



Precious Metals
Consortium



Precious Metals & Rhenium Consortium

General Assembly Meeting

1-2 June 2016 | Wrocław, Poland



Precious Metals
Consortium

1. Welcome and Introduction

Guy Ethier, Umicore

1.1 Confidentiality and Competition Law

DO	DON'T
<u>Application of competition law</u>	
Art. 101 and 102 TFEU may be applicable to the conclusion of any preliminary agreement and activities of any preliminary phase.	Don't assume that conflicts with competition law are excluded simply by the fact that the Agreement complies with the provisions of the REACH Regulation.
<u>Consultation in Matters of Competition Law</u>	
Consult an in-house legal expert or the compliance officer of your company or an external lawyer whenever there are uncertainties respecting compliance with competition law. Stop all meetings/discussions which are not in compliance with these Compliance Guidelines until a legal expert has been involved.	Don't assume that these Compliance Guidelines deal with all competition law issues exhaustively. Basically, compliance with Art. 101 and 102 TFEU can be determined only on the basis of market impact in each individual case. These Compliance Guidelines may therefore be regarded only as a means of providing general conduct recommendations.
<u>Activities in any preliminary phase and at any other stage of operation of the Consortium</u>	
Restrict cooperation within the scope of the preliminary phase to the initially defined goals and purposes of the cooperation.	Pursuant to Art. 101 and 102 TFEU, activities which have the object or the effect of preventing, restricting and/or distorting competition are prohibited within the scope of this Agreement, including: <ul style="list-style-type: none"> - Coming to agreement, including arrangements or collusions, about prices, markets and customers (see Art. 101 paragraph 1 a)-e) TFEU); - Joint boycotting of other companies; - The unjustified unequal treatment of trade partners; - The abusive exploitation of a dominating market position.
<u>Exchange of Confidential Information</u>	
Involve a Trustee for the exchange of Confidential Information.	The exchange of Information concerning market behaviour and having the object or the effect of preventing, restricting and/or distorting competition is inadmissible; in particular, this relates to : <ul style="list-style-type: none"> - Production capacities; - Productions or sales volumes; - Import volumes; - Market shares; - Price policy; - Distribution and marketing terms; - Marketing strategies; - Information regarding the relationship with suppliers.
<u>Documentation on Cooperation</u>	
Keep minutes of all meetings which detail the subject of the meeting. In case of uncertainty, have the contents of the minutes reviewed by an external legal expert prior to sending them to all parties of the Agreement. Stop all meetings which are not in compliance with these Guidelines until a legal expert has been involved.	



1.2 Tour de table, quorum and apologies

Cf. attendance list

Quorum is reached: 66 %



1.3 Approval of the agenda 01/06/2016

1. Welcome and Introduction

1.1. Confidentiality and Competition Law

1.2. Tour de table, quorum and apologies

1.3. Approval of the agenda

1.4. Approval of the minutes of the last meeting (1-2 December 2015, Brussels)
including status of action items

2. PMC Membership news

2.1. Changes in HR

2.2. Reelection of PMC Management Committee for 2017-2019 period

3. Update on PMC Projects

4. Closing remarks



1.4 Approval of the minutes of the last meeting (1-2/12/2015) including status of action items

Actions	Who	When	Status
Prepare a calendar for members for approval and submission of all registrations dossiers	PMC Secretariat	January 2016	DONE
Revisit the discussion on chloropalladates dossier submission	Sub-Assembly Pd	June 2016	DONE
Ensure to conclude on sensitization and keep pressure on Reconsile to receive the data needed	KR	ASAP	DONE
Ensure that IUCLID migration timeline and consequences are communicated clearly by EM but also by PMC in the REACH news	ME	December 2015	DONE
Do a sensitivity analysis on cost sharing formula	Management Committee	March 2016	DONE
Keep the reprotox testing proposal on silver high on the agenda and discuss again at the Ag Sub-Assembly	Sub-Assembly Ag	June 2016	DONE
Document the thinking process behind the weighting factor of 5000 fore the silver nano proposal	FC	March 2016	DONE
Circulate to the GA the note from Legal Counsel on LoA fee	FC	December 2015	DONE
Update the WP budget table with a column summarizing the carry over from one year to the other	FC	March 2016	DONE
Review the balance between HR and projects costs: ensure correct resources are allocated	Management Committee	March 2016	DONE
Issue updated version of the invoices simulation with the minutes	AR	December 2015	DONE
Organize a WS on after 2018 and the future of the PMC+	PMC Secretariat	December 2016	DONE



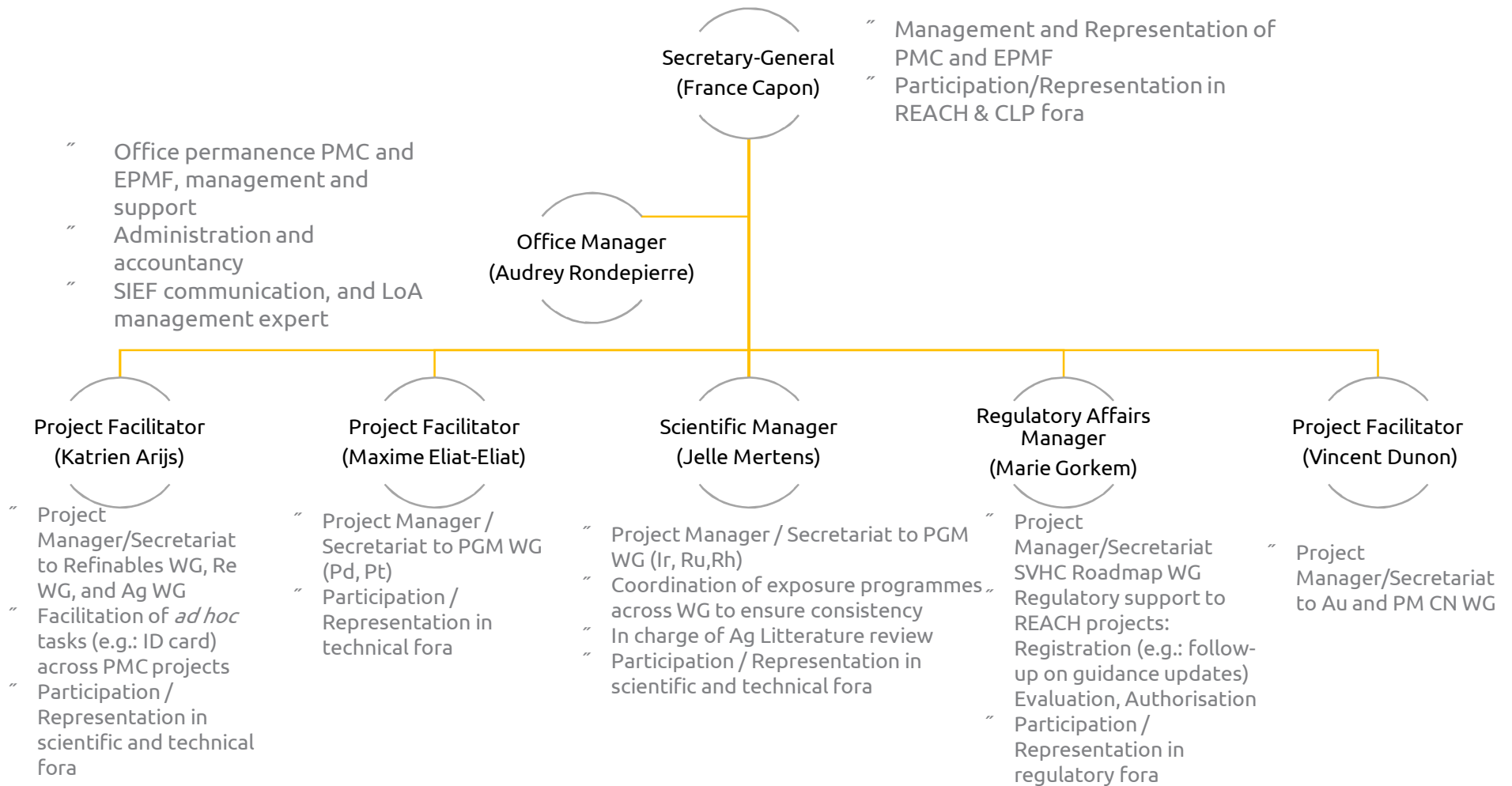


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2. PMC Membership news

France Capon, EPMF

2.1 Changes in HR



2.2 Reelection of PMC Management Committee for 2017-2019 period

- “ Based on article 4.2.1.1. « Elections of the Management Committee shall take place every 3 (three) years+. last elections have been organized end of 2013
- “ Next election: Assembly December 2016





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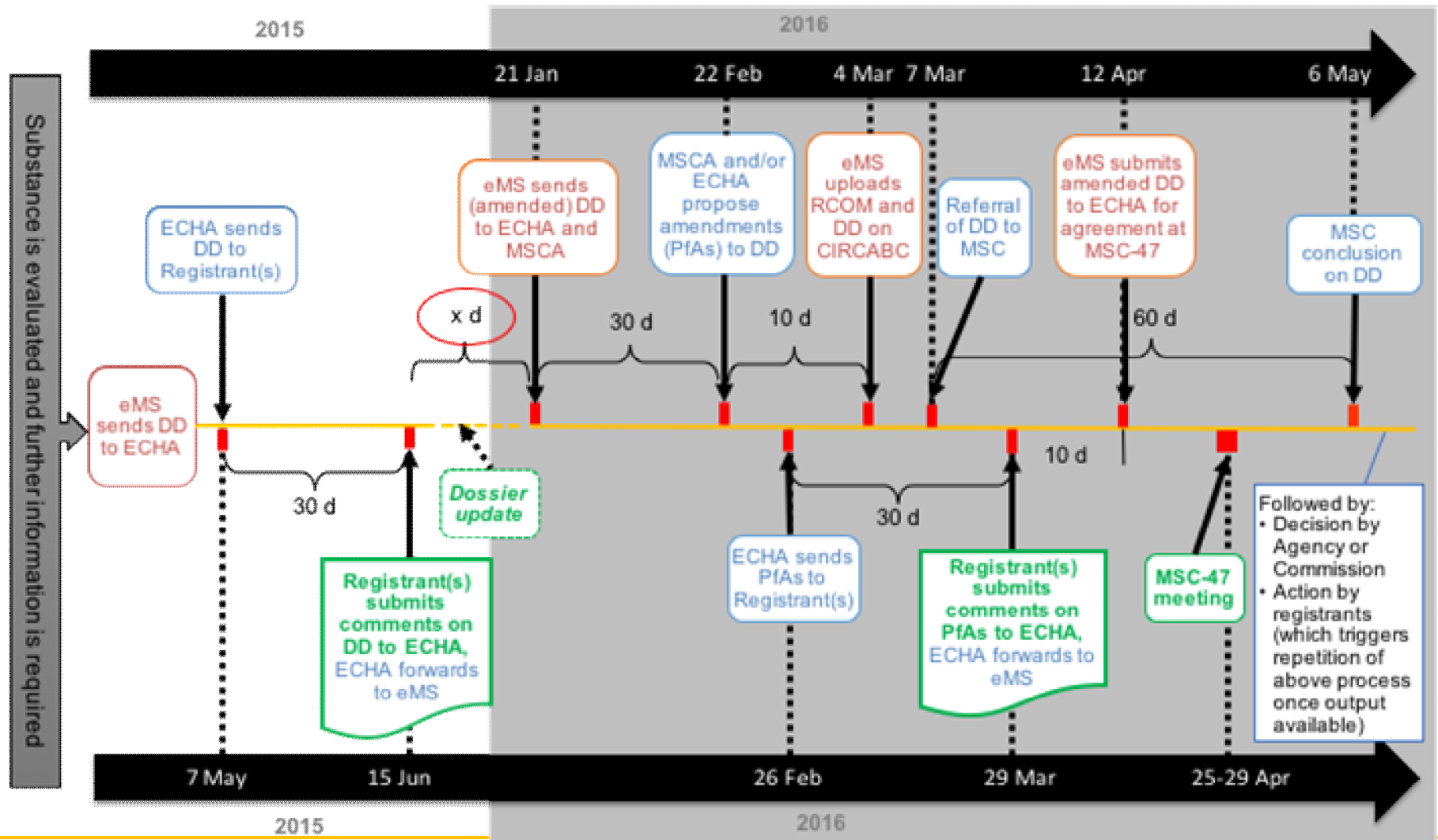
3. Update on PMC Projects



3.1 Ag Project: Status E Substance evaluation

Katrien Arijns

DD = Draft Decision
 PAs = Proposal for Amendments



3.1 Ag Project: Key milestones E Substance evaluation (1)

Katrien Arijs

- ” Scope of SEv limited to **nanofoms of Ag**
- ” **Draft decision (DD)**: eMSCA not convinced about read-across approach and considered that further information was required to clarify initial concerns:
 1. **Phys-chem** properties of each individual form of nanoAg (granulometry, surface area, surface treating agents, dissolution rate, density, point of zero charge)
 2. **Fate** of nanoAg in soil pore water and soil solid fraction: 3 forms of nanoAg and 3 types of soils
 3. **Ecotoxicity** studies for 3 forms of nanoAg (OECD tests with algae, *Daphnia*, soil micro-organisms)
 4. **Use** information for each individual form of nanoAg
- ” 12 months to comply with decision
- ” PMC submitted **comments** on DD and performed **dossier update** in 2015



3.1 Ag Project: Key milestones & Substance evaluation (2)

Katrien Arijs

DD amended by RIVM (received 26 Feb 2016)

“ **PMC comments taken into account in amended DD:**

1. Definition of nanoform included
2. Extension of timeframe from 12 to 24 months
3. More accurate reflection of number of nanoAg registrants (limited to 2!)
4. Soil fate testing: aging process of 12 months included
5. Several methodological concerns phys-chem request and ecotox testing considered

ACCEPTED

“ **PMC comments not taken into account in amended DD:**

1. Concerns on proportionality and research nature of certain requests
2. Re-assessment of WoE read-across (*Based on the existing information the eMSCA is not convinced that nanosilver is less toxic than ionic silver*)
3. Some methodological concerns phys-chem request not considered
4. Soil fate testing: additional study not considered representative for EU soil types

DENIED

“ Furthermore, a number of PMC suggestions have not been specifically addressed in the amended DD (but also not explicitly rejected) e.g. selection of soils



3.1 Ag Project: Key milestones Æ Substance evaluation (3)

Katrien Arijs

Proposals for amendments (PfAs) from ECHA (received 26 Feb 2016)

- “ PMC submitted comments on PfAs by 29 March 2016
 - “ Better justification or, preferably, **removal of phys-chem request** from the decision
 - “ Possibility for **grouping** for phys-chem request + info on uses
 - “ Forms to be tested should represent **worst case**
 - “ Additional PfAs: reflect better the Registrants' comments related to the overlap between the requests on fate in soil and a recently EU funded project; scope of decision; scope of SEv versus BPR; downstream users; small nanoAg tonnage; justify reasoning of the extension of the deadline in the DD, and proposed to replace the definition of a nanoform in the decision.



3.1 Ag Project: Key milestones E Substance evaluation (4)

Katrien Arijs

Member State Committee (MSC) meeting (25-29 April)

MSC conclusions:

- Drop **phys-chem** request for each individual nanoAg form
- Keep **ecotoxicity** request (on algae, Daphnia long term and soil microorganisms) **only** on the smallest nanoAg form with highest specific surface area + sufficient phys-chem characterisation of tested form
- Request on **fate** of nanoAg in soil pore water and the soil solid fraction **only** in case any of the ecotox tests show higher toxicity for nanoAg as compared to ionic silver
- Keep request for information on the **uses** for each individual nanoform registered
- **Timing** will be split: 12 months if soil fate testing not needed and 30 months if soil fate testing needed.



3.1 Ag Project: Next steps Æ Substance evaluation (1)

Katrien Arijs

SEv testing:

- “ **Phys-chem**: Available phys-chem data for 2 registered nanoforms screened and compared to SEv requests; identifying CROs that can conduct testing still needed for smallest nanoform; awaiting final decision to initiate testing
- “ **Ecotoxicity** testing:
 - “ Pilot testing done at Fraunhofer to assess the viability of the Daphnia media modifications suggested in the DD modified media has very little effect on test outcome
 - “ Awaiting final decision to start further ecotox testing
- “ **Soil fate** testing: on hold



3.1 Ag Project: Next steps Ë Substance evaluation (2)

Marie Gorkem

DD request on **uses**:

- “ *It is requested to **provide information on the uses of each individual form of (nano)silver**. Based on the provided information, a selection of relevant exposure scenarios and relevant (surface modified) nanosilver forms can be made. To ensure safe use of nanosilver, it may be necessary to provide **exposure estimations** in a follow up of the present decision.+*
- “ **12 months** to generate information from the date of adoption of the final decision.
- “ Final decision likely to be adopted mid June so deadline is **mid June 2017**



3.1 Ag Project: Next steps Ë Substance evaluation (3)

Marie Gorkem

Uses currently in Ag dossier:

- “ Manufacture, refining and recycling of Ag metal
- “ Re-melting and alloying
- “ Production of batteries
- “ Electronics, contact materials and electroplating
- “ Production, preparation and use of chemicals, preparations or catalysts
- “ Welding in industrial settings
- “ Welding in professional settings
- “ Professional uses of Ag containing preparations (excluding alloys)
- “ Soldering and brazing in professional settings
- “ Service life for consumers of
 - Jewellery
 - Cutlery and Ag table ware
 - Installed dental appliances and fillings containing Ag
 - Massive objects containing Ag metal at ambient temperature
 - Articles containing Ag being encapsulated in the internal part of the product
 - Batteries

Uses in **yellow** were previously identified as relevant for both non-nano and nanoAg

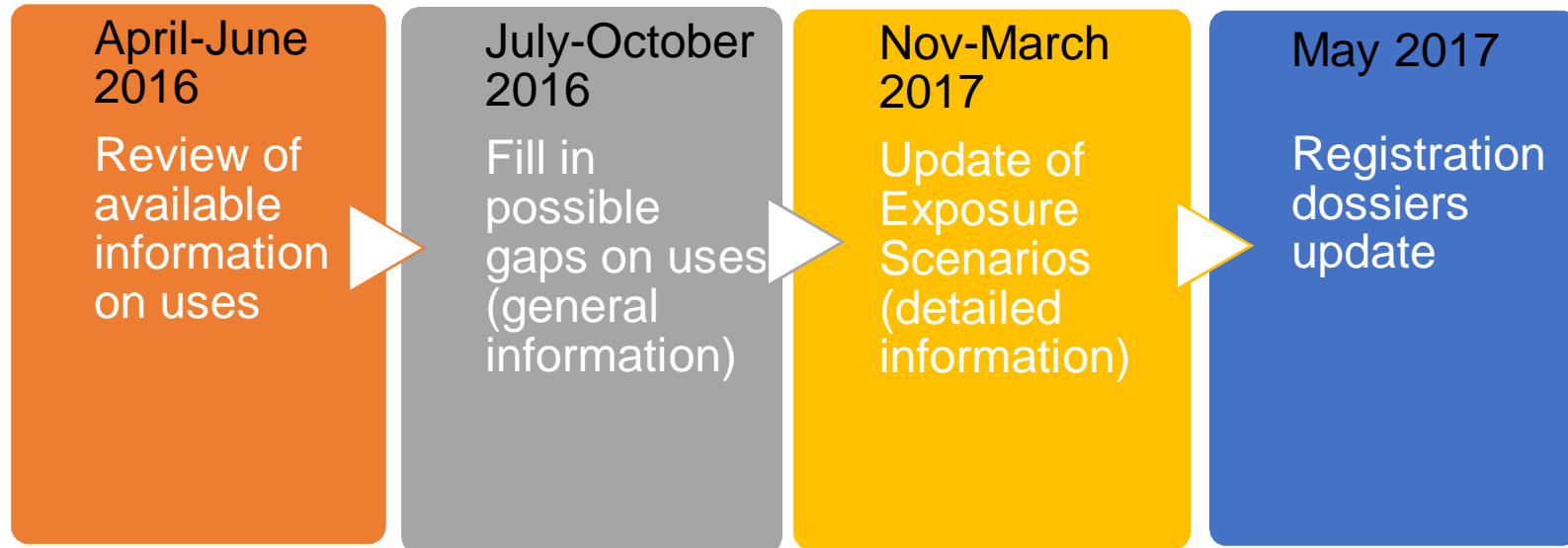
No consumer use reported by nanoAg registrants and/or (nano)Ag registrantsqDU



3.1 Ag Project: Next steps Ë Substance evaluation (4)

Marie Gorkem

- “ In addition to gathering information on uses of the two nanosilver forms, ongoing parallel review of uses of silver and silver compounds
- “ Timeline:



3.1 Ag Project: Status Æ CLH proposals SCAS* ((1)

Katrien Arijs

* Silver containing Active Substances

	Ag REACH	Ag BPR
Scope	PMC Ag project includes eight substances/Dossiers: 1. Silver 2. Disilver oxide 3. Silver nitrate 4. Disilver sulphate 5. Disilver carbonate 6. Silver chloride 7. Silver bromide 8. Silver iodide	ESTF single core active substance dossier supporting eight substances: 1. Silver 2. Silver (reaction mass with SiO ₂) 3. Silver chloride (reaction mass with TiO ₂) 4. Silver nitrate 5. Silver sodium hydrogen zirconium phosphate 6. Silver phosphate glass 7. Silver zinc zeolite 8. Silver copper zeolite
Under review by	RIVM, Dutch CA	KEMI, Swedish CA
CLH	Not a requirement (only as a possible conclusion from the SEv itself)	Requirement

+ nanosilver?

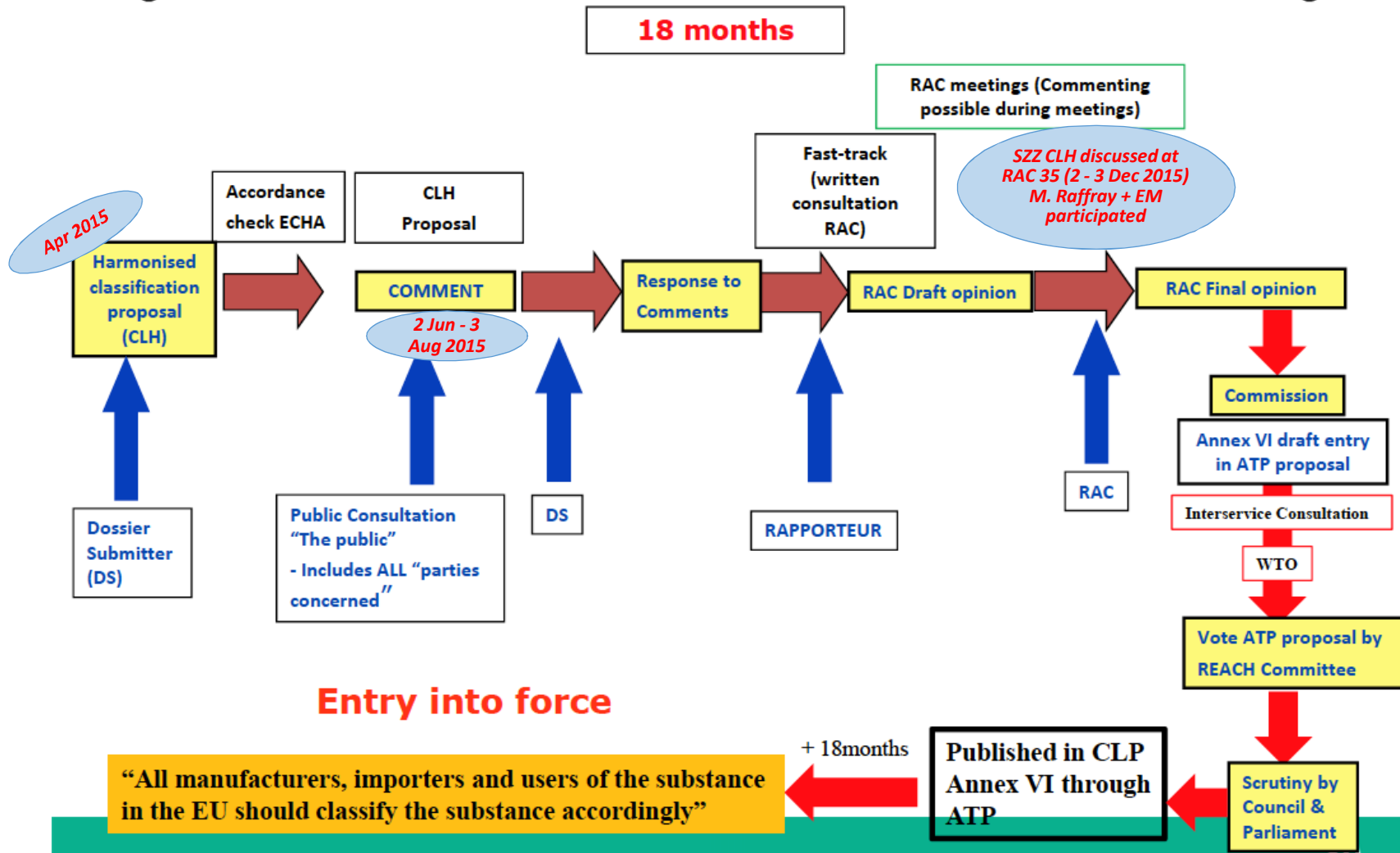
Proposed future entry in Annex VI of CLP Regulation

- Carc. 2, H351
- Repr. 1B, H360D
- Skin Irrit. 2, H315
- Eye Dam. 1, H318
- STOT RE 2, H373
- Aquatic Acute 1, H400
- Aquatic Acute 1. M-factor=100
- Aquatic Chronic 1, H410
- Aquatic Chronic 1. M-factor=100

Effects attributed to Ag ion . > need to avoid domino effect on REACH Ag dossiers!



3.1 Ag Project: Status Æ CLH proposals SCAS (2)



3.1 Ag Project: Key milestones & CLH proposals SCAS (1)

Katrien Arijs

SZZ classification

“ **Carc. Cat.2**

- ✓ Classification based on leukemia occurrence in F 344 rat study; relevance disputed + no supporting evidence
- ✓ RAC: short and straightforward discussion leading to **no classification**

“ **Repr. Cat.1B**

- ✓ Classification mainly based on observed pup effects in 2-gen SZZ rat study; can arguably be explained as secondary effects - not discrete developmental effects
- ✓ RAC: very lengthy discussion BUT grounds for classification not strong **Cat.2** classification
- ✓ Reprotox data gap for Ag PMC submitted EOGRTS TP

“ **STOT RE Cat.2**

- ✓ Classification mainly based on tissue pigmentation (**argyria**); not clearly associated with pathological damage
- ✓ RAC: concluded that evidence was not sufficient for classification **no classification**

“ **Remaining HH endpoints:** no changes to proposed classification



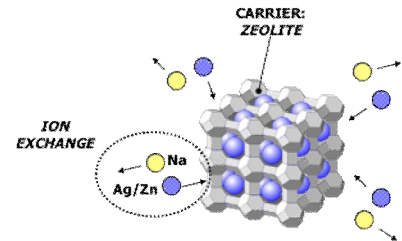
3.1 Ag Project: Key milestones & CLH proposals SCAS (2)

Katrien Arijs

SZZ classification

Environment Acute 1 / Chronic 1 & M-factor 100

- ✓ Eurométaux raised a number of principle issues related to the interpretation of the **metals classification guidance**
 - Full dataset for Ag and Zn not taken into account (Ag more ecotoxic than Zn but dissolution kinetics different)
 - Incorrect application of metals classification scheme:
 - Metal speciation unclear but RAC and rapporteur assumed metal compound
 - Lack of T/D data Chronic Cat.4 classification
 - PMC recommended ESTF to generate T/D data for SZZ + other SCAS (+ suggested data-sharing for T/D data available).
 - Lack of data regarding rapid removal of Ag from the water column
 - Soluble Ag ions bind to CRS in water, forming Ag₂S
 - Needs to be demonstrated in waters at EU wide level
- ✓ No changes to proposed classification but classification could be changed if new information becomes available (e.g. T/D data; data regarding removal from the water column)

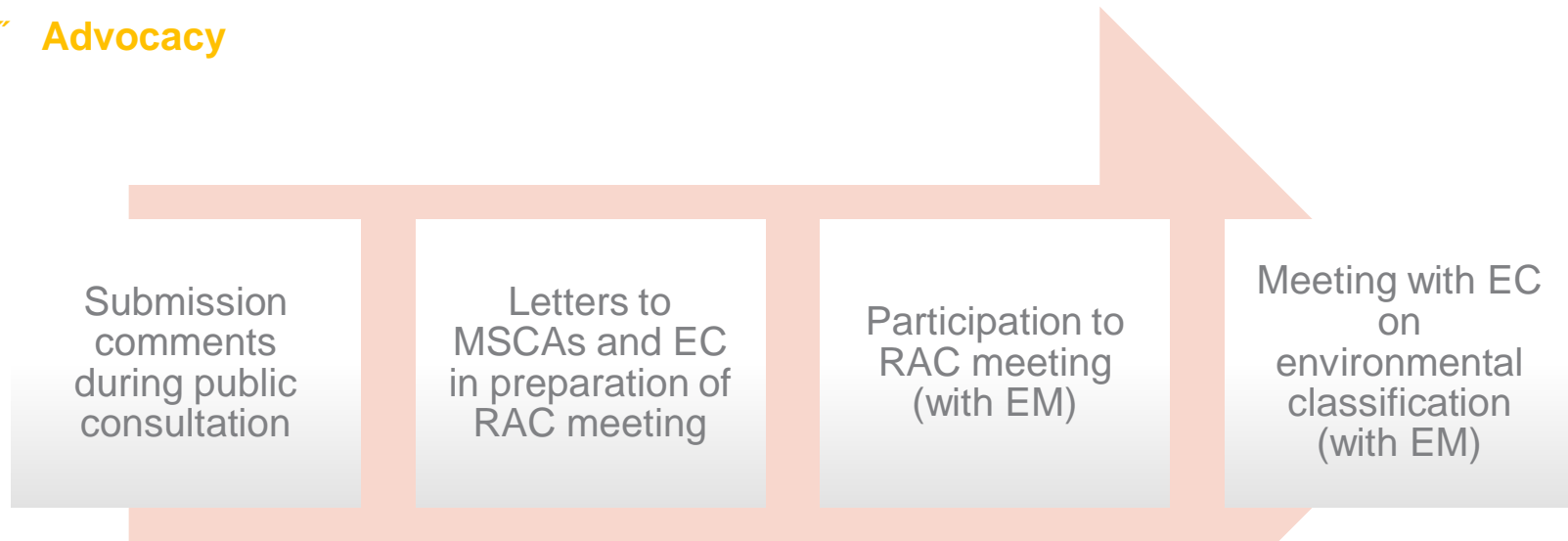


3.1 Ag Project: Key milestones – CLH proposals SCAS (3)

Katrien Arijs

SZZ classification

“ Advocacy



+ EM asked ECHA for update / better dissemination of the guidance on metals RA, for better expertise at RAC level on environment and more consistency between REACH and BPR (in data and methods used)



3.1 Ag Project: Next steps & CLH proposals SCAS

Katrien Arijs

- “ PMC to conduct further work regarding rapid removal of Ag from the water column
- “ Next SCAS: timing unsure

Substance (SCAS)	Product types supported	Possible draft CAR timing (assuming SE includes all PTs in a single CAR)
Silver zinc zeolite	2,4,7,9	draft CAR available
Silver zeolite	2,4,7,9	31/12/2016 earliest date for PT4
Silver copper zeolite	2,4,7,9	31/12/2016 earliest date for PT4
Silver sodium hydrogen zirconium phosphate	1,2,4,7,9	31/12/2016 earliest date is for PT4
Silver (metallic)	2,4,5,11	31/12/2016 earliest date is for PT4
Silver nitrate	1 (2,3,4,5,7,9,11,12)	31/12/2018 Also expected 31/12/2016 date for PT1 as the only review programme active/PT combination, others are new active/PT combinations
Silver phosphate glass	2,7,9	31/12/2018 earliest date is for PT2
Silver chloride/titanium dioxide composite	1,2,6,7,9,10,11	31/12/2018 earliest date is for PT1 and PT2
Silver/silicon dioxide composite	9	31/12/2020 may be earlier depending on progress and opinions for the other SCAS



3.2 Refinables Project: Status

Katrien Arijs

- “ Refinables dossiers originally submitted in 2010 as SCC intermediates, most upgraded to full registration dossiers in 2014, further dossier maintenance prepared in 2015
- “ **Substance identification (SID):**
 - “ SID review: SID decision tree and PM refining process definitions document developed, further refinement SID ongoing
 - “ UVCB SID discussions Eurométaux / ECHA ongoing
- “ **Exposure and risk assessment:**
 - “ Update of environmental exposure assessment based on additional driving constituents / additional emission data
 - “ Combined toxicity approach discussed at Eurométaux level



3.2 Refinables Project: Key milestones (1)

Katrien Arijs

“ Substance identification (SID):

- “ UVCB SID discussions Eurométaux / ECHA: ECHA showed openness to listen to inorganic UVCB difficulties and to cooperate with NFM sector to develop common approach but still concerns about possible over-grouping
- “ Refined SID sheets according to Eurométaux template drafted for all Refinables: clear overview of sameness criteria for those substance parameters with least variation

Substance identity parameters	Sameness criteria (try to be as specific, measurable, reproducible and accurate as possible)	Indication of variability: describe if FIXED or with very low variation
Process		
Sources (input materials)		
Elemental composition		
Speciation/mineralogical information/composition		
Physical characteristics (e.g. physical state and form, particle size distribution,...)		



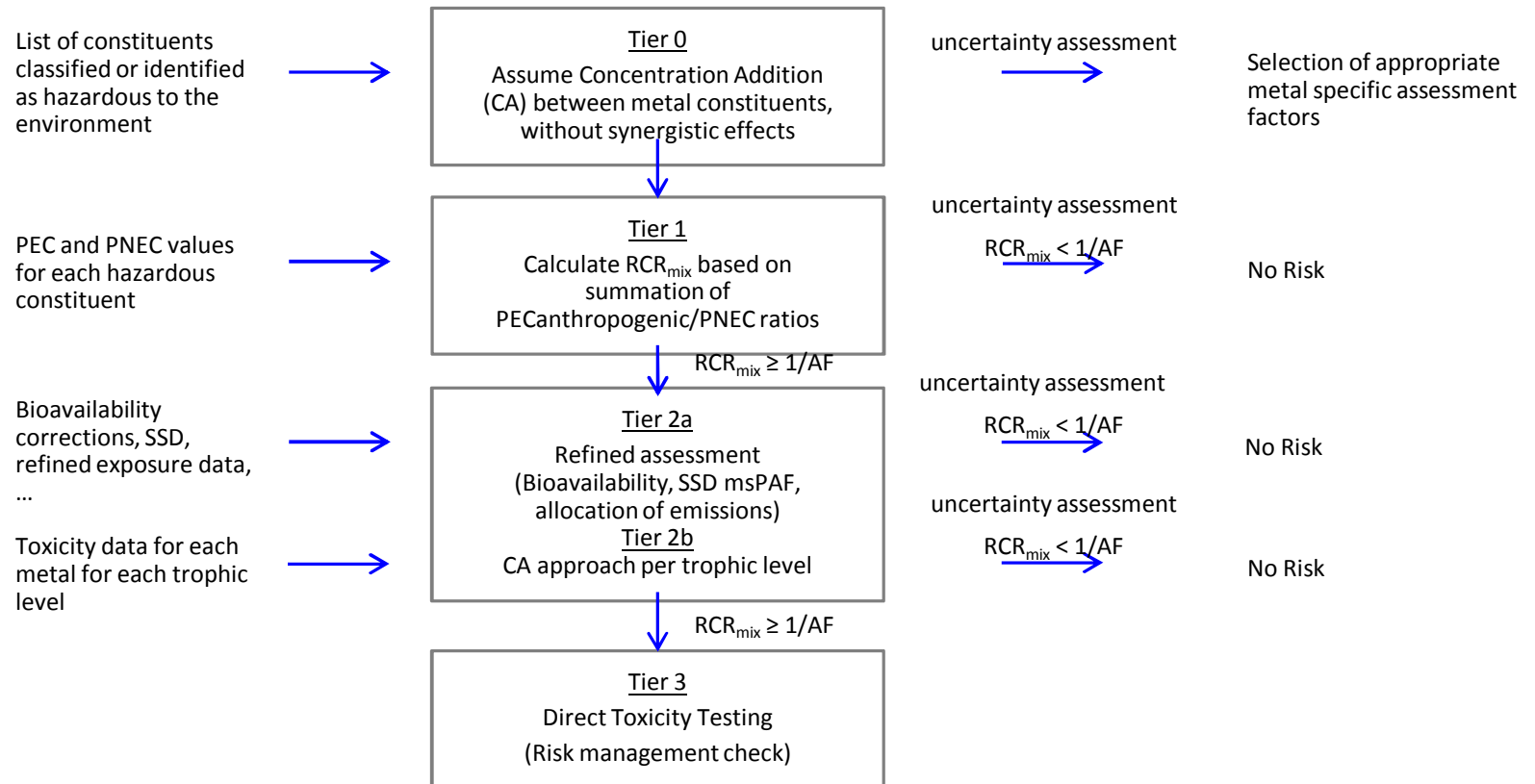
3.2 Refinables Project: Key milestones (2)

Katrien Arijs

“ Exposure and risk assessment:

“ Combined toxicity tiered approach developed at Eurométaux level

“ Testing of approach ongoing



3.2 Refinables Project: Next steps

Katrien Arijs

Dossier maintenance

- “ **Substance identification (SID):**
 - “ Finalisation SID review
 - “ Input to discussions Eurométaux / ECHA
 - “ Speciation testing **if needed**

- “ **Effects assessment and classification:**
 - “ Classification review following SID review
 - “ T/D testing & phys-chem testing for splitted dossiers
 - “ Validation testing **if needed**

- “ **Exposure and risk assessment:** MvE assessment, combined toxicity, update exposure & risk assessment

- “ **Compilation of IUCLID 6 file & Registration Dossiers:** dossier updates not before 2017



3.3 Au Project: Status

Vincent Dunon

PHASE III: Testing program

“ **Tetrachloroauric acid:**

“ **Physchem testing:**

- “ Water Solubility - Ongoing
- “ Particle Size Distribution - Ongoing

“ **Fate:**

- “ Adsorption/Desorption testing: finalized

“ **Mammalian Toxicity:**

- “ Combined repeated dose toxicity (OECD 422) - Retest
- “ In vivo micronucleus assay (OECD 474) - Submission testing proposal

“ **Gold:**

“ **Fate:**

- “ Adsorption/Desorption testing - Read-across from TCA



3.3 Au Project: Status

Vincent Dunon

PHASE IV: Exposure Scenario Data Collection

“ Tetrachloroauric acid:

- “ Waste assessment - Completed
- “ Environmental Exposure Scenarios - Ongoing
- “ Occupational Exposure Scenarios - Delayed



3.3 Au Project: Status

Vincent Dunon

- “ **TCA Toxicity testing Covance**
- “ Reimbursement requested:
 - “ Maximum Tolerated Dose (MTD) followed by a 7 Day Fixed Dose Oral (Gavage) Administration Toxicity Study in the Rat
 - “ Oral (Gavage) Combined Repeated Dose Toxicity Study with the Reproduction/Developmental Toxicity Screening Test in the Rat (OECD 422)
 - “ Rat Bone Marrow Micronucleus Assay (OECD 474)
 - “ Validation of Assay Method for the Determination of Gold in Tetrachloroauric acid (TCA) Formulations and the Determination of the Stability and Homogeneity of TCA Formulations
- “ Deadline for Covance to respond, 31th May 2016



3.3 Au Project: Key milestones

Vinecnt Dunon

PHASE V: Dossier finalisation

- “ **Gold:** Registered
- “ **Balsams:** Registered
- “ **Aurio:** In process of registration by LR



3.3 Au Project: Next steps

Vincent Dunon

“ Tetrachloroauric acid:

- “ Initiate new combined repeated dose toxicity study (OECD 422)
- “ Update the substance ID card



3.4 PM CN- Project: Status

Vincent Dunon

PHASE III: Testing program

“ **AgCN:**

All tests finalised

“ **KAu(CN)₂:**

All tests finalised

“ **KAg(CN)₂:**

“ **Mammalian Toxicity:**

“ Genotox testing . Ongoing, OECD 490 initiated

“ Repeated exposure . Ongoing



3.4 PM CN- Project: Key milestones

Vincent Dunon

PHASE IV: Exposure Scenario Data Collection

- “ **AgCN & KAu(CN)₂:**
 - “ Waste assessment - Completed
 - “ Environmental Exposure Scenarios - Completed
 - “ Occupational Exposure Scenarios - Completed
- “ **KAg(CN)₂:**
 - “ Waste assessment - Completed
 - “ Environmental Exposure Scenarios - Completed



3.4 PM CN- Project: Next steps

Vincent Dunon

PHASE IV: Exposure Scenario Data Collection

- “ **KAg(CN)₂**:
 - “ Generation of DNELs
 - “ Drafting of Occupational ES

PHASE V: Dossier finalisation

- “ **AgCN & KAg(CN)₂**: Start review process of IUCLID dossier, registration summer 2016



3.5 Ir Project: Status

Jelle Mertens

- “ Ir metal and ammonium hexachloroiridate (1-10 tpa, Annex III exempted):
 - “ REACH dossiers: approved and finalized **(22 April 2016)**

- “ Hexachloroiridic acid (1-10 tpa, Annex III exempted):
 - “ REACH dossier: approved and finalized **(10 May 2016)**



3.5 Ir Project: Key milestones

Jelle Mertens

- “ Ir metal and ammonium hexachloroiridate:
 - “ Dossier registered by LR (under invoicing process)
 - “ Registration by co-registrants: dossiers and guidance will be sent to relevant registrants as soon as LR registration finalisation

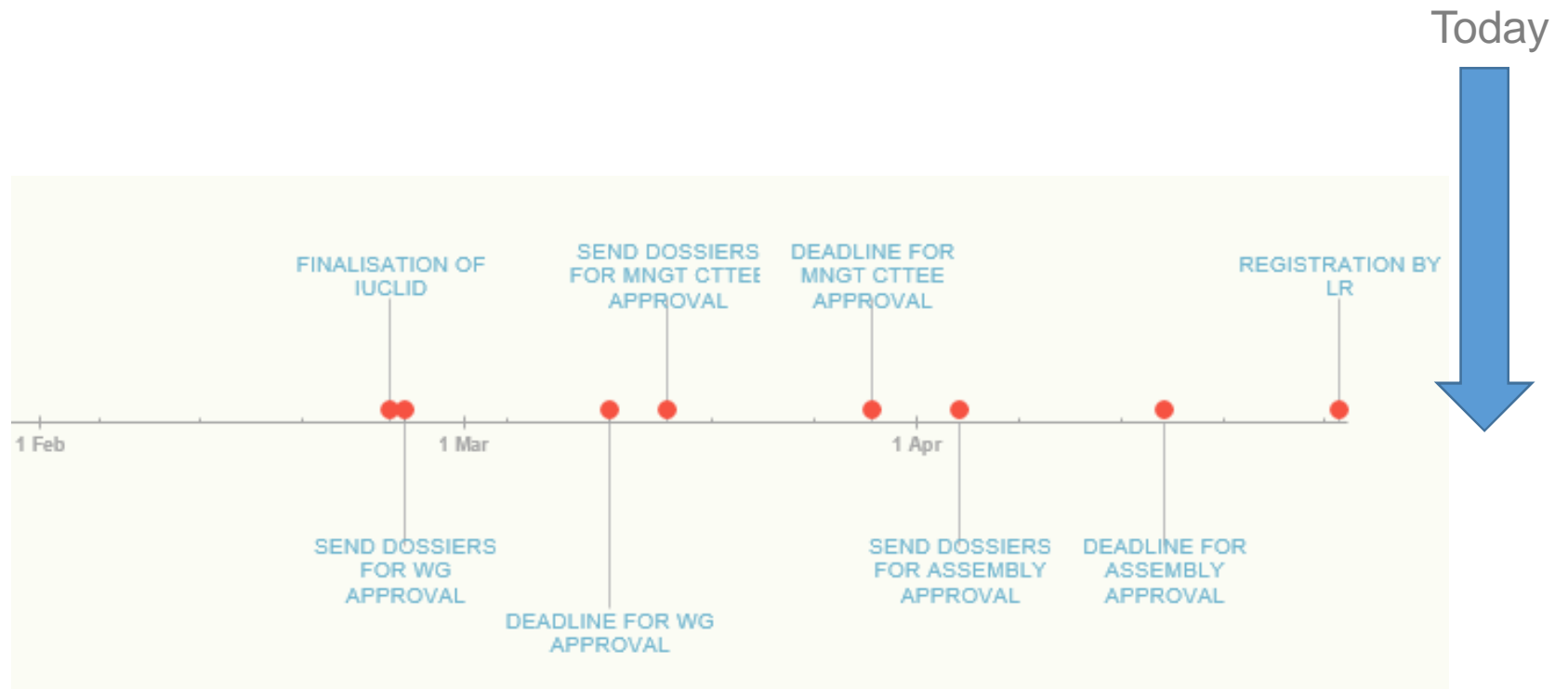
- “ Hexachloroiridic acid:
 - “ Approval via ~~fast-track~~ procedure+:
 - “ LR only registrant
 - “ Formal approval required within 2 weeks from
 - “ WG and Sub-Assembly: mainly the registrant representative
 - “ Management Committee: mandatory in the overall process (cf. consortium agreement)
 - “ Ready for submission by Lead-Registrant

- “ Next step after registration = MAINTENANCE



3.5 Ir Project: Timeline

Jelle Mertens



3.6 Pd Project: Status

Maxime Eliat

- “ **Dossiers are reaching their final status:**
 - “ Occupational and environmental exposure scenarios approved
 - “ DNEL reports revised and updated
 - “ IUCLID input updated where needed (e.g. genotox section for tetraammine Pd)
 - “ Finalisation SID cards
 - “ Gathering missing info from LR

- “ New human health classifications (Acute tox 4 (oral), Eye Dam. 1, Skin Sens. 1.) for Pd(OH)₂ so ES are being drafted

- “ **Phys chem testing** still ongoing for the **solid** form of:
 - “ Palladium dinitrate
 - “ Tetramminepalladium(2+) diacetate
 - “ Palladium sulphate



3.6 Pd Project: Status

Maxime Eliat

“ PROCs missing for some manufacturing and formulation scenarios:

- “ Only for the substances not requiring ES
- “ Because all registrants claimed it as confidential

“ How to resolve?

- “ Remove the formulation scenarios without PROCs
- “ Include a set of generic PROCs for the manufacture
 - “ PROCs: 1, 3, 4, 8a, 8b, 9, 15, 26 (only for solid).



3.6 Pd Project: Key milestones

Maxime Eliat

- “ Annex III exempted substances will be registered earlier via fast-track procedure (<21 June 2016) by lead registrant and co-registrants

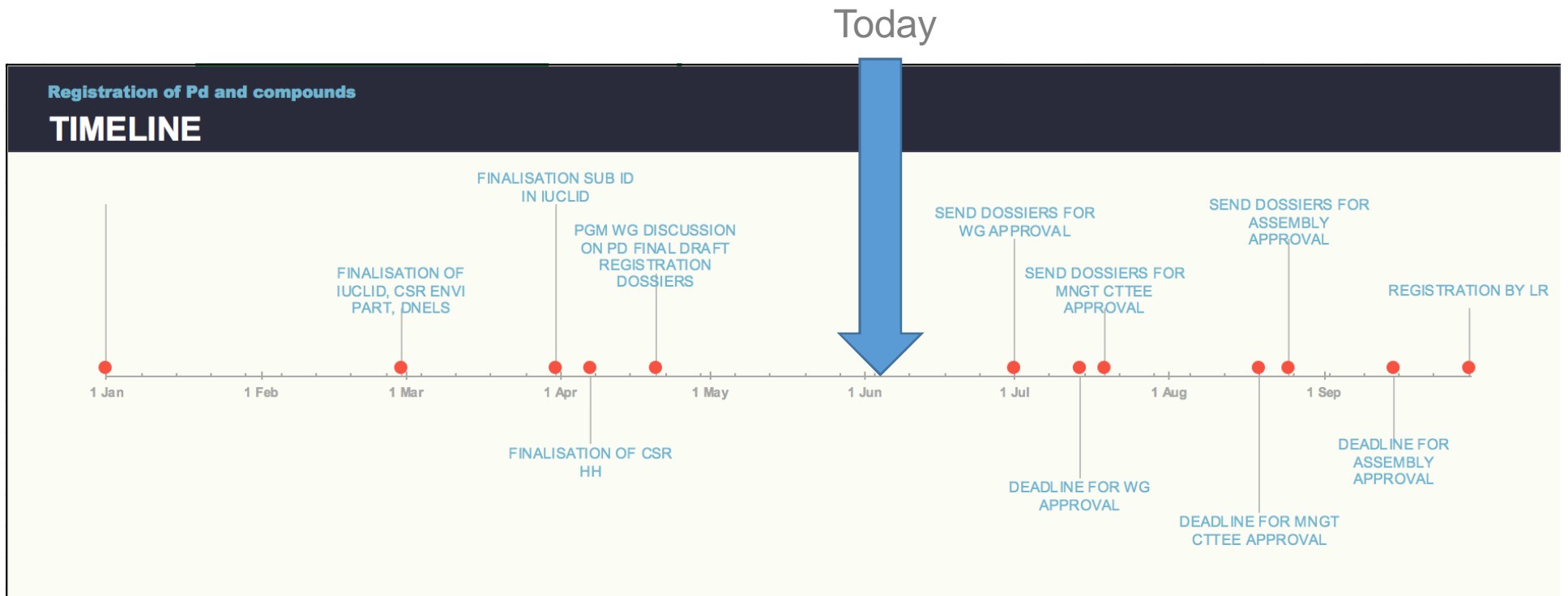
Substance	CAS
Dichlorobis(triphenylphosphine)palladium	13965-03-2
Palladium(II) acetate	3375-31-3
Tetraamminepalladium (II) nitrate	13601-08-6
Tetraamminepalladium(2+) dihydroxide	68413-68-3
Tetrakis(triphenylphosphine)palladium	14221-01-3
Palladium sulphate	13566-03-5

- “ Include the results from the last batch of phys-chem testing
- “ Merge all the documents together into a REACH dossier **by 30 June 2016**
- “ **Final review by the WG, Mgmt Cmt and the Sub Assembly in Q3**
- “ Have the lead registrant submit the REACH dossier **by 30 September 2016**
- “ Have the co-registrants submit the REACH dossier afterwards
- “ **Submit the chloropalladate dossiers in Q4 2017**



3.6 Pd Project: Timeline

Maxime Eliat



3.7 Pt Project: Status

Maxime Eliat

- “ **Phys chem testing** still ongoing for the solid form of:
 - “ Platinum dinitrate

- “ **Ecotox testing** ongoing for HHPA-2AE and Karstedt Concentrate

- “ No further hydrolysis test for Karstedt after preliminary testing (include waiving statement in dossier)

- “ **Mammalian tox testing** ongoing for Karstedt Concentrate and HHPA-2AE
 - “ Key OECD 422 study expected to start in July 2016

- “ **Pt genotox:**
 - “ External expert will be contracted to review database
 - “ Aim: help us develop intelligent in vivo testing strategy (to be included as testing proposals in REACH dossiers)



3.7 Pt Project: Status

Maxime Eliat

“ **Platinum PNECs**

- “ Will be derived following completion of ecotox testing with HHPA-2AE (expected end of June)
- “ Revision might be needed after finalisation ecotox testing Karstedt concentrate

“ **Platinum DNELs**

- “ CIPts: DNELs qualitative based on resp. sens.
- “ Non-CIPts:
 - “ Systemic DNELs inhalation: 2 µg/m³ (ACGIH OEL)
 - “ Systemic DNELs dermal: under revision

- “ Interviews for the Occupational health ES by EBRC (WebEx format)



3.7 Pt Project: Status

Maxime Eliat

“ Platinum PNECs

- “ Will be derived following completion of ecotox testing with HHPA-2AE (expected end of June)
- “ Revision might be needed after finalisation ecotox testing Karstedt concentrate

“ Platinum DNELs

- “ CIPts: DNELs qualitative based on resp. sens.
- “ Non-CIPts:
 - “ Systemic DNELs inhalation: $2 \mu\text{g}/\text{m}^3$ (ACGIH OEL)
 - “ Systemic DNELs dermal: under revision

- “ Interviews for the Occupational health ES by EBRC (WebEx format)



3.7 Pt Project: Status

Maxime Eliat

“ Occupational exposure chloro platinates

- “ Meeting on the 25th of May
- “ Qualitative assessment
- “ EXPOSURE DATA LINKED TO OPERATIONAL CONDITIONS IS KEY!
- “ Questionnaire will be sent by EBRC on 1 June
- “ Data to be provided by companies (15 June)
- “ Data to be included in ES by EBRC (21 June)
- “ Risk characterisation based on ALARA (as low as reasonably achievable) principle and BV (benchmark value)
- “ Next meeting to follow up on the 7th of July



3.7 Pt Project: Key milestones

Maxime Eliat

- “ Annex III exempted substances will be registered earlier via fast-track procedure (<21 June 2016) by lead registrant and co-registrants

Substance	CAS
Diammineplatinum (II) nitrite	14286-02-3
Tetraammineplatinum dichloride	13933-32-9
Platinum dioxide	1314-15-4

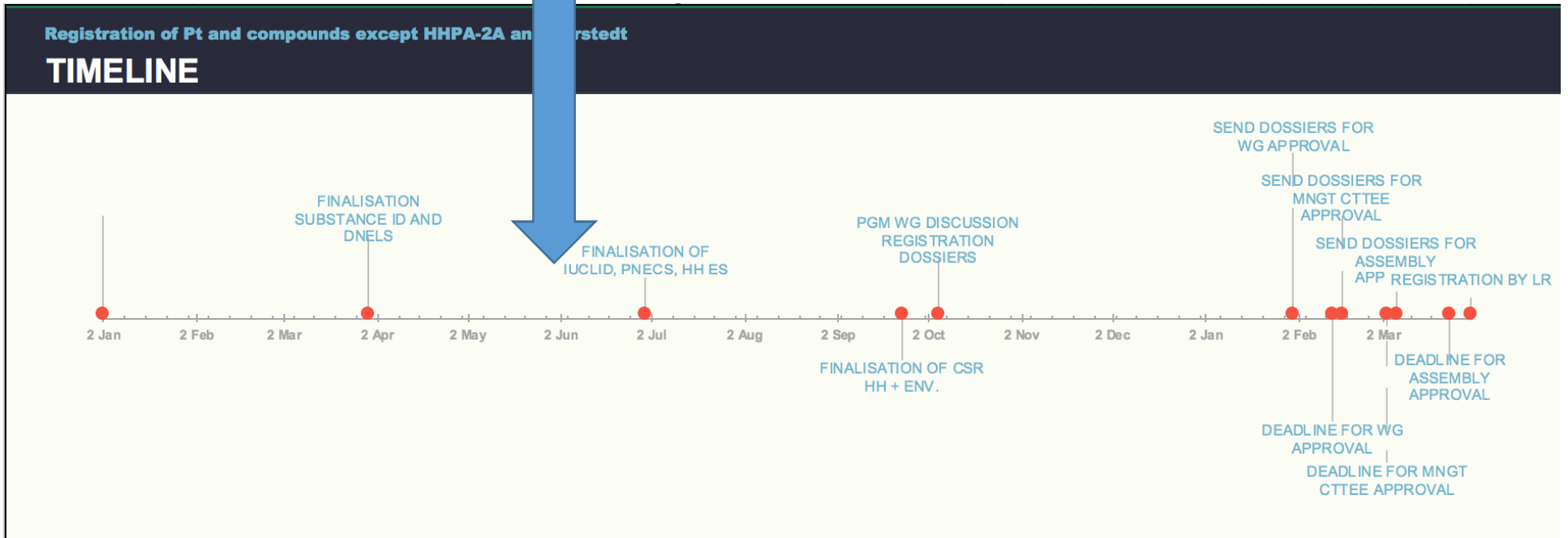
- “ Finalise the phys-chem (TBD), ecotox (TBD) and tox testing phase (**Karstedt <end Nov 2016, HHPA-2AE <end 2016**)
- “ Derive final PNECs (not including Karstedt testing) and DNELs (not including Karstedt and HHPA-2AE testing) **<30 June 2016**
- “ Prepare environmental and occupational exposure scenarios (**<30 June 2016**)
- “ Generate CSRs (**<23 Sept 2016**)
- “ Compile everything together and generate REACH Dossiers (including Karstedt) (**<31 Jan 2017**)
- “ **Finalisation HHPA-2AE dossier foreseen mid Oct 2017**
- “ **Submit the chloroplatinates dossiers in Q4 2017**



3.7 Pt Project: Timelines

Maxime Eliat

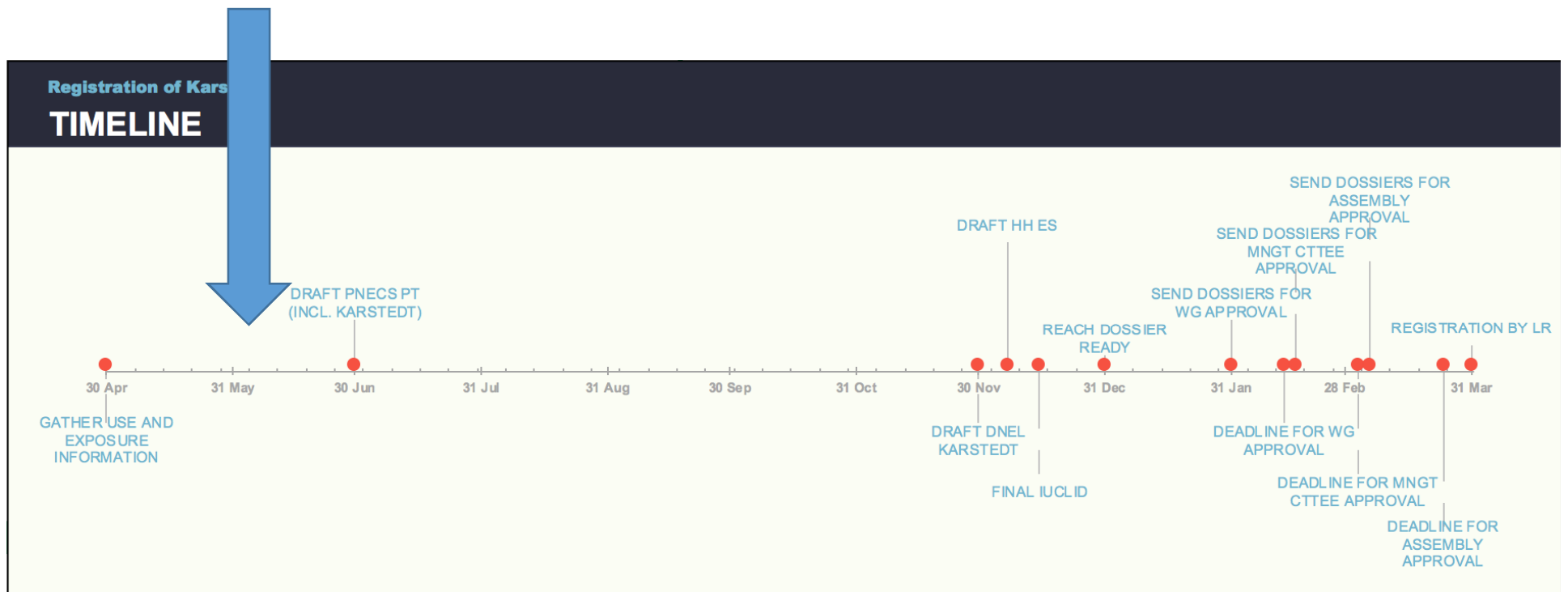
Today



3.7 Pt Project: Timelines

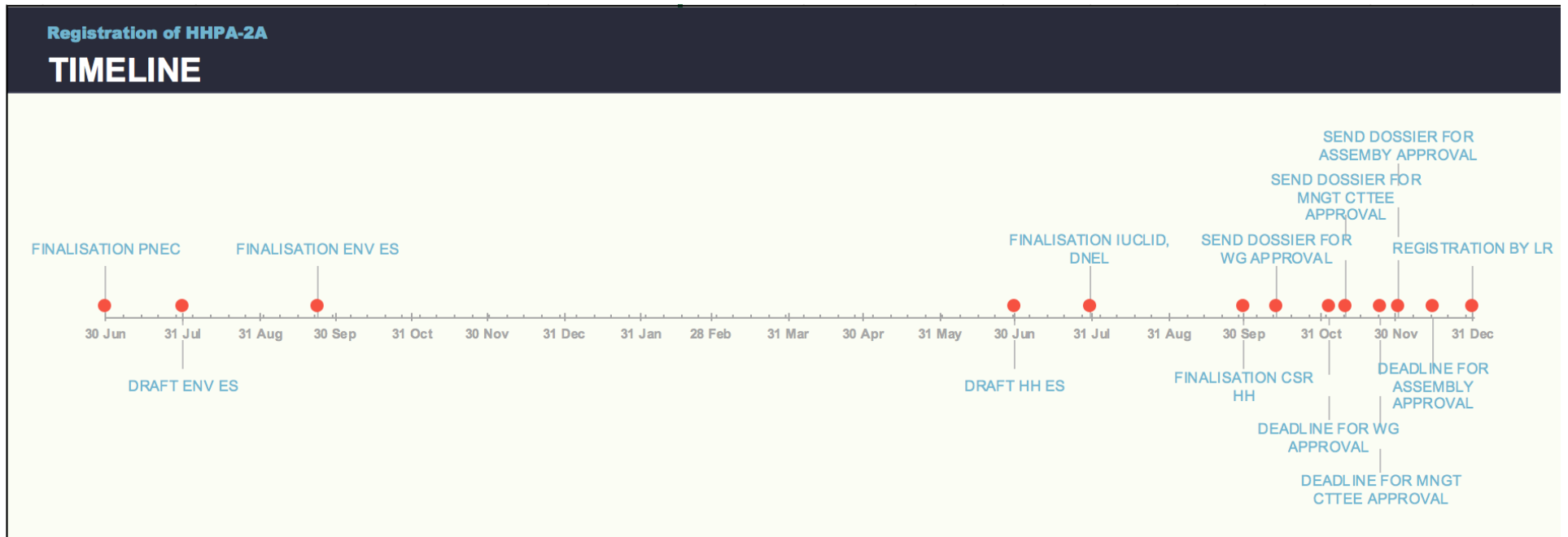
Maxime Eliat

Today



3.7 Pt Project: Timelines

Maxime Eliat



3.7 Pt Project: AoA Chloroplatinates (1)

Marie Gorkem

“ Chloroplatinates, as potential SVHC candidates, may be selected by ECHA / Member states for further regulatory action shortly after registration

N.B.: For such substances, anticipate on possible risk management measures is key!

“ Beyond hazard, prioritization criteria for further regulatory action include: exposure/uses, substitution potential, tonnage

“ Industry RMOAs, AoAs, when conducted proactively

“ can help Industry identify weaknesses and adopt strategy accordingly

“ serve as useful sources for Authorities and drive towards common approach towards risk management

“ Last year RMOA on chloroplatinates identified need to strengthen argument around absence of alternatives for identified uses, requiring further investigation

“ Dossier update needed?

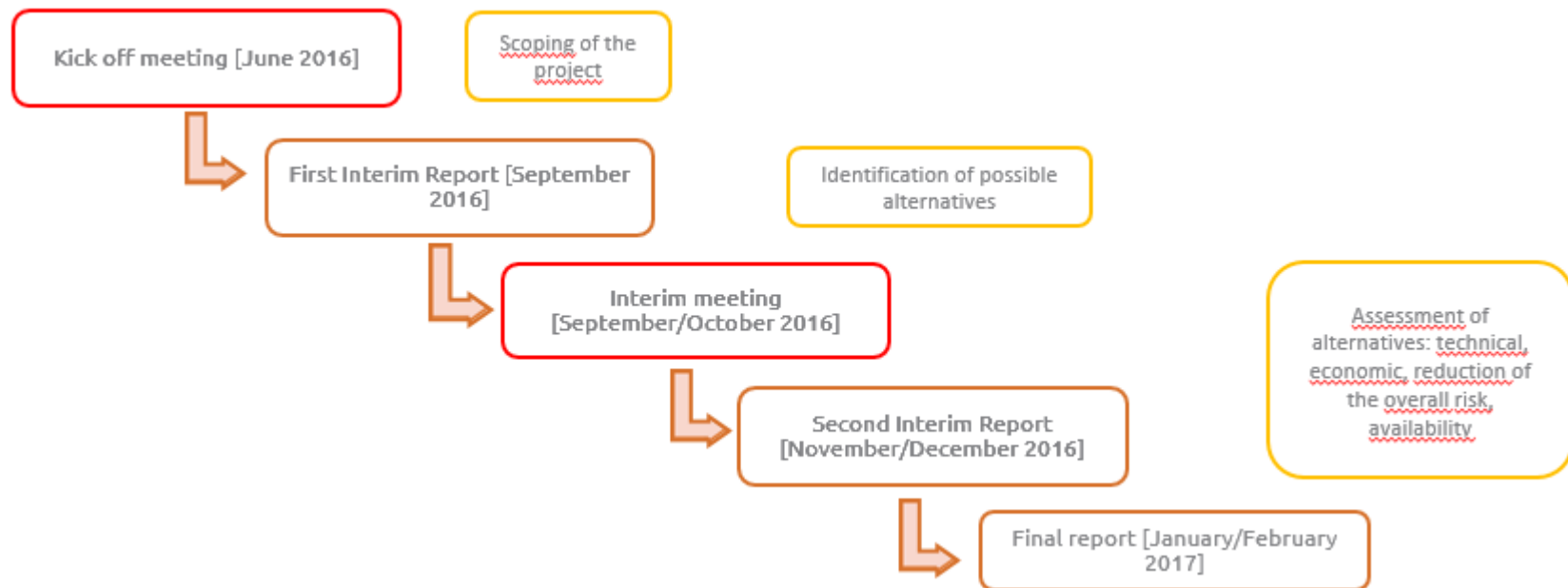
Uses already part of the registration dossiers	Uses not yet part of the registration dossiers
Refining of platinum	Plating
Catalysis	Photographic films, Ceramic colouring



3.7 Pt Project: AoA Chloroplatinates (2)

Marie Gorkem

- “ Kick off meeting on Wednesday 22 June
- “ DHI appointed as consultant
 - “ DHI Team leader: Jens Torslov
 - “ Experts: Dr Martin Lok (catalysts) and Dr Hubert Schmidbaur (refining, plating)
- “ Ambition to complement / challenge our internal knowledge with external experts views



3.8 Rh Project: Status

Jelle Mertens

- “ Rh(III) genotoxicity:
 - “ Rh nitrate: genotox testing (AMES) finalised . tested positive
 - “ Decision PGM WG:

Substance	Genotox classification	Basis
Rhodium sulphate, -trichloride, -nitrate, -acetate, triammonium hexachlororhodate	Muta 2	Positive testing
Diammonium sodium hexakis(nitrito-N)rhodate	Muta 2	Precautionary basis
Rhodium metal	Not classified	Inert metal
Rh tris(2-ethylhexanoate), Rh triiodide, -trioxide, -trihydroxide	?	*

for these substances:

- “ Perform AMES test
 - “ Review existing Rh(III) genotox dataset internally
 - “ Decide on intelligent in vivo testing program (to be included as testing proposals)
-
- “ Rhodium tris(2-ethylhexanoate): potential additional phys-chem tests if solid can be isolated



3.8 Rh Project: Status

Jelle Mertens

- “ Rh(I) compounds registered in 1-10 tpa band:
 - “ Annex III exempted dossiers (no Wide Dispersive Uses, not Carcinogenic/Mutagenic/Reprotox)
 - “ Early REACH registration (<21 June 2016)

Substance	CAS
Carbonyl(pentane-2,4-dionato-O,O')(triphenylphosphine)rhodium	25470-96-6
Carbonylhydrotris(triphenylphosphine)rhodium	17185-29-4
Dicarbonyl(pentane-2,4-dionato-O,O')rhodium	14874-82-9
Di- μ -chloro-bis(hapto-1,5-cyclooctadiene)dirhodium(I)	12092-47-6
Tris(triphenylphosphine) rhodium (I) chloride	14694-95-2

- “ Gathering required information with LR (manufacturing process, Guidance on Safe Use)
- “ Identified uses approved by members (25 May 2016)



3.8 Rh Project: Status

Jelle Mertens

- “ Exposure assessment: Identified uses merged & draft PNECs derived
- “ Project *%RGM Removal in Sewage Treatment Plants+-* finalised
 - “ Removal efficiency estimated
 - “ Data used in Environmental Risk Assessment

Metal	Pd	Pt	Rh	Ru
Removal Efficiency	79 %	57 %	48 %	46 %

- “ Project *%RGM Occupational Monitoring+-* running
 - “ Aim:
 - “ Collect occupational exposure data & populate database
 - “ Allow refined occupational exposure assessment
 - “ 6 participating companies
 - “ Kick-off meeting in Feb 2016
 - “ 4 site visits performed in April/May, reports being drafted



3.8 Rh Project: Key milestones

Jelle Mertens

- “ Rh(I) dossier submissions:
 - “ LR to provide missing information (<end May)
 - “ Finalise SID cards (<end May)
 - “ Finalise IUCLID files and Annex III justification reports (<end May)
 - “ **Fast-track approval process (1st 2 weeks June)**
 - “ **Registration by Lead-Registrants and co-registrants <21 June 2016**

- “ Rh(III) dossier:
 - “ Perform missing AMES tests, internal review genotox database and decide on intelligent in vivo testing strategy (**<31 Dec 2016**)
 - included in dossier as testing proposals

- “ Environmental assessment:
 - “ **Members to revise identified uses (<end June-tbc)**
 - “ Finalise PNEC and **approval by members (July-August 2016-tbc)**
 - “ Perform environmental risk assessment (< 30 Sept 2016):



3.8 Rh Project: Key milestones

Jelle Mertens

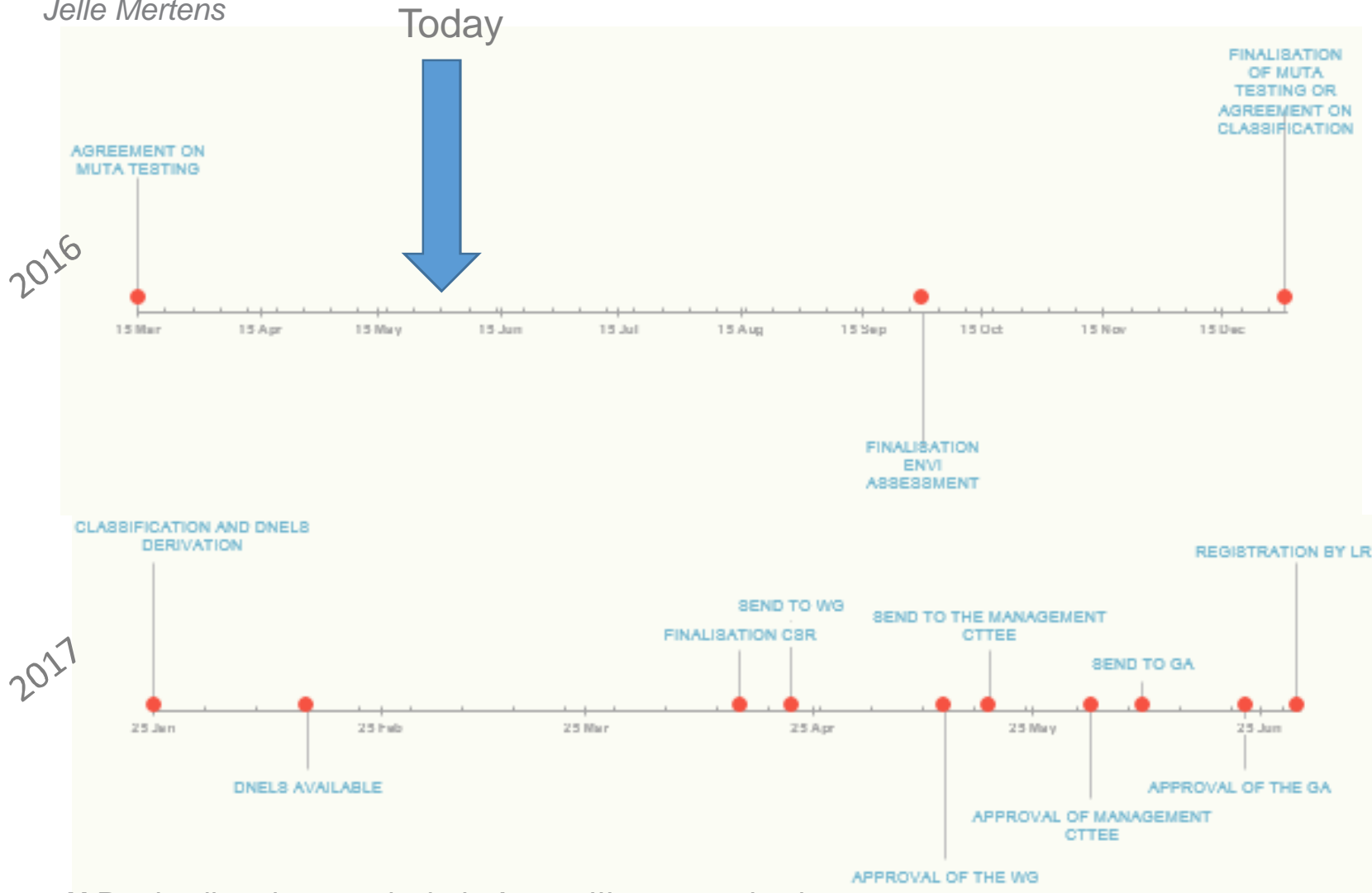
“ Occupational monitoring project:

Action	By whom	Duration	Time
Agree on date for site visit	Companies / EBRC	1 month	Mid March 2016
<i>Easter break</i>	<i>All</i>		<i>End March 2016</i>
Perform site visit	Companies / EBRC (/EPMF)	2 weeks	Mid April 2016
Draft site visit report	EBRC	2 weeks	End April 2016
Revise / approve site visit report	Companies	1 month	End May 2016
Develop data submission form	EBRC	1 month	End June 2016
<i>Summer break</i>	<i>All</i>		<i>End July 2016</i>
Submit monitoring data	Companies	1 month	Mid Aug 2016
Generate database	EBRC	2 weeks	End Aug 2016
Conduct sampling	Sampling institute / Companies	2 weeks	Mid Sep 2016
Sample analysis & drafting report	Sampling institute / EBRC	1.5 month	End Oct 2016
Finalisation of database	EBRC	2 weeks	Mid Nov 2016



3.8 Rh Project: timeline Rh(III)

Jelle Mertens



N.B.: timeline does not include Annex III exempted substances



3.9 Ru Project: Status

Jelle Mertens

- “ RuCl3 - Ecotox testing
 - “ Activated Sludge Respiration Inhibition Test - finalised
 - “ Acute Toxicity Test fish (OECD203) and algae (OECD201) - ongoing
 - “ Range finder test:
 - “ Issues with solubility and maintaining concentrations
 - “ No effects at any dose tested
 - “ PGM WG: decision to test 2 additional concentrations

- “ RuCl3 - Mammalian tox testing
 - “ Genotox testing program finalized . not genotoxic
 - “ Repeated dose toxicity (oral): Dose Range Finder test initiated 12 May, awaiting results



3.9 Ru Project: Status

Jelle Mertens

- “ TetradoRu - Mammalian tox testing
 - “ Genotox testing program finalized . not genotoxic
 - “ Acute toxicity (oral) finalized . not classified for acute tox
 - “ Repeated dose toxicity (oral)
 - “ Dose Range Finder finalised, no severe effects observed
 - “ PGM WG decision to do combined study (OECD422 - repeat dose oral toxicity with reproduction/developmental toxicity screening)

- “ Exposure assessment: Identified uses merged in overview document



3.9 Ru Project: Status

Jelle Mertens

- “ Ru compounds registered in 1-10 tpa band:
 - “ Annex III exempted dossiers (no Wide Dispersive Uses, not Carcinogenic/Mutagenic/Reprotox)
 - “ Early REACH registration (<21 June 2016)

Substance	CAS
Ruthenium (IV) oxide	12036-10-1
Tris(nitrato-O)nitrosylruthenium	34513-98-9
Hexakis[μ-(acetato-O:O')]- 3-oxo-triangulo-triruthenium acetate / Ruthenium acetate	55466-76-7
Ruthenium trihydroxide	12135-42-1

- “ Gathering required information with LR (manufacturing process, Guidance on Safe Use)
- “ Identified uses approved by members (25 May 2016)



3.9 Ru Project: Key milestones

Jelle Mertens

- “ RuCl₃ ecotox testing:
 - “ Test 2 additional doses for Dose Range Finder
 - “ Decide on doses for final testing + test (<30 Sept 2016)

- “ RuCl₃ mammalian tox testing:
 - “ Revise outcome Dose Range Finder
 - “ Confirm test type (OECD407+421), decide on test doses and test (<March 2017)

- “ TetradoRu mammalian tox testing (OECD422)
 - “ Decide on test doses + test (<March 2017)



3.9 Ru Project: Key milestones

Jelle Mertens

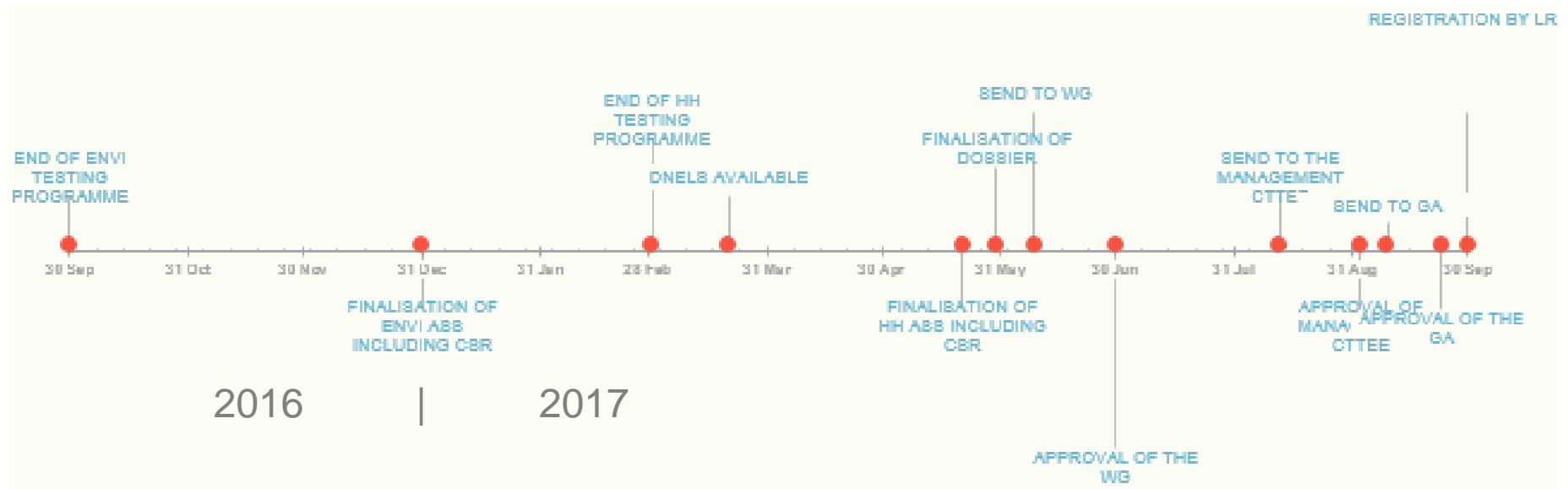
- “ Environmental assessment:
 - “ **Members to revise identified uses (<end June-tbc)**
 - “ Finalise PNEC and **approval by members (Oct-Nov 2016-tbc)**
 - “ Perform environmental risk assessment (< 31 Dec 2016):

- “ Ru Annex III exempted dossier submissions:
 - “ LR to provide missing information (<end May)
 - “ Finalise SID cards (<end May)
 - “ Finalise IUCLID files and Annex III justification reports (<end May)
 - “ **Fast-track approval process (1st 2 weeks June)**
 - “ **Registration by Lead-Registrants and co-registrants <21 June 2016**



3.9 Ru Project: Timeline

Jelle Mertens



N.B.: timeline does not include Annex III exempted substances



3.10 Re Project: Status & milestones

Katrien Arijs

- “ 5/6 dossiers (sodium rhenate, ammonium perrhenate, perrhenic acid, potassium perrhenate and rhenium) completed and submitted in 2013 and 2014
- “ 1 remaining dossier (dirhenium heptasulphide) not yet submitted



3.10 Re Project: Next steps

Katrien Arijs

- “ Dirhenium heptasulphide dossier to be submitted once necessary information from LR received
- “ Follow-up ECHA Annex III list to check presence of Re substances and check if dossier updates are needed
- “ Except for some light dossier maintenance work (literature review and subsequent update of dossiers), no further work anticipated



3.11 SVHC Roadmap Project: Activities 1st half 2016 (1)

Marie Gorkem

“ Working Group **Mandate** established:

“ Identify and monitor **substances and policy issues critical to PMC** under the EU SVHC Roadmap (except Precious Metals/Precious Metals Compounds)

- Processes monitored include: Authorisation, Restriction, SVHC, RMOA, CoRAP, HA (REACH); CLP

→ **Think as Downstream Users!**

“ Conduct **advocacy** in order to prevent or mitigate the potential impacts that the implementation of the Roadmap may have on the Precious Metals Industry

→ **Critical substance:** relevant for at least 3 members and for which substitution poses a significant technical and/or economic challenge



3.11 SVHC Roadmap Project: Activities 1st half 2016 (2)

Marie Gorkem

- “ **Stock-taking Survey** on ALL substances currently in the scope of the SVHC Roadmap (~1000 substances)
- “ Outcome: **~30 substances currently in the SVHC Roadmap** being relevant for at least 3 members

Process at stake	Substances (non exhaustive)	PM-related uses
Authorisation	Chromium trioxide	Refinables
	Diarsenic trioxide	Refinables
Recommended for Authorisation	Borates	Analytics, electroplating, soldering fluxes
	RCFs	Insulation, catalysts
	Lead dinitrate	Catalysts, gold cyanidation, electroplating
SVHC	Hydrazine	Reducing agent
	Lead monoxide, Lead oxide sulfate, Lead diacetate	Refining, frits production, analytics, catalysts, Electroplating
	Cadmium, Cadmium chloride, Cadmium oxide	Refinables, analytics
RMOA	Formaldehyde	Catalysts, refining
CoRAP	Carbon black, Cerium dioxide, Zinc oxide, Titanium dioxide, Silicon dioxide	Refining, refinables, catalysts, contact materials
CLH	Lead metal, nitric acid	Refining



3.11 SVHC Roadmap Project: Activities 1st half 2016 (3)

Marie Gorkem

- “ **No critical substance as part of the next update of the Authorisation list** (summer 2016) based on Substance survey

- “ **4 Pb compounds as part of ECHA's draft 7th list** (for inclusion in Authorisation list late 2016/early 2017):
 - “ Lead monoxide (PbO): several identified uses (PM refining, fire assaying, frits production)

- “ **PMC submitted input to the public consultation of the ECHA's draft 7th list**
 - “ REACH provides for an exemption possibility from Authorisation for uses for which the risks are already properly controlled through other specific EU legislation.
 - “ In line with ILA, PMC advocated for such exemption based on existing binding OEL for Pb and Pb compounds



3.11 SVHC Roadmap Project: Next steps (1)

Marie Gorkem

“ Meeting on Pb compounds/Pb in Precious Metals production (22 June)

- “ Map out all steps of Precious Metals production and identify steps which may be « authorisable »
- “ Assess exemption possibilities (58.2, intermediate uses) and agree on next steps

“ Keep close monitoring of other substances of concern

“ Borates

- “ Inclusion in Authorisation on hold but may be considered again in 2017
- “ PMC uses identified, further work (alternatives, socio-economic impacts) may be required if borates come back on the list
- “ PMC joined the DU platform of EBA (European Borates Association)

“ RCFs

- “ Very limited scope of « authorisable » uses
- “ Inclusion in Authorisation on hold, recent OEL proposal

“ Hydrazine

- “ Less likely to be included soon following information provided by industry showing limited exposure
- “ PMC already collected data on occupational exposure demonstrating compliance with most stringent OELs (DE), no further data gathering planned



3.11 SVHC Roadmap Project: Next steps (2)

Marie Gorkem

- “ **Development of supporting documents**
 - “ Check list+on actions to be taken by downstream users of a substance to be subject to Authorisation
 - “ Roles and frame of action for DUs under the different processes of the Roadmap
- “ **Ongoing dialogue with ECHA to prevent or mitigate Authorisation impact on recycling** (with Eurometaux)
 - “ Exemption possibility based on binding OEL, Intermediate status, Mixing
 - “ UVCBs (particularly relevant in the context of refinables)
- “ **Review of REACH and other chemical legislation** (with Eurometaux)
 - “ No revision of REACH text expected but work towards better implementation and coordination with other regulations
 - “ Systematic analysis of best Risk Management Options prior to regulatory action, and according to an harmonised methodology (Eurometaux issued guidance on RMOA earlier this year)
 - “ Better use of all the data generated under REACH by other chemical legislation (BPR, PPP) to avoid inconsistencies in assessment of same/similar substances
 - “ Further recognition and implementation of metal-specific methodologies across chemical legislation





Precious Metals
Consortium

4. Closing remarks

Guy Ethier, Umicore



Precious Metals
Consortium

1. Welcome and Introduction

Guy Ethier, Umicore

1.1 Confidentiality and Competition Law

DO	DON'T
<u>Application of competition law</u>	
Art. 101 and 102 TFEU may be applicable to the conclusion of any preliminary agreement and activities of any preliminary phase.	Don't assume that conflicts with competition law are excluded simply by the fact that the Agreement complies with the provisions of the REACH Regulation.
<u>Consultation in Matters of Competition Law</u>	
Consult an in-house legal expert or the compliance officer of your company or an external lawyer whenever there are uncertainties respecting compliance with competition law. Stop all meetings/discussions which are not in compliance with these Compliance Guidelines until a legal expert has been involved.	Don't assume that these Compliance Guidelines deal with all competition law issues exhaustively. Basically, compliance with Art. 101 and 102 TFEU can be determined only on the basis of market impact in each individual case. These Compliance Guidelines may therefore be regarded only as a means of providing general conduct recommendations.
<u>Activities in any preliminary phase and at any other stage of operation of the Consortium</u>	
Restrict cooperation within the scope of the preliminary phase to the initially defined goals and purposes of the cooperation.	Pursuant to Art. 101 and 102 TFEU, activities which have the object or the effect of preventing, restricting and/or distorting competition are prohibited within the scope of this Agreement, including: <ul style="list-style-type: none"> - Coming to agreement, including arrangements or collusions, about prices, markets and customers (see Art. 101 paragraph 1 a)-e) TFEU); - Joint boycotting of other companies; - The unjustified unequal treatment of trade partners; - The abusive exploitation of a dominating market position.
<u>Exchange of Confidential Information</u>	
Involve a Trustee for the exchange of Confidential Information.	The exchange of Information concerning market behaviour and having the object or the effect of preventing, restricting and/or distorting competition is inadmissible; in particular, this relates to : <ul style="list-style-type: none"> - Production capacities; - Productions or sales volumes; - Import volumes; - Market shares; - Price policy; - Distribution and marketing terms; - Marketing strategies; - Information regarding the relationship with suppliers.
<u>Documentation on Cooperation</u>	
Keep minutes of all meetings which detail the subject of the meeting. In case of uncertainty, have the contents of the minutes reviewed by an external legal expert prior to sending them to all parties of the Agreement. Stop all meetings which are not in compliance with these Guidelines until a legal expert has been involved.	



1.2 Tour de table, quorum and apologies

Cf. attendance list

Quorum is reached: 69 %



1.3 Approval of the agenda 02/06/2016

1. Welcome and Introduction

- 1.1. Confidentiality and Competition Law
- 1.2. Tour de table, quorum and apologies
- 1.3. Approval of the agenda

2. PMC Finances

- 2.1. 2015 accounts
- 2.2 2016 status

3. PMC Workplan 2016: timeline and registration status

4. PMC Workplan 2017-2019

5. Data sharing

- 5.1 Status
- 5.2 Data sharing Implementing act

6. Communication : new and updated tools

7. PMC after 2018

8. AOB, next meeting and closing remarks





Precious Metals
Consortium

2. PMC Finances

France Capon, EPMF

2.1 2015 accounts audited

	2015 Budget	2015 Expenses	%
Generic costs	" 789.928	" 800.410	101
Ag-specific costs	" 241.415	" 167.485	69
Au-specific costs	" 56.650	" 68.528	121
PM CN- -specific costs	" 193.900	" 213.883	110
PGM-specific costs	" 1.168.010	" 699.018	60
Re-specific costs	" 9.450	" 4.292	45
Refinables-specific costs	" 365.824	" 17.685	5
Hydrazine-specific costs	" 78.000	" 46.249	59
TOTAL	Ö2.903.177	Ö2.017.550	69

N.B.: significant amount of money was carried over to 2016 due to multi-annual projects



2.1 2015 accounts audited

For recommendation of the PMC Assembly to EPMF Assembly to approve the PMC 2015 audited accounts.



2.1 2015 accounts audited

PMC reserves after audit

	Available cash flow by 31/12/2015	Committed reserves by 31/12/2015	Carry over to 2016	Reserves
Generic costs	" 254.854	" 0	" 0	" 254.855
Ag-specific costs	" 338.521	" 0	" 0	" 338.521
Au-specific costs	" 68.385	" 13.000	" 30.150	" 25.235
PM CN- -specific costs	" 177.589	" 13.000	" 87.300	" 77.289
PGM-specific costs	" 2.056.963	" 1.181.610	" 706.400	" 168 953
Re-specific costs	" 189.468	" 0	" 0	" 189.468
Refinables-specific costs	" 641.403	" 169.000	" 326.000	" 146.403
SVHC Roadmap-specific costs	" 0	" 0	" 0	" 0
Hydrazine-specific costs	" 86.208	" 0	" 0	" 86.208
TOTAL	Ö3.813.392	Ö1.376.610	Ö1.149.850	Ö1.286.932



2.2 2016 status: Forecast

		2016 Budget to be spent	2016 Budget to be invoiced	2016 Forecast	Expenses by 30/04/2016	Committed	Remaining available budget (2016 budget- Expenses- Committed)
2.1	Administrative costs	Ö618.800	Ö618.800	Ö618.800	Ö152.540	Ö286.558	Ö179.702
2.2	Ag-specific costs	Ö681.250	Ö689.903	Ö681.250	Ö53.213	Ö146.407	Ö481.630
2.3	Au-specific costs	Ö122.700	Ö79.550	Ö307.450	Ö38.139	Ö68.565	Ö15.996
2.4	PM CN- -specific costs	Ö388.500	Ö288.200	Ö388.500	Ö53.421	Ö200.418	Ö134.661
2.5	PGM-specific costs	Ö2.478.250	Ö1.785.448	Ö2.479.608	Ö347.895	Ö1.651.745	Ö478.610
2.5	<i>PGM- horizontal costs</i>					" 486.902	" -486.902
2.5a	<i>Pt-specific costs</i>	" 1.183.955	" 645.102	" 1.183.955	" 97.252	" 582.656	" 504.047
2.5b	<i>Pd-specific costs</i>	" 572.405	" 622.173	" 572.405	" 166.083	" 11.714	" 394.608
2.5c	<i>Rh-specific costs</i>	" 162.470	" 171.217	" 162.470	" 23.935	" 73.011	" 65.524
2.5d	<i>Ru-specific costs</i>	" 558.420	" 345.956	" 558.420	" 50.933	" 496.104	" 11.383
2.5e	<i>Ir-specific costs</i>	" 1.000	" 1.000	" 2.358	" 9.692	" 1.358	" -10.050
2.6	Re-specific costs	Ö11.400	Ö11.400	Ö11.400	Ö936	Ö5.000	Ö5.464
2.7	Refinables-specific costs	Ö772.550	Ö277.550	Ö772.550	Ö3.986	Ö246.065	Ö522.499
2.8	SVHC Roadmap-specific costs	Ö20.000	Ö20.000	Ö0	Ö0	Ö0	Ö20.000
	TOTAL	Ö5.093.450	Ö3.770.851	Ö5.259.558	Ö650.130	Ö2.604.758	Ö1.838.562





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3. PMC Workplan 2016: timeline and registration status

France Capon, EPMF

Overall status of PMC Registrations

In GREEN = registered!

Name of the substance	Identification numbers		LR	JSO created	Registered by LR
	CAS	EC			
Silver	7440-22-4	231-131-3	Aurubis		Nov 2010
Silver nitrate	7761-88-8	231-853-9	Ames		Nov 2010
Disilver oxide	20667-12-3	243-957-1	Ames		Oct 2010
Silver carbonate	534-16-7	208-590-3	Johnson Matthey		Mar 2012
Disilver(1+) sulphate	10294-26-5	233-653-7	Johnson Matthey		Mar 2012
Silver chloride	7783-90-6	232-033-3	Agfa Gevaert		Mar 2013
Silver bromide	7785-23-1	232-076-8	Agfa Gevaert		Mar 2013
Silver iodide	7783-96-2	232-038-0	Agfa Gevaert		Mar 2013
Gold	7440-57-5	231-165-9	C. Hafner	Done	Apr 2016
Tetrachloroauric acid	16903-35-8	240-948-4	Johnson Matthey		
Aurio(1+) 2,6,6-trimethylbicyclo[3.1.1]heptanethiolate	68365-87-7	269-858-3	Johnson Matthey	Ongoing	Ongoing
Balsams, copaiba, sulfurized, mixed with turpentine, gold salts	68990-27-2	273-589-7	Heraeus Deutschland GmbH and Co. KG	Done	Apr 2016
Potassium dicyanoargentate	506-61-6	208-047-0	Saxonia Edelmetalle GmbH		
Silver cyanide	506-64-9	208-048-6	Saxonia Edelmetalle GmbH		
Potassium dicyanoaurate	13967-50-5	237-748-4	Umicore Galvanotechnik GmbH	Done	



Overall status of PMC Registrations

Name of the substance	Identification numbers		LR	JSO created	Registered by LR
	CAS	EC			
Palladium	7440-05-3	231-115-6	Umicore NV/SA	Done	
Palladium dichloride	7647-10-1	231-596-2	BASF	Done	
Dihydrogen tetrachloropalladate(2-) (in solution)	16970-55-1	241-047-9	Heraeus	Done	
Diamminedichloropalladium	14323-43-4	238-269-3	Heraeus	Done	
Dichlorobis(triphenylphosphine)palladium	13965-03-2	237-744-2	Heraeus	Done	
Palladium (II) di(4-oxopent-2-en-2-oate)	14024-61-4	237-859-8	Heraeus	Done	
Palladium(II) acetate	3375-31-3	222-164-4	Heraeus	Done	
Palladium monoxide	1314-08-5	215-218-3	Heraeus	Done	
Tetraamminepalladium (II) nitrate	13601-08-6	237-078-2	Johnson Matthey	Done	
Tetraamminepalladium(2+) dichloride	13815-17-3	237-489-7	Umicore AG&Co.KG	Done	
Tetraamminepalladium(2+) dihydroxide	68413-68-3	270-241-6	Heraeus	Done	
Tetrakis(triphenylphosphine)palladium	14221-01-3	238-086-9	Umicore AG&Co.KG	Done	
Palladium sulphate	13566-03-5	236-957-8	Heraeus	Done	
Tetraamminepalladium(2+) diacetate	61495-96-3	262-819-1	Umicore AG&Co.KG	Done	
Disodium tetrachloropalladate	13820-53-6	237-502-6	BASF	Done	
Palladium dinitrate	10102-05-3	233-265-8	Heraeus	Done	
Palladium dihydroxide	12135-22-7	235-219-2	Umicore AG&Co.KG	Done	
Diammonium hexachloropalladate	19168-23-1	242-854-9	Johnson Matthey	Done	
Dipotassium hexachloropalladate	16919-73-6	240-974-6	C. Hafner	Done	
Platinum	7440-06-4	231-116-1	Vale		
Hexachloroplatinic acid	16941-12-1	241-010-7	Johnson Matthey		
Tetraammineplatinum dichloride	13933-32-9	237-706-5	Johnson Matthey	Done	
Tetraammineplatinum dinitrate (in solution)	20634-12-2	243-929-9	Umicore AG&Co.KG	Done	
Diammineplatinum (II) nitrite	14286-02-3	238-203-3	Heraeus		
Dipotassium tetrachloroplatinate	10025-99-7	233-050-9	Heraeus		
Platinum dioxide	1314-15-4	215-223-0	Umicore AG&Co.KG	Done	
Dihydrogen hexahydroxyplatinate, compound with 2-aminoethanol (1:2) (in solution)	68133-90-4	268-717-3	BASF		
Dipotassium hexachloroplatinate	16921-30-5	240-979-3	Heraeus		
Platinum dinitrate	18496-40-7	242-383-9	Heraeus		
Platinum, 1,3-diethenyl-1,1,3,3-tetramethyldisiloxane complexes / Karstedt concentrate (in solution)	68478-92-2	270-844-4	Heraeus		
Diammonium hexachloroplatinate	16919-58-7	240-973-0	Johnson Matthey		
Dihydrogen hexahydroxyplatinate	51850-20-5	257-471-2	Johnson Matthey		

Annex III exempted substances highlighted



Overall status of PMC Registrations

Name of the substance	Identification numbers		LR	JSO created	Registered by LR
	CAS	EC			
Iridium	7439-88-5	231-095-9	Johnson Matthey	Done	May 2016
Hexachloroiridic acid, Hydrogen hexachloroiridate (IV)	16941-92-7	241-012-8	Heraeus Deutschland GmbH and Co. KG	Done	Ongoing
Diammonium hexachloroiridate	16940-92-4	241-007-0	Johnson Matthey	Done	May 2016
Rhodium	7440-16-6	231-125-0	Johnson Matthey		
Carbonyl(pentane-2,4-dionato-O,O')(triphenylphosphine)rhodium	25470-96-6	247-015-0	Johnson Matthey	Done	
Carbonylhydrottris(triphenylphosphine)rhodium	17185-29-4	241-230-3	Umicore AG&Co.KG	Done	
Dicarbonyl(pentane-2,4-dionato-O,O')rhodium	14874-82-9	238-947-9	Umicore AG&Co.KG	Done	
Rhodium tris(2-ethylhexanoate) (in solution)	20845-92-5	244-079-1	Umicore AG&Co.KG	Done	
Rhodium trichloride (hydrate)	10049-07-7	233-165-4	Heraeus		
Di-μ-chloro-bis(hapto-1,5-cyclooctadiene)dirhodium(I)	12092-47-6	235-157-6	Heraeus		
Tris(triphenylphosphine) rhodium (I) chloride	14694-95-2	238-744-5	Umicore AG&Co.KG	Done	
Rhodium triiodide	15492-38-3	239-521-5	Umicore AG&Co.KG	Done	
Dirhodium trisulphate	10489-46-0	234-014-5	Umicore AG&Co.KG	Done	
Dirhodium trioxide	12036-35-0	234-846-9	Umicore AG&Co.KG	Done	
Rhodium (III) acetate	42204-14-8	255-707-9	Umicore AG&Co.KG	Done	
Rhodium trinitrate	10139-58-9	233-397-6	Johnson Matthey		
Rhodium trihydroxide	21656-02-0	244-508-2	Heraeus		
Triammonium hexachlororhodate	15336-18-2	239-364-2	Vale		
Diammonium sodium hexakis(nitrito-N)rhodate	64164-17-6	264-713-0	Vale		
Ruthenium	7440-18-8	231-127-1	Heraeus		
Ruthenium trichloride (hydrate)	10049-08-8	233-167-5	Heraeus		
Ruthenium (IV) oxide	12036-10-1	234-840-6	Heraeus	Done	
Tris(nitrato-O)nitrosylruthenium	34513-98-9	252-068-8	Umicore AG&Co.KG	Done	
Hexakis[μ-(acetato-O:O)]- 3-oxo-triangulo-triruthenium acetate / Ruthenium acetate	55466-76-7	259-653-7	Johnson Matthey	Done	
Tetraammonium decachloro-μ-oxodiruthenate(4-)	85392-65-0	286-924-7	Heraeus		
Ruthenium trihydroxide	12135-42-1	235-221-3	Umicore NV/SA	Done	

Annex III exempted substances highlighted



Overall status of PMC Registrations

Name of the substance	Identification numbers		LR	JSO created	Registered by LR
	CAS	EC			
Rhenium	7440-15-5	231-124-5	KGHM Metraco		Sept 2013
Perrhenic acid (in solution)	13768-11-1	237-380-4	Heraeus Deutschland GmbH and Co. KG		Nov 2013
Ammonium perrhenate	13598-65-7	237-075-6	Heraeus Deutschland GmbH and Co. KG		Jul 2013
Sodium rhenate (in aq. solution)	13472-33-8	236-742-9	Climax Molybdenum		Mar 2014
Potassium perrhenate	10466-65-6	233-953-8	Heraeus Deutschland GmbH and Co. KG		Aug 2013
Dirhenium heptasulphide	12038-67-4	234-882-5	Johnson Matthey		TBC

AND ALL THE REFINABLES!



TCA

- “ TCA repeated 422 testing
 - “ Approval by Mngt Cttee (28 January 2016) to repeat OECD 422 testing which failed
 - “ Au WG tried to ~~save~~ the study but without success and confirmed in April 2016 that the test must be repeated
 - “ Request of reimbursement from Covance is ongoing (120.000” for OECD 422 and OECD 474 which failed too)
 - “ Another CRO has been contracted
- “ Timeline will be impacted: Q3 ~~2016~~ but Q2 or Q3 2017.



Early registration of Annex III exempted substances

Name of the substance	Identification numbers		LR
	CAS	EC	
Dichlorobis(triphenylphosphine)palladium	13965-03-2	237-744-2	Heraeus
Palladium(II) acetate	3375-31-3	222-164-4	Heraeus
Tetraamminepalladium (II) nitrate	13601-08-6	237-078-2	Johnson Matthey
Tetraamminepalladium(2+) dihydroxide	68413-68-3	270-241-6	Heraeus
Tetrakis(triphenylphosphine)palladium	14221-01-3	238-086-9	Umicore AG&Co.KG
Tetraammineplatinum dichloride	13933-32-9	237-706-5	Johnson Matthey
Diammineplatinum (II) nitrite	14286-02-3	238-203-3	Heraeus
Dipotassium tetrachloroplatinate TO BE PREPARED BUT NOT SUBMITTED	10025-99-7	233-050-9	Heraeus
Platinum dioxide	1314-15-4	215-223-0	Umicore AG&Co.KG
Carbonyl(pentane-2,4-dionato-O,O')(triphenylphosphine)rhodium	25470-96-6	247-015-0	Johnson Matthey
Carbonylhydrotris(triphenylphosphine)rhodium	17185-29-4	241-230-3	Umicore AG&Co.KG
Dicarbonyl(pentane-2,4-dionato-O,O')rhodium	14874-82-9	238-947-9	Umicore AG&Co.KG
Di- μ -chloro-bis(hapto-1,5-cyclooctadiene)dirhodium(I)	12092-47-6	235-157-6	Heraeus
Tris(triphenylphosphine) rhodium (I) chloride	14694-95-2	238-744-5	Umicore AG&Co.KG
Ruthenium (IV) oxide	12036-10-1	234-840-6	Heraeus
Tris(nitrato-O)nitrosylruthenium	34513-98-9	252-068-8	Umicore AG&Co.KG
Hexakis[μ -(acetato-O:O)]- 3-oxo-triangulo-triruthenium acetate / Ruthenium acetate	55466-76-7	259-653-7	Johnson Matthey

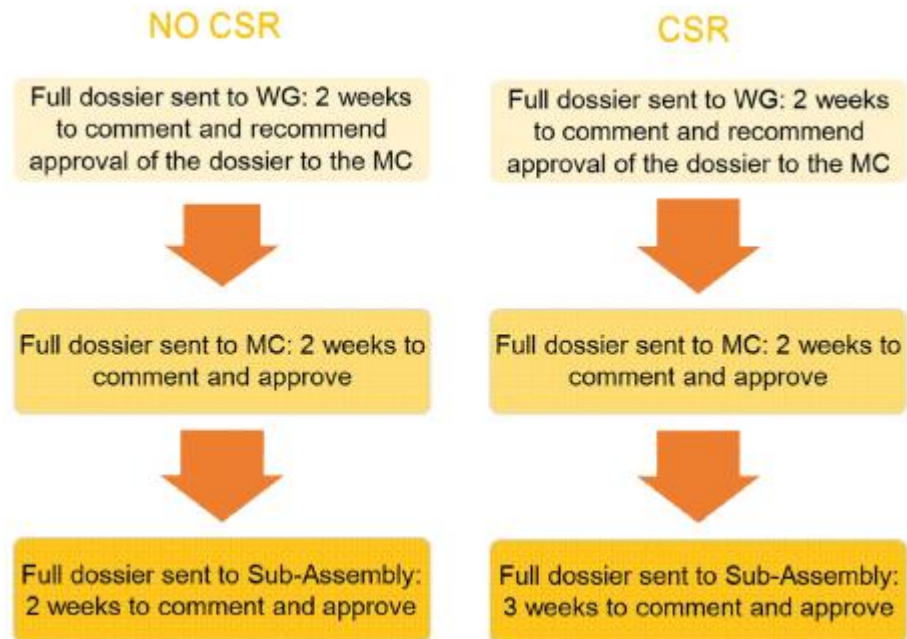


Phys-chem testing on some Pd compounds

- “ Change in registration strategy of some Pd compounds: registration of the anhydrous instead of the hydrated form
- “ Csq: Additional phys-chem tests required
- “ Potential impact on registration deadline (Q3 2016) of:
 - “ Palladium dinitrate
 - “ Tetraamminepalladium(2+) dihydroxide
 - “ Tetramminepalladium(2+) diacetate



Approval process - Standard procedure



Approval process - « Fast track » procedure

“ If:

“ only one registrant (at WG and Sub-Assembly, only the approval of this member is requested)

“ Annex III exempted dossier (only phys-chem data included)

⇒ ONE SENDING to relevant WG, Management Committee, relevant Sub-Assembly

⇒ 2 weeks for approval





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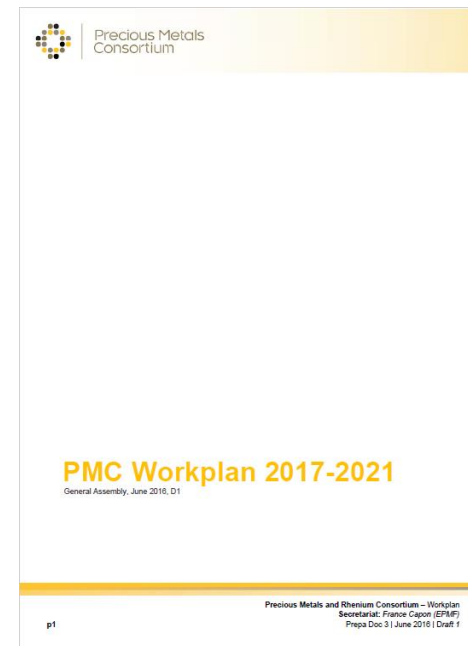
4. PMC Workplan 2017-2019

France Capon, EPMF

PMC 2017 Workplan - Main activities

- “ Ag: Substance Evaluation
- “ Au: finalisation of TCA dossier
- “ PM CN: finalisation of dicyanorgentate dossier
- “ Pd: no activity except if resources allow a shadow RMO on chloropalladates
- “ Pt: registration Q1 2017
- “ Rh: registration Q2 2017
- “ Ru: registration Q3 2017
- “ SVHC Roadmap: ongoing monitoring

N.B.: Socio-economic data will be needed for IUCLID 6!



2017 Draft Budget and HR

	PMC 2017 Budget to be spent	PMC 2017 Budget to be invoiced	PMC 2017 HR
2.1 Administrative costs	632.500 €	632.500 €	2
2.2 Ag-specific costs	897.950 €	897.950 €	1,027
2.3 Au-specific costs	145.150 €	145.150 €	0,1
2.4 PM CN- specific costs	48.150 €	39.650 €	0,1
2.5.A Platinum-specific costs	131.983 €	116.483 €	0,3
2.5.B Palladium-specific costs	35.111 €	35.111 €	0,1
2.5.C Rhodium-specific costs	165.122 €	147.622 €	0,7
2.5.D Ruthenium-specific costs	168.883 €	151.383 €	0,5
2.5.E Iridium-specific costs	1.000 €	1.000 €	0,1
2.6 Re-specific costs	11.400 €	11.400 €	0,02
2.7 Refinables-specific costs	424.700 €	102.200 €	0,3
2.8 SVHC Roadmap-specific costs	30.000 €	30.000 €	0,5
TOTAL	2.691.950 €	2.310.450 €	5,747

N.B.:

- “ Generic costs: SEA project to be added?
- “ Ag project amendments needed due to positive outcome of the MSC meeting on Substance Evaluation
- “ Au project: amendments needed due to TCA issue
- “ Amendments needed to Budget to be spent depending on the expected « carry over » end of 2016



2017 draft indicative invoices

ID Code	2017 Ag-applicable cost-share per Member	2017 Au-applicable cost-share per Member	2017 PM CN - applicable cost-share per Member	2017 Pt-applicable cost-share per Member	2017 Pd-applicable cost-share per Member	2017 Rh-applicable cost-share per Member	2017 Ru-applicable cost-share per Member	2017 Ir-applicable cost-share per Member	2017 Re-applicable cost-share per Member	2017 Ref-applicable cost-share per Member	2017 SVHC/Roadmap-applicable cost-share per Member	Amount to be invoiced in 2017
1	0,00 €	0,00 €	0,00 €	0,00 €	0,00 €	0,00 €	0,00 €	0,00 €	0,00 €	0,00 €	0,00 €	0,00 €
2	0,00 €	3.939,39 €	0,00 €	0,00 €	6.043,43 €	1.145,69 €	16.499,74 €	19.542,06 €	2.502,36 €	0,00 €	0,00 €	52.683,23 €
3	13.270,96 €	7.005,94 €	0,00 €	0,00 €	4.401,28 €	1.145,69 €	0,00 €	0,00 €	0,00 €	0,00 €	0,00 €	28.834,43 €
5	40.829,24 €	7.005,94 €	0,00 €	0,00 €	0,00 €	0,00 €	0,00 €	0,00 €	0,00 €	0,00 €	0,00 €	78.263,81 €
6	28.771,66 €	0,00 €	9.700,91 €	4.401,28 €	1.902,52 €	0,00 €	0,00 €	0,00 €	0,00 €	4.994,50 €	0,00 €	52.781,42 €
7	23.720,90 €	3.939,39 €	8.214,03 €	0,00 €	0,00 €	0,00 €	0,00 €	0,00 €	0,00 €	0,00 €	0,00 €	38.884,87 €
8	15.520,62 €	7.005,94 €	3.649,07 €	0,00 €	0,00 €	0,00 €	0,00 €	0,00 €	0,00 €	0,00 €	0,00 €	29.186,17 €
9	28.771,66 €	13.362,64 €	0,00 €	9.609,25 €	2.280,93 €	0,00 €	0,00 €	0,00 €	0,00 €	0,00 €	0,00 €	57.035,03 €
10	12.849,15 €	3.939,39 €	5.188,11 €	0,00 €	1.145,69 €	16.499,74 €	0,00 €	0,00 €	0,00 €	0,00 €	0,00 €	42.632,64 €
11	59.423,22 €	10.296,09 €	9.700,91 €	24.763,97 €	8.590,18 €	65.030,45 €	53.022,49 €	2.502,36 €	0,00 €	24.692,39 €	0,00 €	261.032,62 €
12	15.520,62 €	7.005,94 €	0,00 €	4.401,28 €	1.145,69 €	0,00 €	0,00 €	0,00 €	0,00 €	0,00 €	0,00 €	31.084,08 €
13	40.829,24 €	3.939,39 €	0,00 €	0,00 €	0,00 €	0,00 €	0,00 €	0,00 €	0,00 €	3.914,85 €	0,00 €	51.694,03 €
14	41.864,94 €	0,00 €	0,00 €	0,00 €	0,00 €	0,00 €	0,00 €	0,00 €	0,00 €	0,00 €	0,00 €	44.875,49 €
15	164.296,25 €	13.586,24 €	6.727,16 €	28.235,95 €	9.347,01 €	46.836,22 €	65.230,82 €	2.684,18 €	3.197,25 €	11.333,01 €	0,00 €	354.484,65 €
16	20.599,50 €	3.939,39 €	0,00 €	9.421,57 €	1.506,42 €	31.323,25 €	30.492,57 €	2.593,27 €	0,00 €	11.370,43 €	0,00 €	114.256,96 €
17	39.193,48 €	7.005,94 €	8.214,03 €	0,00 €	1.145,69 €	0,00 €	0,00 €	0,00 €	0,00 €	0,00 €	0,00 €	58.569,69 €
18	13.270,96 €	0,00 €	0,00 €	0,00 €	0,00 €	0,00 €	0,00 €	0,00 €	0,00 €	0,00 €	0,00 €	16.281,51 €
19	13.270,96 €	0,00 €	0,00 €	0,00 €	0,00 €	0,00 €	0,00 €	0,00 €	0,00 €	0,00 €	0,00 €	16.281,51 €
20	15.520,62 €	7.005,94 €	0,00 €	0,00 €	1.145,69 €	0,00 €	0,00 €	0,00 €	0,00 €	3.909,99 €	0,00 €	30.592,79 €
21	15.520,62 €	7.005,94 €	0,00 €	4.401,28 €	1.145,69 €	0,00 €	0,00 €	0,00 €	0,00 €	0,00 €	0,00 €	31.084,08 €
23	12.849,15 €	3.939,39 €	0,00 €	0,00 €	0,00 €	0,00 €	0,00 €	0,00 €	0,00 €	0,00 €	0,00 €	19.799,09 €
24	12.849,15 €	3.939,39 €	0,00 €	4.401,28 €	1.145,69 €	0,00 €	0,00 €	0,00 €	0,00 €	0,00 €	0,00 €	25.346,07 €
25	47.365,64 €	10.519,69 €	0,00 €	18.211,00 €	4.859,10 €	29.982,62 €	47.954,18 €	2.593,27 €	1.977,82 €	20.342,09 €	0,00 €	186.815,97 €
27	13.270,96 €	0,00 €	0,00 €	0,00 €	0,00 €	0,00 €	0,00 €	0,00 €	0,00 €	0,00 €	0,00 €	16.281,51 €
28	0,00 €	0,00 €	0,00 €	0,00 €	0,00 €	0,00 €	0,00 €	0,00 €	2.160,04 €	0,00 €	0,00 €	2.160,04 €
29	0,00 €	3.939,39 €	0,00 €	0,00 €	0,00 €	0,00 €	0,00 €	0,00 €	0,00 €	0,00 €	0,00 €	6.949,94 €
30	0,00 €	0,00 €	0,00 €	0,00 €	0,00 €	0,00 €	0,00 €	0,00 €	1.459,22 €	0,00 €	0,00 €	1.459,22 €
31	0,00 €	0,00 €	0,00 €	0,00 €	0,00 €	0,00 €	0,00 €	0,00 €	1.272,33 €	0,00 €	0,00 €	1.272,33 €
32	13.270,96 €	0,00 €	0,00 €	0,00 €	0,00 €	0,00 €	0,00 €	0,00 €	0,00 €	4.994,50 €	0,00 €	21.276,01 €
33	21.021,31 €	0,00 €	0,00 €	0,00 €	0,00 €	0,00 €	0,00 €	0,00 €	0,00 €	0,00 €	0,00 €	24.031,86 €
34	0,00 €	0,00 €	0,00 €	0,00 €	0,00 €	0,00 €	0,00 €	0,00 €	0,00 €	3.900,28 €	0,00 €	6.910,83 €
35	0,00 €	0,00 €	0,00 €	0,00 €	0,00 €	0,00 €	0,00 €	0,00 €	1.459,22 €	0,00 €	0,00 €	1.459,22 €
36	13.270,96 €	3.939,39 €	0,00 €	4.401,28 €	1.145,69 €	0,00 €	0,00 €	0,00 €	0,00 €	0,00 €	0,00 €	25.767,88 €
39	13.270,96 €	7.005,94 €	0,00 €	4.401,28 €	1.145,69 €	0,00 €	0,00 €	0,00 €	0,00 €	8.218,88 €	0,00 €	37.053,30 €
40	31.443,13 €	7.005,94 €	5.135,94 €	4.510,76 €	2.623,98 €	0,00 €	0,00 €	0,00 €	0,00 €	13.536,01 €	0,00 €	67.266,31 €
41	13.270,96 €	0,00 €	0,00 €	0,00 €	0,00 €	0,00 €	0,00 €	0,00 €	0,00 €	0,00 €	0,00 €	16.281,51 €
42	0,00 €	3.939,39 €	0,00 €	4.401,28 €	0,00 €	0,00 €	0,00 €	0,00 €	0,00 €	0,00 €	0,00 €	11.351,22 €
43	49.001,40 €	3.939,39 €	0,00 €	0,00 €	1.506,42 €	0,00 €	0,00 €	2.502,36 €	0,00 €	14.215,51 €	0,00 €	74.175,63 €
44	0,00 €	0,00 €	0,00 €	0,00 €	0,00 €	0,00 €	0,00 €	0,00 €	0,00 €	0,00 €	0,00 €	0,00 €
45	13.270,96 €	3.939,39 €	0,00 €	6.043,43 €	1.506,42 €	16.499,74 €	0,00 €	0,00 €	0,00 €	0,00 €	0,00 €	44.270,50 €
46	15.520,62 €	0,00 €	0,00 €	0,00 €	0,00 €	0,00 €	0,00 €	0,00 €	0,00 €	0,00 €	0,00 €	18.531,17 €
47	13.270,96 €	3.939,39 €	0,00 €	4.401,28 €	1.145,69 €	16.499,74 €	19.542,06 €	2.502,36 €	1.459,22 €	0,00 €	0,00 €	65.771,26 €
48	163.874,44 €	0,00 €	0,00 €	4.401,28 €	1.145,69 €	0,00 €	0,00 €	0,00 €	0,00 €	0,00 €	0,00 €	172.431,96 €
49	0,00 €	0,00 €	0,00 €	0,00 €	0,00 €	0,00 €	0,00 €	0,00 €	0,00 €	0,00 €	0,00 €	0,00 €
50	21.443,12 €	0,00 €	0,00 €	16.271,69 €	4.119,95 €	26.611,90 €	0,00 €	0,00 €	0,00 €	0,00 €	0,00 €	71.457,22 €
TPR 1									1.790,94 €			1.790,94 €
TOTAL	1.071.309,35 €	162.030,17 €	56.530,17 €	167.123,85 €	51.991,28 €	265.783,42 €	235.784,19 €	17.880,17 €	14.776,03 €	152.840,51 €	114.400,85 €	2.310.450,00 €





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5. Data sharing

France Capon, EPMF

5.1 Status E LoA 2016 fees and updated agreement

Project / Dossier	Band	2007-2016		TOTAL LoA
		Admin costs	Other applicable costs	
Ag	Intermediate	€ 14.292	€ 279	€ 14.572
	1-10	€ 14.292	€ 32.790	€ 47.082
	10-100	€ 14.292	€ 36.966	€ 51.258
	100-1000	€ 14.292	€ 58.906	€ 73.198
	> 1000	€ 14.292	€ 272.604	€ 286.897
	Nano intermediate	€ 14.292	€ 82.535	€ 96.827
	Nano 1-10	€ 14.292	€ 115.009	€ 129.301
	Nano 10-100	€ 14.292	€ 119.049	€ 133.341
	Nano 100-1000	€ 14.292	€ 140.270	€ 154.562
Nano > 1000	€ 14.292	€ 346.496	€ 360.788	
Au	Intermediate	€ 10.469	€ 1.303	€ 11.772
	1-10	€ 10.469	€ 20.501	€ 30.971
	10-100	€ 10.469	€ 38.800	€ 49.269
PM CN-	Intermediate	€ 31.407	€ 3.266	€ 34.674
	1-10	€ 31.407	€ 48.838	€ 80.245
	10-100	€ 31.407	€ 92.507	€ 123.915
Pt	Intermediate	€ 17.049	€ 2.021	€ 19.069
	1-10	€ 17.049	€ 31.570	€ 48.619
	10-100	€ 17.049	€ 60.566	€ 77.614
Pd	Intermediate	€ 16.226	€ 1.504	€ 17.730
	1-10	€ 16.226	€ 23.413	€ 39.639
	10-100	€ 16.226	€ 45.252	€ 61.478
Rh	Intermediate	€ 35.412	€ 3.674	€ 39.085
	1-10	€ 35.412	€ 38.705	€ 74.117
	10-100	€ 35.412	€ 88.642	€ 124.054
Ru	Intermediate	€ 48.319	€ 4.990	€ 53.309
	1-10	€ 48.319	€ 64.365	€ 112.683
	10-100	€ 48.319	€ 130.741	€ 179.060
Ir	Intermediate	€ 20.971	€ 2.081	€ 23.052
	1-10	€ 20.971	€ 19.623	€ 40.594
Re	Intermediate	€ 20.874	€ 2.068	€ 22.942
	1-10	€ 20.874	€ 23.404	€ 44.278
	10-100	€ 20.874	€ 49.218	€ 70.092
Refinables	Intermediate	€ 27.883	€ 151	€ 28.034
	1-10	€ 27.883	€ 21.694	€ 49.577
	10-100	€ 27.883	€ 23.957	€ 51.840
	100-1000	€ 27.883	€ 35.873	€ 63.756
	> 1000	€ 27.883	€ 153.886	€ 181.769



5.2 Data sharing Implementing act – Points of attention

Published in OJ on 5 January 2016

Enters into force on 26 January 2016

- “ Better use of data-sharing and joint submission provisions
 - Good management practices
 - Costs to be determined in a fair, transparent and non-discriminatory manner
 - ECHA empowered to resolve data-sharing (and joint submission) disputes
- “ **Clear description and identification of costs** → Annual records, proof of costs, itemisation, kept for a minimum of 12 years as from submission of Dossier:
 - “ Itemisation of data to be shared, including cost and link with applicable information requirement (technical costs)
 - “ Itemisation of costs of creating and managing the joint submission (administrative costs)
 - “ Separate out future additional information costs from confirmed costs
 - “ Record of any compensation received from new registrants
 - “ For costs/compensations incurred before Implementing Regulation: make every effort to collate proof or make best approximation
- “ **Cost-sharing model with reimbursement mechanism** → Proportional redistribution to each participant, viability of reimbursement where the cost of reimbursement is higher than the amount to be reimbursed



5.2 Data sharing Implementing act – Existing guidance

“ Version 2.0, April 2012

- “ Data-sharing
- “ Cost-sharing
- “ Dispute resolution by ECHA
- “ Forms of cooperation



Description
Generic examples

“ Also:

- “ ECHA Factsheet %Typical cost elements in data-sharing negotiations+(June 2015)
- “ ECHA Practical advice for data sharing negotiations
- “ ECHA Dos and Don'ts for data sharing negotiations

“ And:

- “ ECHA DCG Document on %Fair, transparent, and non-discriminatory cost-sharing in SIEFs+(Oct 2014, marked as obsoleteqsoon)



5.2 Data sharing Implementing act – Guidance changes

Descriptions and examples on:

“ Fair, transparent and non-discriminatory data- and cost-sharing

→ Various types of data-sharing agreements

“ Itemisation

→ From data and costs related to group of substances (e.g. category or read-across) to substance-specific itemisation

→ What is a reasonable level of itemisation

“ Reimbursement scheme

→ Unpredictability of future REACH Dossier maintenance and update work

→ Two directions

→ Administrative cost, accountancy/tax issues

→ Possible solutions

“ ECHA’s judgement on %every effort+in disputes

→ What is %every effort+?



N.B.:

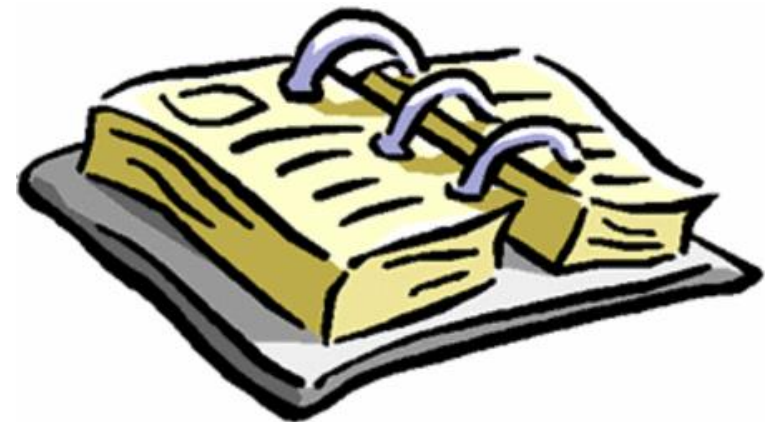
“ collective input from industry (Eurometaux, Concawe, Cefic)

“ PMC submitted examples and comments



5.2 Data sharing Implementing act Æ Guidance timeline

- “ **March 2016:** election of EM (Caroline Braibant) as PEG member
- “ **Early April 2016:** draft updated guidance available
- “ **19th April 2016:** comments sent to ECHA by EM (PMC contributed)
- “ **15th June 2016:** PEG meeting at ECHA
- “ **December 2016:** provisional date for publication



5.2 Data sharing Implementing act – Draft guidance

Main issues identified going beyond legal requirements

- “ Yearly calculation of reimbursement
- “ Role of potential registrants+
- “ Default approach: Equal sharing . equal ownership rights
- “ Inter-SIEF data sharing
- “ 2 years rules+extended to read-across
- “ Affiliate approach
- “ Unanimous consent ALWAYS needed
- “ Detailed recommendation of costs itemisation
- “ Last minutes+requests from new Registrants



5.2 Data sharing Implementing act – Draft guidance

Potential consequences for PMC

- “ If approved, this new guidance could lead to changes in PMC current data sharing system like:
 - “ Adding a Yearly reimbursement process
 - “ Reviewing ownership rules
 - “ Changing the %company+approach into a %legal entity+approach
 - “ Changing the current itemisation system
 - “ Bringing uncertainties to the overall PMC work and especially to the data sharing system due to power given to %late comers+



5.2 Data sharing Implementing act – Draft guidance

EM and PMC Activities

- “ Meetings with European Commission
- “ Contribution to written comments procedure on guidance
- “ Participation to the next PEG meeting (EM)
- “ Continuous advocacy activities to defend key principles (e.g.: companies versus affiliates)
- “ If needed, request legal advice (at EM or PMC level?)





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6. Communication: new and updated tools

Audrey Rondepierre, EPMF

New and updated tools



WEBSITE

- “ Re-shaping of EPMF/PMC website is ongoing: new page on data-sharing & LoA is now available: <http://www.epmf.be/index.php/reach-consortiumleft/data-sharing-loa>
- “ Identified Uses and Exposure Scenarios will be posted on website by end of Q3

UPDATED TOOLS

- “ Collaboration with REACHCentrum regarding SharePoint (Shared Database), LinkinSIEF (SIEF communication) and LoA e-shop ended in Q1 2016
- “ Communication with SIEFs are done via emails (use of web designer Bluespark, as recommended by other metals consortia)
- “ Test reports can be directly requested by the members to the Secretariat
- “ LoA are sold directly by PMC





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7. PMC after 2018

France Capon, EPMF

2018 is not the end!

Å Just the beginningÅ

Need for a reflection regarding PMC role: brainstorming scheduled on **7th October 2016 (AM)**



Legal obligations

- “ Maintenance of the dossier
- “ Data sharing
- “ Evaluation:
 - “ Testing proposals
 - “ Compliance check
 - “ Substance Evaluation



Key questions

- “ Authorisation or not Authorisation of PMC substances and/or critical substances for PM industry (e.g.: borates, hydrazine, etc.)
- “ Focus on EU or extend the scope outside the EU (e.g. Korean REACH)?
- “ Focus on REACH or extend to EHS issues?
- “ Others?



More to come after Summer in preparation of the brainstorming session!





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8. AOB, next meeting and closing remarks

Guy Ethier, Umicore

” A.O.B.?

” Next General Assemblies:

> 6-7 December 2016, Brussels



> 31/05-01/06/2017, Pforzheim





THANK YOU

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