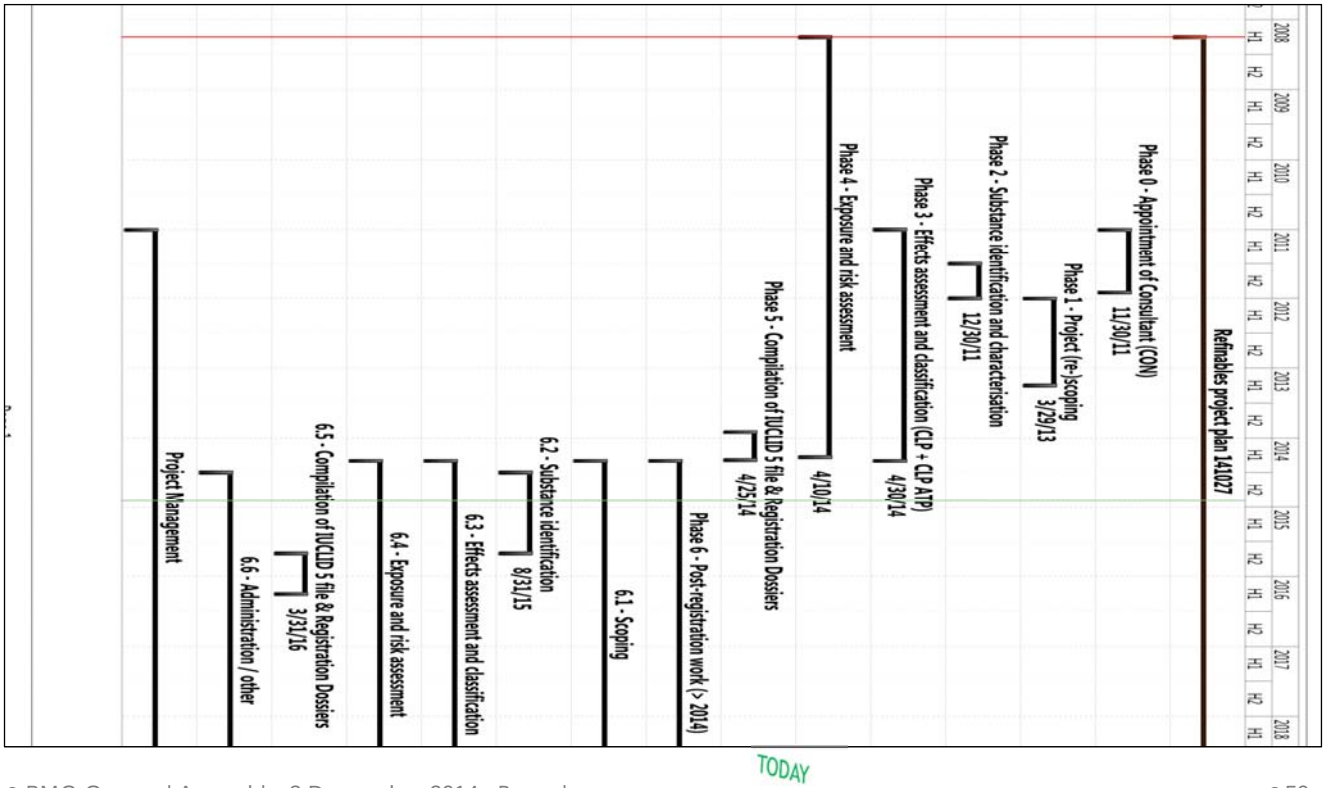
3.7.3. a) Ref 2014 work programme

- 11 non-SCC intermediate dossier '**upgrades**' from REACH Article 17/18 to Article 10 dossiers have been prepared & submitted by 30 Apr ECHA deadline
- Hazard and exposure assessment done on the basis of 'read-across' from Refinables' constituents
  - Approach developed in **collaboration with other consortia/consultants** under Eurométaux
  - Generic + site-specific environmental **exposure assessment** developed
  - 'Generic' (describing methodology) + site-specific occupational exposure assessment developed
  - **Data-sharing agreements** signed between PMC and the relevant consortia to ensure an equal sharing of the same data across registrants of inorganic UVCB
  - **Next**: further refinements needed
- ID cards updated + **classifications reviewed** -> submitted with the dossier upgrades
- **Phys-chem data** (not required for Art 17/18 registrations but required for Art 10 registrations) generated for those Refinables where data gaps were identified
- **SID check** ongoing for all 13 Refinables (2 SCC + 11 non-SCC), to ensure variability does not result from over-grouping of streams and can be justified on the basis of source and process

3.7.3. b) Ref 2015 work programme

- First focus on SID/splitting of Refinables and postpone further data-collection to refine the occupational exposures to 2016, once we have more clarity on the number of dossiers
- **SID check**:
  - Clear signals received from ECHA that further justification of our SID approach and splitting for some Ref will be needed (4 Apr Eurométaux/ECHA SID call + 6-7 Oct ECHA SID workshop)
  - Agreed splitting for **PM slags**: currently registered as 1 substance with splitting approach documented in CSR, waiting for feedback ECHA before registering separately
  - SID decision tree under development to identify weaknesses SID for all remaining Refinables and need for further splitting / justification
  - Split dossiers and initiate testing where needed
- **Further dossier updates**:
  - Consideration of combined toxicity, improvement of uncertainty analysis, ECHA advocacy (in collaboration with other consortia/consultants under Eurométaux)
  - Update SCC dossiers
  - Inclusion additional constituents for environmental assessment
- **MSDS generation**

3.7.4. Ref Roadmap



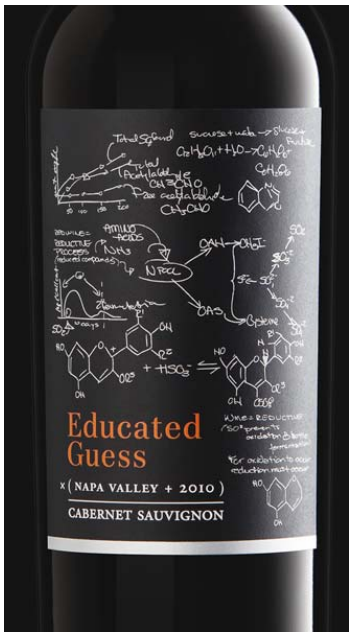
‘Predictable’ Budget risks

ECHA report last February:

61% of dossiers evaluated for compliance in 2013 had deficiencies/ insufficient information related to:

- Substance identity
- Physical-chemical properties
- Repeat dose toxicity studies
- Prenatal developmental toxicity studies
- Exposure assessment

Most likely to be subject to ECHA requests for significant work, e.g. extended or repeat studies etc.



ECHA’s other key area of interest:

- Nanoforms, especially data gaps in dossiers also covering bulk substances

More likely to be impacted:

- **PGMs** (numbers game…), possibly **Refinables**
- NB Substance evaluation too: Ag (previously covered)



4. Authorisation

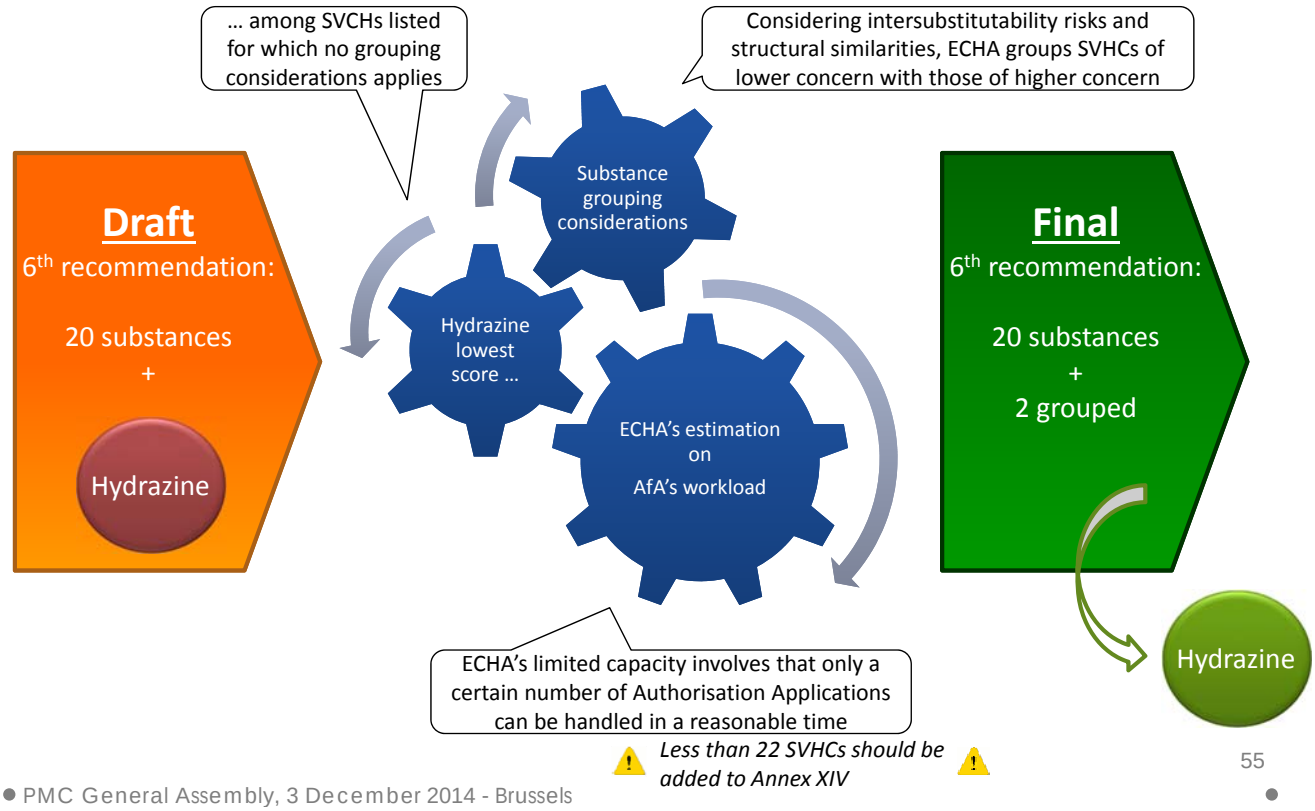
Renaud Nicolay
Mark Raffray

4.1 Overview of Authorisation status for substances of interest

- RCF:
  - Statu quo: not proposed for authorisation since 5th list cancellation
  - Not scored anymore in the ranking of substances up for Authorisation
  - Temporary status: should come back in a future Recommendation list

- Lead Monoxide and Borates:
  - Prioritised for Authorisation on the 6th Recommendation List
  - Interested Members have been invited to comment by themselves on the Public Consultations ending 30 Nov 2014, with support of Secretariat for general questions and ensuring communications with ILA and EBA

4.2 Hydrazine (1/2)
Out of 6th Recommendation List



⚠ *Less than 22 SVHCs should be added to Annex XIV* ⚠

4.2 Hydrazine (2/2)
Regulatory threats defence

- Real progress: AoA position is now robust
- PM sector asserted workplace exposures to Hydrazine are well controlled but …
- Actual datasets limited, variable techniques, LOD differ, not consistent with latest expectations of 'negligible exposure'
  - ➔ More robust exposure dataset is a clear need
- Other regulatory needs (OEL, Carcinogens Dir.)
- **Time for a definite decision:**
  - o OEL trend downward / complicated by analytical & monitoring challenges !
  - o Companies need to evolve monitoring & datasets anyway due to regulatory drivers !





➔ (Collective) Industrial Hygiene Assessment initiated

- ➔ targeting the lowest proposed (German) OEL
- ➔ completion foreseen Q2/Q3 2015
- ➔ Estimate: 78.000 € (all in 2015), to be confirmed





5. PMC Finances

Guy Ethier



5.1. PMC past and current accounts overview



5.1.1. Total Expenses 2007-2014

Budget line	Set-up year	Total expenses up to Sep 2014*	Comments
Generic	2007	€ 2.783.572	Mainly staff costs, office, meeting costs
Ag	2008	€ 2.715.381	Registered in 2010, on going work until…
Au	2009	€ 532.079	Registration activities on track
PM CN-	2009	€ 499.577	Decision on unexpected increase of testing costs
PGM	2008	€ 3.125.745	Most expensive project, > 60 registrations
Re	2008	€ 429.803	Registered in 2013, only maintenance work left
Ref	2010	€ 1.501.156	Dossier upgrades in 2014, further updates on going
Hydrazine	2011	€ 51.814	Authorisation expected and pending OEL
	TOTAL	**€ 11.639.127**	

*** Actual total cost of each project since their set-up**



5.1.2. 2014 Budget / Expenses (by 31 Oct 14)

Project	2014 Budget	2014 Expenses by 31 Oct	2014 Expenses estimated Nov-Dec	2014 Total expenses estimated
Generic	€ 745.140	€ 489.248	€ 255.892	€ 754.140
Ag	€ 210.285	€ 151.406	€ 101.977	€ 253.383
Au	€ 117.300	€ 150.388	€ 63.705	€ 214.093
PM CN	€ 165.300	€ 117.968	€ 194.822	€ 312.790
PGM	€ 817.650	€ 865.284	€ 521.781	€ 1.387.065
Re	€ 9.450	€ 2.368	€ 4.900	€ 7.268
Ref	€ 612.064	€ 307.314	€ 22.500	€ 329.814
Hyd	€ 60.000	€ 5.543	€ 0	€ 5.543
TOTAL	**€ 2.737.189**	**€ 2.089.519**	**€ 1.165.577**	**€ 3.255.096**

5.1.3. Cumulative Reserves

Budget line	Reserves end 2013	Estimated reserves end 2014	Comment
Generic	€ 520.777	€ 51.024	
Ag	€ 218.461	-€ 34.922	Need for additional invoicing
Au	€ 163.654	-€ 14.966	Need for additional invoicing
PM CN-	€ 240.830	-€ 27.075	Need for additional invoicing
PGM	€ 2.257.892	€ 970.944	Enough reserves available
Re	€ 139.399	€ 132.131	Enough reserves available
Ref	€ 612.064	€ 282.250	Enough reserves available
Hydrazine	€ 1.508	€ 54.457	Enough reserves available
TOTAL	**€ 4.154.586**	**€ 1.413.844**	

- Reserves used to limit the invoices in 2014

5.1.4. Securing minimum required reserves

466.030 €

	2014	2007 - Sep 2014	2015		
	Estimated Reserves end 2014 (K)=J-G	Total specific costs (L)	Min. reserves to be retained in-house (M)	Available reserves / additional demand for 2015 invoices (N)=K-M	Additional amounts to be invoiced / reserves to be used in 2015 (O)
Generic	*51.024 €*	*2.783.572 €*	*167.412 €*	*-116.388 €*	*-116.388 €*
Ag	*-34.922 €*	*2.715.381 €*	*208.607 €*	*-243.529 €*	*-243.529 €*
Au	*-14.966 €*	*532.079 €*	*26.604 €*	*-41.570 €*	*-41.570 €*
PM CN-	*-27.075 €*	*499.577 €*	*37.468 €*	*-64.543 €*	*-64.543 €*
PGM	*970.944 €*	*3.125.745 €*	*234.431 €*	*736.514 €*	*400.000 €*
Re	*132.131 €*	*429.803 €*	*21.490 €*	*110.641 €*	*9.450 €*
Refinables	*282.250 €*	*1.501.156 €*	*112.587 €*	*169.663 €*	*0 €*
Hydrazine	*54.457 €*	*51.814 €*	*2.591 €*	*51.866 €*	*0 €*
TOTAL	***1.413.844 €***	***11.639.127 €***	***811.190 €***	***602.654 €***	***-56.580 €***

409.450 €

Previously indicated retroactive Ag invoicing 2014: **568.892 €**

- Ag reserves of 218.461 € at end 2013 were not considered
- 2014 additional spent was overestimated by 106.902 €

=> difference of 325.363 € between the previous calculation and the current calculation

5.2. 2015 budget and invoices

5.2.1. Proposed 2015 Budget for approval



Project	Budget 2015	Amounts to be invoiced	Comments
Generic	€ 789.929	€ 891.316,52	2015 Budget + acquisition minimum reserves – bank interests (€ 15.000)
Ag	€ 241.415	€ 484.944,22	2015 Budget + 2014 budget retroactive payment + acquisition minimum reserves
Au	€ 56.650	€ 98.219,53	2015 Budget + 2014 budget retroactive payment + acquisition minimum reserves
PM CN	€ 193.900	€ 258.443,36	2015 Budget + 2014 budget retroactive payment + acquisition minimum reserves
PGM	€ 1.168.010	€ 768.009,80	2015 Budget - use fraction of reserves
Ref	€ 365.824	€ 365.824	2015 Budget
Re	€ 9.450	€ 0	2015 Budget – use fraction of reserves
Hyd	€ 78.000	€ 78.000	2015 Budget
TOTAL	**€ 2.903.178**	**€ 2. 944.757**	



5.2.2. 2015 indicative invoices (1)

Exact amounts to be invoiced will be confirmed in March 2015 upon closure of 2014 accounts and confirmation of 2014 reserves

ID Code	2015 Generic cost-share per Member + acquisition min. Generic reserves	2015 Ag-specific cost-share per Member + 2014 Ag budget retroactive payment + acquisition min. Ag reserves	2015 Au-specific cost-share per Member + 2014 Au budget retroactive payment + acquisition min. Au reserves	2015 PM CN- -specific cost-share per Member + 2014 PM CN- budget retroactive payment + acquisition min. PM CN- reserves	2015 PGM-specific cost-share per Member - use fraction of PGM reserves	2015 Re-specific cost-share per Member - use fraction of Re reserves	2015 Ref-specific cost-share per Member	2015 Hz-specific cost-share per Member	INDICATIVE ONLY Amount to be invoiced in 2015
1	19.807,03 €	0,00 €	0,00 €	0,00 €	0,00 €	0,00 €	0,00 €	0,00 €	19.807,03 €
2	19.807,03 €	0,00 €	2.226,37 €	0,00 €	27.152,97 €	0,00 €	0,00 €	9.750,00 €	58.936,37 €
3	19.807,03 €	5.078,91 €	4.301,43 €	0,00 €	5.763,78 €	0,00 €	0,00 €	0,00 €	34.951,15 €
5	19.807,03 €	45.545,93 €	4.301,43 €	0,00 €	0,00 €	0,00 €	51.403,43 €	0,00 €	121.057,82 €
6	19.807,03 €	13.999,21 €	0,00 €	49.478,30 €	14.409,44 €	0,00 €	5.711,49 €	0,00 €	103.405,48 €
7	19.807,03 €	13.499,14 €	2.226,37 €	39.786,67 €	0,00 €	0,00 €	0,00 €	0,00 €	75.319,21 €
8	19.807,03 €	8.378,98 €	4.301,43 €	10.031,68 €	0,00 €	0,00 €	0,00 €	0,00 €	42.519,12 €
9	19.807,03 €	13.999,21 €	8.602,86 €	0,00 €	23.055,11 €	0,00 €	0,00 €	9.750,00 €	75.214,21 €
10	19.807,03 €	4.460,15 €	2.226,37 €	20.063,37 €	5.763,78 €	0,00 €	0,00 €	0,00 €	52.320,69 €
11	19.807,03 €	58.962,57 €	6.527,79 €	49.478,30 €	168.523,56 €	0,00 €	34.268,95 €	9.750,00 €	347.318,21 €
12	19.807,03 €	8.378,98 €	4.301,43 €	0,00 €	5.763,78 €	0,00 €	0,00 €	0,00 €	38.251,21 €
13	19.807,03 €	45.504,68 €	2.226,37 €	0,00 €	0,00 €	0,00 €	6.000,00 €	0,00 €	73.538,08 €
14	19.807,03 €	18.536,80 €	0,00 €	0,00 €	0,00 €	0,00 €	0,00 €	0,00 €	38.343,83 €
15	19.807,03 €	13.457,89 €	8.754,16 €	30.095,05 €	180.051,12 €	0,00 €	28.557,46 €	9.750,00 €	290.472,71 €
16	19.807,03 €	4.501,40 €	2.226,37 €	0,00 €	53.089,97 €	0,00 €	45.691,94 €	0,00 €	125.316,71 €
17	19.807,03 €	22.378,19 €	4.301,43 €	39.786,67 €	8.645,67 €	0,00 €	0,00 €	9.750,00 €	104.668,99 €
18	19.807,03 €	5.078,91 €	0,00 €	0,00 €	0,00 €	0,00 €	5.711,49 €	0,00 €	30.597,44 €
19	19.807,03 €	5.078,91 €	0,00 €	0,00 €	0,00 €	0,00 €	0,00 €	0,00 €	24.885,95 €
20	19.807,03 €	8.378,98 €	4.301,43 €	0,00 €	2.881,89 €	0,00 €	17.134,48 €	0,00 €	52.503,80 €
21	19.807,03 €	8.378,98 €	4.301,43 €	0,00 €	5.763,78 €	0,00 €	0,00 €	0,00 €	38.251,21 €
23	19.807,03 €	4.460,15 €	2.226,37 €	0,00 €	0,00 €	0,00 €	0,00 €	0,00 €	26.493,55 €
24	19.807,03 €	4.460,15 €	2.226,37 €	0,00 €	5.763,78 €	0,00 €	0,00 €	9.750,00 €	42.007,33 €
25	19.807,03 €	27.457,10 €	6.679,10 €	0,00 €	91.891,29 €	0,00 €	51.403,43 €	9.750,00 €	206.987,95 €
27	19.807,03 €	5.078,91 €	0,00 €	0,00 €	0,00 €	0,00 €	0,00 €	0,00 €	24.885,95 €



5.2.2. 2015 indicative invoices (2)

Exact amounts to be invoiced to be confirmed in March 2015 upon closure of 2014 accounts and confirmation of 2014 reserves

ID Code	2015 Generic cost-share per Member + acquisition min. Generic reserves	2015 Ag-specific cost-share per Member + 2014 Ag budget retroactive payment + acquisition min. Ag reserves	2015 Au-specific cost-share per Member + 2014 Au budget retroactive payment + acquisition min. Au reserves	2015 PM CN- -specific cost-share per Member + 2014 PM CN- budget retroactive payment + acquisition min. PM CN- reserves	2015 PGM-specific cost-share per Member - use fraction of PGM reserves	2015 Re-specific cost-share per Member - use fraction of Re reserves	2015 Ref-specific cost-share per Member	2015 Hz-specific cost-share per Member	INDICATIVE ONLY Amount to be invoiced in 2015
28	19.807,03 €	0,00 €	0,00 €	0,00 €	0,00 €	0,00 €	0,00 €	0,00 €	19.807,03 €
29	19.807,03 €	0,00 €	2.226,37 €	0,00 €	0,00 €	0,00 €	0,00 €	0,00 €	22.033,40 €
30	19.807,03 €	0,00 €	0,00 €	0,00 €	0,00 €	0,00 €	0,00 €	0,00 €	19.807,03 €
31	19.807,03 €	0,00 €	0,00 €	0,00 €	0,00 €	0,00 €	0,00 €	0,00 €	19.807,03 €
32	19.807,03 €	5.078,91 €	0,00 €	0,00 €	0,00 €	0,00 €	5.711,49 €	0,00 €	30.597,44 €
33	19.807,03 €	5.078,91 €	0,00 €	0,00 €	0,00 €	0,00 €	0,00 €	0,00 €	24.885,95 €
34	19.807,03 €	0,00 €	0,00 €	0,00 €	0,00 €	0,00 €	5.711,49 €	0,00 €	25.518,53 €
35	19.807,03 €	0,00 €	0,00 €	0,00 €	0,00 €	0,00 €	0,00 €	0,00 €	19.807,03 €
36	19.807,03 €	5.078,91 €	2.226,37 €	0,00 €	5.763,78 €	0,00 €	0,00 €	0,00 €	32.876,09 €
39	19.807,03 €	5.078,91 €	4.301,43 €	0,00 €	5.763,78 €	0,00 €	28.557,46 €	0,00 €	63.508,61 €
40	19.807,03 €	17.918,04 €	4.301,43 €	19.723,31 €	18.111,71 €	0,00 €	57.114,92 €	0,00 €	136.976,44 €
41	19.807,03 €	5.078,91 €	0,00 €	0,00 €	0,00 €	0,00 €	0,00 €	0,00 €	24.885,95 €
42	19.807,03 €	0,00 €	2.226,37 €	0,00 €	2.881,89 €	0,00 €	0,00 €	0,00 €	24.915,29 €
43	19.807,03 €	50.583,59 €	2.226,37 €	0,00 €	8.949,66 €	0,00 €	22.845,97 €	0,00 €	104.412,62 €
44	19.807,03 €	0,00 €	0,00 €	0,00 €	20.173,22 €	0,00 €	0,00 €	0,00 €	39.980,26 €
45	19.807,03 €	5.078,91 €	2.226,37 €	0,00 €	38.072,54 €	0,00 €	0,00 €	0,00 €	65.184,85 €
46	19.807,03 €	12.839,13 €	0,00 €	0,00 €	0,00 €	0,00 €	0,00 €	0,00 €	32.646,16 €
47	19.807,03 €	5.078,91 €	2.226,37 €	0,00 €	14.409,44 €	0,00 €	0,00 €	0,00 €	41.521,76 €
48	19.807,03 €	12.839,13 €	0,00 €	0,00 €	5.763,78 €	0,00 €	0,00 €	9.750,00 €	48.159,94 €
49	19.807,03 €	0,00 €	0,00 €	0,00 €	20.173,22 €	0,00 €	0,00 €	0,00 €	39.980,26 €
50	19.807,03 €	10.157,82 €	0,00 €	0,00 €	29.426,87 €	0,00 €	0,00 €	0,00 €	59.391,73 €
TPR 1	TPR 1					0,00 €			0,00 €
TOTAL	891.316,52 €	484.944,22 €	98.219,53 €	258.443,36 €	768.009,80 €	0,00 €	365.824,00 €	78.000,00 €	2.944.757,43 €

6. Next meetings, AOB, and closing remarks

Guy Ethier

Next meetings

- 2015 PMC Plenary meeting: Milan, 4 June 2015

  > *Invitation will be sent in Feb/March 2015*



- 2015 PMC Assembly meeting: Brussels, 2 December 2015

Any Other Business and closing remarks

