Precious Metals Consortium

Precious Metals & Rhenium Consortium

SVHC Roadmap Work Group

5 October 2016
09:30:00-12:00 CET

Precious Metals Consortium

1. Welcome and Introduction

Competition Law and Confidentiality

Attendees should refrain from any discussion on pricing, market shares and volumes and other information that could be considered as market sensitive and covered by antitrust legislation

DO	DON'T
Application of competition law	
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.
Consultation in Matters of Competition Law	
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.
Activities in any preliminary phase and at any other stage of operation of the Consortium	
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 of the effect of preventing, restricting and/or distorting competition are prohibited within the scope of this Agreement, including: - 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.
Exchange of Confidential Information	
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 : - Production capacities; - Productions or sales volumes; - Import volumes; - Market shares; - Price policy; - Distribution and marketing terms; - Marketing strategies; - Information regarding the relationship with suppliers.
Documentation on Cooperation	
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.	

Tour de table

Approval of the agenda

1. Welcome and Introduction

- 1.1 Confidentiality and Competition Law
- 1.2. Tour de table
- 1.3 Approval of the agenda
- 1.4 Status of actions from last meeting

2. General facts on SVHC Roadmap Implementation

- 2.1 ECHA's integrated regulatory strategy
- 3.2 Relevant policy developments (e.g. sensitisers, impurities in substances)

3. DU advocacy potential

- 3.1 Presentation of factsheet on DU advocacy potential

4. Outcome of SVHC Roadmap monitoring

- 4.1 Outcome of monthly monitoring
- 4.2 Latest developments

5. REACH Authorisation PMC

- 5.1 Presentation of Authorisation checklists
- 5.2 REACH Authorisation and Recycling
- 5.3 COM proposal to update Authorisation list
- 5.4 ECHA's 7th list
  - 5.4.1 State of play
  - 5.4.2 PbO
- 5.5 ECHA's 8th list
  - 5.5.1 State of play
  - 5.5.2 Update on borates, RCFs, hydrazine

6. Workplan and budget

7. AOB, next meeting, closing remarks

Status of action points from last meeting (20/04/16)

Actions	By when	By who	Status
Identify new substances added to the Roadmap and follow developments for relevant substances.	Ongoing	Secretariat	DONE
Revise the draft WG mandate to include substance criticality criteria in addition to „minimum 3 members“ criteria for prioritisation of PMC work	15/05/16	Secretariat	DONE
Substance screening input (last call)	15/05/16	Members	DONE
Upcoming Annex XIV update: send last call reminder on: - CTP-HT - Nonylphenol	1st week May	Secretariat	DONE
Send check list on actions to be taken ahead of possible inclusion of a substance in Authorisation list as well as on possible options for submitting AfAs	End May	Secretariat	DONE
Send paper on potential roles of DUs in the different prioritisation processes from screening to RMM decisions and implementation	End May	Secretariat	DONE
Borates – clarification on uses to be sent to Secretariat	End May	Members	DONE
RCFs – clarification on uses to be sent to Secretariat	End May	Members	DONE
Discuss Borates activities at EM level as other potential collaborations on other SVHC which are used by different commodities.	May (A/ R platform meeting)	Secretariat	ONGOING
Monitoring of developments related to borates and RCFs	Ongoing	Secretariat	DONE

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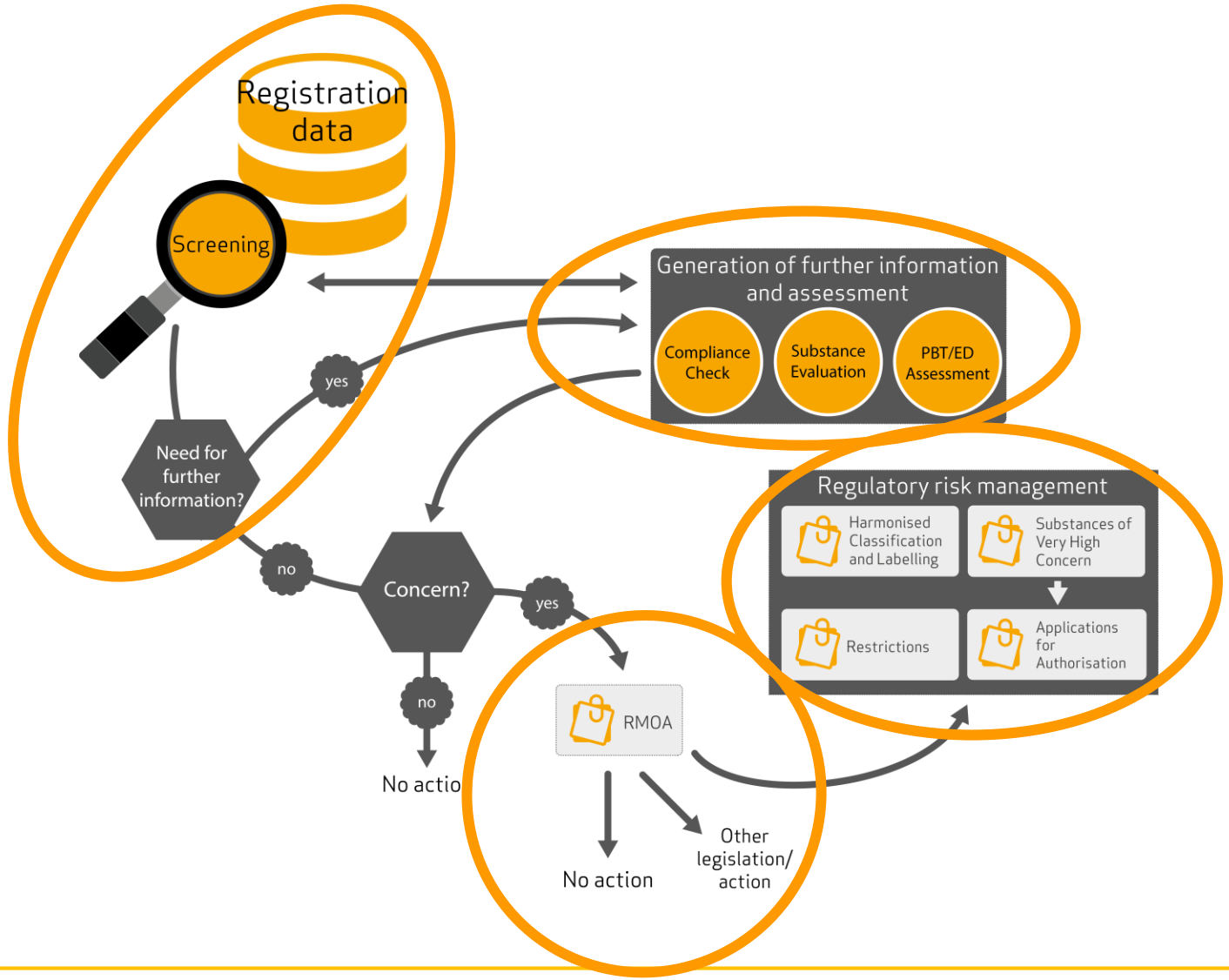
2. General facts on SVHC Roadmap Implementation

ECHA's integrated regulatory strategy

- From data-gathering to knowledge management
- **Two pillars** in the integrated strategy:
  - **Common screening** of substances for all REACH processes and CLP
    - Hazard criteria: CMR, PBT, ED, Sensitiser, STOT
    - Non-hazard criteria: exposure, tonnage
  - **RMOA** to determine the need for further action when a substance raises a concern
- ECHA's Progress report on REACH and CLP 2016:
  - Vast majority of the known registered CMRs have been scrutinized, and subject to regulatory action (Candidate list, Restriction, or RMOA)
  - 18 PBTs and 5 EDs included in the Candidate list
  - **"Resources can now be directed to new CMRs, PBTs, EDs and other SVHCs"!**
- ECHA intends to minimise the gaps between the various processes, for instance by running some of them in parallel
- ECHA will develop **sectorial approaches**, incl. for metals
  - Better recognition of metal specificities
  - **Possible deprioritisation of good registration dossiers**

Identification of substances of concern



Mapping the « universe of registered substances » (NEW!)

- ECHA's ambition is by the end of 2018, to gradually map the 'universe of registered substances'

No regulatory action Substances for which available data suggest that no regulatory action is needed at present
Information generation required Substances for which there is at present uncertainty regarding the hazardous properties and/or the potential for release to environment or exposure of humans; risk cannot be excluded although it cannot be established based on currently available data
Risk management required Substances for which there is risk and risk management has already been initiated or can be initiated on the basis of currently available data
Low priority substances Substances for which risk is unlikely but they need to be monitored

Possibility of deprioritisation!

SVHC Roadmap – Key figures (all substances, not only metals)

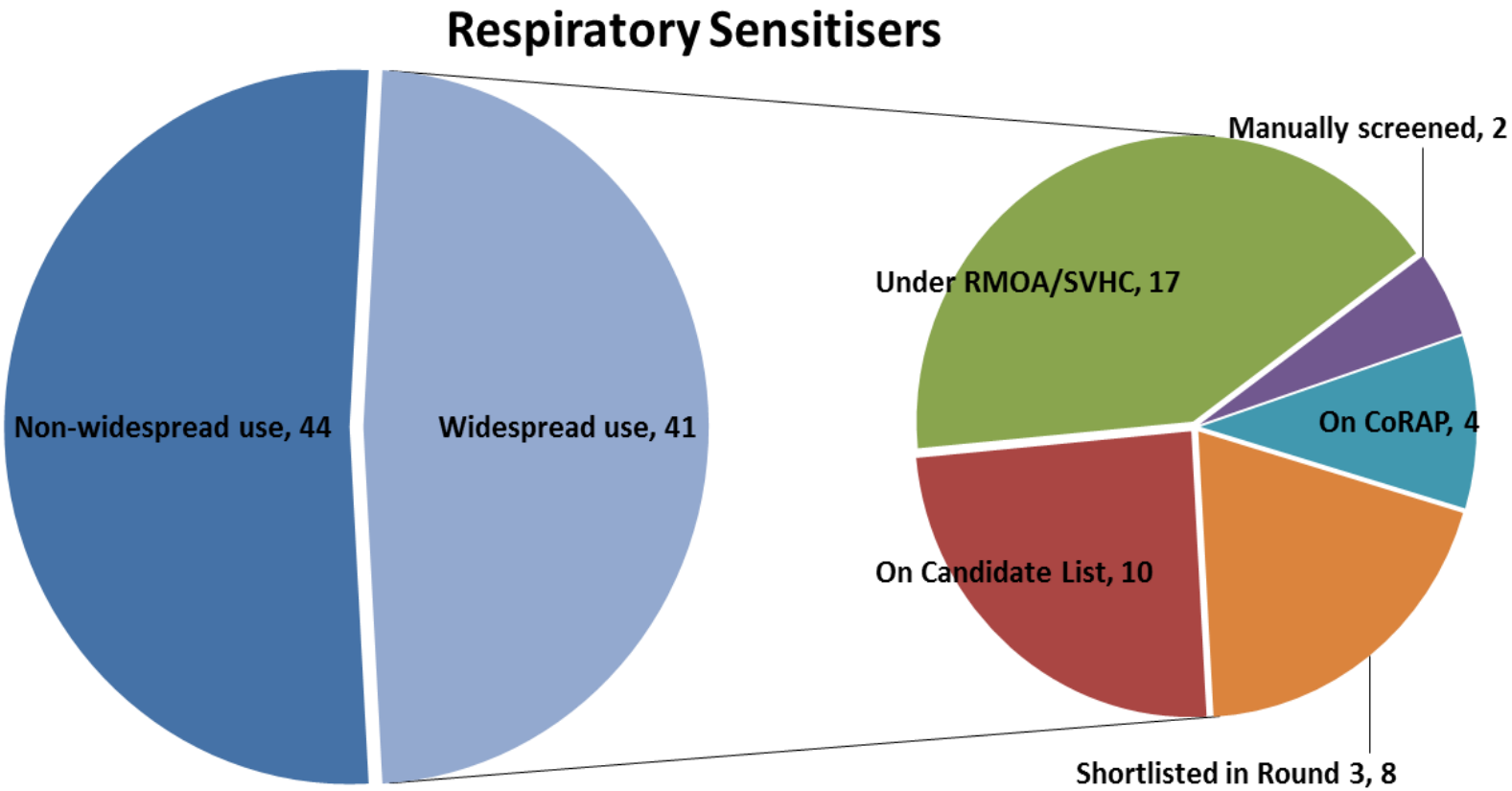
31	Substances subject to Authorisation
20	Restrictions
200	Opinions on Harmonised Classification
340	Ongoing/concluded RMOA/HA
319	Ongoing/concluded Substance evaluations
14000	Substances registered under REACH

Focus on sensitisers

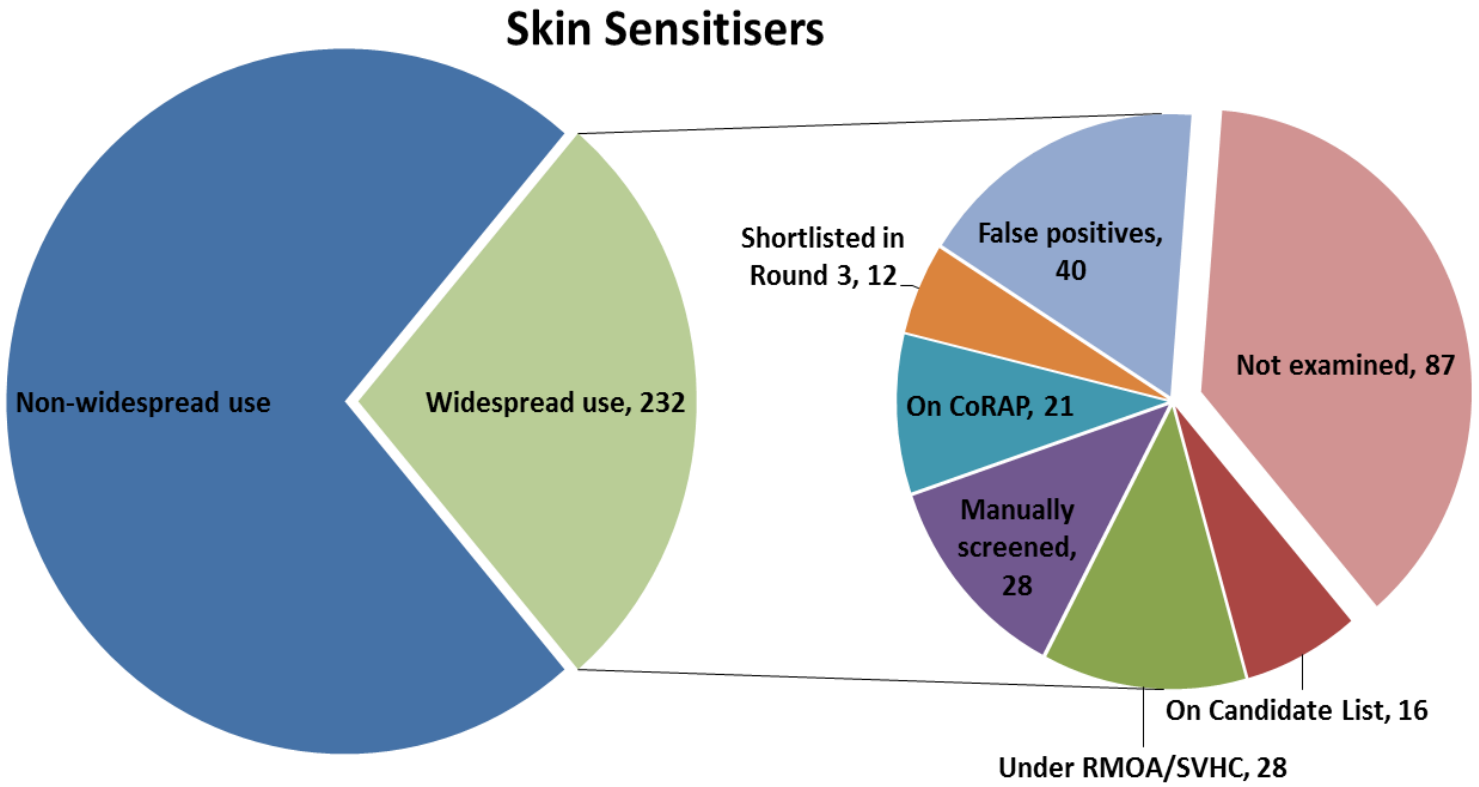
- To date, around **800 skin sensitisers** and around **80 respiratory sensitisers** have been registered.
- **Systematic screening** of sensitisers (can potentially be considered of equivalent level of concern to CMRs)
- Member States have analysed **all respiratory sensitisers** already registered and **most skin sensitisers**
  - Highest priority to those with widespread uses
  - Next priority goes to substances with at least some widespread uses
- **Systematic screening will start again after the 2018 registration deadline!**

Respiratory Sensitisers

Although the substances are resp. sensitisers, the properties for which further regulatory action has been proposed can be different! (e.g. Candidate list)



Skin sensitisers



Recent development: SVHC identification of hexamethylene diacrylate (HDDA), proposed by Sweden, was rejected by the "REACH Committee", due to **insufficient evidence of equivalent level of concern**

Other relevant developments

- **REACH/OSH interface**:
  - Recent cases of REACH restriction proposals addressing exclusively workplace uses (NMP, DMF)
  - European Commission (DG GROW, DG EMPL, DG ENV) to develop a **Common Understanding document** (January 2017)
    - Will define criteria to use OSH instead of REACH for workplace uses!
  - **Taskforce set up between RAC and SCOEL** to assess respective methodologies
- Pending **restriction proposal for lead in shot in wetland areas**: may be the first restriction proposal for a metal based on environmental concerns
- **Criteria for endocrine disruptors** proposed under the **pesticides** and **biocides** regulations:
  - Key aspect: the substance must be "known to cause an adverse effect relevant for human health with an endocrine mode of action"
  - Ongoing discussions at national experts level under biocides and pesticides legislation, but **later inclusion in REACH possible**
- Substances identified as **SVHCs due to impurities** (no desired function):
  - Such substances or their impurities may be added to the SVHC list! (e.g. benzo[a]pyrene which is not registered, and only occurs as impurity)
  - Implications for Authorisation not clear yet!

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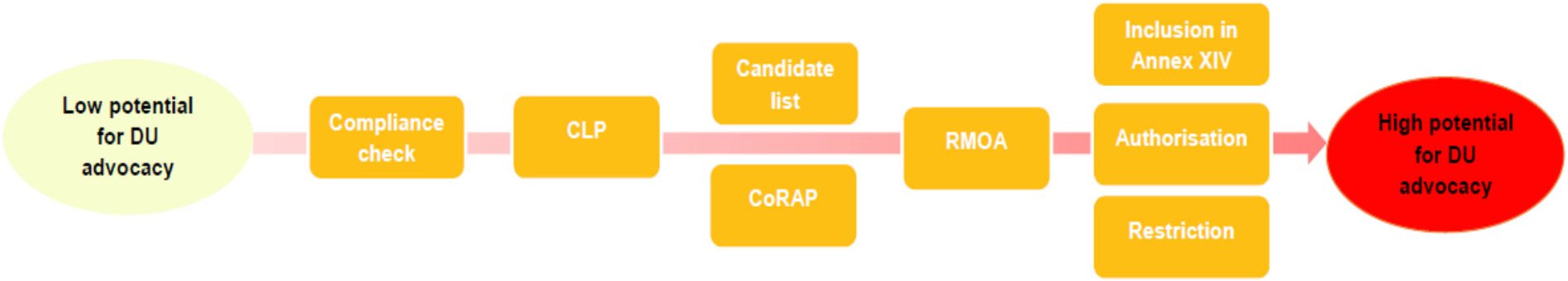
3. DU advocacy potential

DU advocacy potential



Any information on uses (e.g. intermediate uses, tonnage, exposure) that could contribute to "de-prioritising" the substance from regulatory scrutiny should be submitted **as early as possible**

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4. Outcome of SVHC Roadmap monitoring

Current list of substances relevant for at least 3 PMC members

Regulatory process	Substances	PM-related uses
ECHA's 7th list	PbO	Refining, fire assaying, frits production
Recommended for Autorisation (ECHA's 5th, 6th lists)	Borates	Soldering fluxes, analytics, electroplating
	RCFs	Insulation, catalysts
SVHC	Hydrazine	Reducing agent in PM refining
	Cadmium, cadmium chloride, cadmium oxide	May be present in refinables, analytics
RMOA	Formaldehyde	Reducing agent in PM refining
CoRAP	Carbon black, cerium dioxide, zinc oxide, titanium dioxide, silicon dioxide	Refining, catalysts, contact materials,
Harmonised Classification (CLH)	Nitric acid, lead	Refining
	Cobalt	Alloys, analytics, electroplating

Latest developments

Substance	Latest developments	PMC actions
Formaldehyde	RMOA: Draft final report available, public consultation until end Sept	1 member confirmed use, PMC will not conduct advocacy
Cadmium and Cadmium compounds	Will be screened for 8th list	No PMC action planned except general monitoring
Carbon black	Evaluation to start in 2018, includes nanoforms, wide dispersive use	
Cerium dioxide	Evaluation to start in 2017, main focus on nanoform, wide dispersive use	
Zinc oxide		
Titanium dioxide		
Silicon dioxide	Completed, decision under appeal	
Nitric acid	Awaiting launch of public consultation on CLH proposal	
Lead	CLH adopted for lead in massive form (GCL of 0,3%) and powder form (SCL of 0,03%) /Mandatory as from March 2018	PMC will monitor subsequent regulatory action on lead
Cobalt	Carc 1B, Repro 1B, and Muta 2 with a SCL of 0,01%. Awaiting launch of public consultation on CLH proposal	Input from 3 members, only 1 member with 1 critical use relevant for CLH – sent to CDI

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5. REACH Authorisation

Authorisation checklists

- 4 check-lists

  1. Initial screening and assessment

  2. Check-list for SVHC-eligible substances not yet included in the SVHC Roadmap

  3. Check-list for SVHC-eligible substances already included in the SVHC Roadmap (except SVHC/Authorisation)

  4. Check-list for substances included in the Candidate list / steps towards preparing an AfA

1. Initial screening and assessment

Action	Comments
Conduct a **screening** of **all substances used** in your company's precious metals activities in order to identify **substances meeting SVHC criteria**	Substances may be used as such or in a mixture. SVHC criteria are as follows: CMR (Cat. 1 or 2), PBT, vPvB, or "equivalent concern" such as sensitisers, STOT-RE, endocrine disruptors.[1] No substance meeting SVHC criteria should be overlooked!
Assess **criticality** of SVHC eligible substances, for your PM-related activities	Can the substance be substituted technically and economically, if so, within which timeframe?
Set up a **list of „critical SVHC eligible substances"** for your company and **inform PMC**	PMC compiles the input received from members as regards critical substances. PMC may support with monitoring and advocacy for substances being critical for **at least 3 members**
Identify the **regulatory status** of each substance: - Already included in the SVHC Roadmap, if so under which process? - Not yet included in the SVHC Roadmap?	**How to check if the substance is already identified as SVHC?** Substances already identified as SVHC are listed in the so-called "candidate list". Furthermore, for substances identified as SVHC, it is necessary to check if the substance is already subject to Authorisation (included in Annex XIV of REACH, or recommended for inclusion). **How to check if the substance is already included in the SVHC Roadmap and under which process?** The SVHC Roadmap encompasses several processes for which there isn't yet a common substance list. The following lists should be checked: Registry of Intentions (for CLP and SVHC Candidate list), CoRAP and RMOA (PACT) lists. You may also refer to the **PMC screening table** (until April 2016) and subsequent **PMC monthly monitoring reports**

2. Check-list for SVHC-eligible substances not yet included in the SVHC Roadmap[2]

Action	Comments
*For such substances, industry, including downstream users should take advantage of having more time to **carry out pro-active actions** and to prepare for the possibility of regulatory scrutiny.*	
Check eSDS and discuss with suppliers to make sure that your use is adequately covered in the registration dossier If weaknesses are identified, address such weaknesses as soon as possible Alternatively a DU CSR should be compiled if no registration of your use is foreseen or if your use is not covered in the registration dossier due to confidentiality reasons	ECHA's screening process is mainly based on the registration dossiers and focuses on the following criteria: - Hazard profile - Tonnage - **Uses and Exposure** - RCRs All these aspects need to be clearly documented in the registration dossier to **avoid "unnecessary" prioritisation** Consult ECHA's guidance for downstream users as well as ECHA's guidance on Information Requirements and CSA for further information
If weaknesses are identified with respect to **exposure** in relation to your use, consider the launch of a study on exposure/monitoring data.	PMC may coordinate such activity for PM critical substances *PMC already performed such a review of occupational exposure for uses of hydrazine in the precious metals sector*

Key recommendations

- ACT on the points below prior to regulatory scrutiny:

  1. Screening of substances: Do I use for my PM-activities substances meeting SVHC criteria (CMR, PBT/vPvB, ED, Sensitisers, STOT)

  2. Is the substancs critical for PMs?

  3. Check the regulatory status of the substance

  4. Analyse your use: does my use fall in the scope of Authorisation (e.g. Intermediates are excluded from Authorisation)

  5. Check SDS, discuss with suppliers how the use is registered and identify possible weaknesses

  6. Address such weaknesses (exposure data, tonnage data)

  7. Take part in shadow RMOAs, AoAs

  8. Get familiar with the Authorisation procedure (components, timing)

PMC may support for substances being critical for at least 3 members

Eurometaux activities on AfAs capacity building (learnings from Cr Auth., MvE, seminar with ECHA on CTP-HT)

REACH Authorisation and Recycling

- Report contracted by Eurometaux to assess the impact of REACH Authorisation on metals recycling
- PM recycling was part of the case studies
- Outreach:
  - ECHA – 6 June 2016: positively received by ECHA and proposed mitigation measures expected in October
  - Netherlands – 2 September 2016: very interested and highly interactive debate. Will consider how to bring the issue to CARACAL. Liked the integrated thinking with Circular Economy and Waste legislation objectives
  - European Commission – 14 October 2016
  - RIME – October: initial debate expected

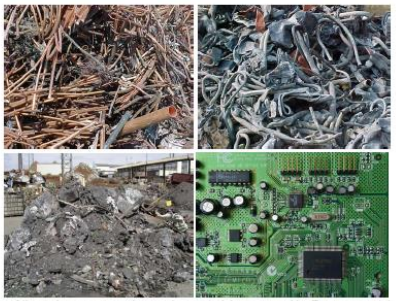

Illustration of the various scraps and secondary materials processed by European metal recyclers

Eurometaux: Metals Sector Risk Management Support Programme Recycling and Authorisation: a first impact assessment to define mitigation measures

Studies to investigate the business impact of Authorisation on recycling

Main Conclusions

Version 2: 25/7/2016

EMRC

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Proposed prevention and mitigation measures

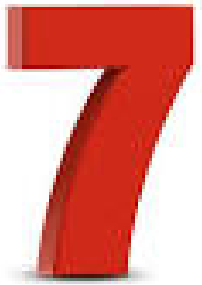
The use of the **OSH legislation** as risk management route instead of REACH Authorisation for workplace uses
Exclude "basic" mixing (i.e. in order to obtain an optimal blend of input materials) from the scope of Authorisation (basic mixing should not be regarded as a "use" but as a pre-treatment/ ancillary step to refining/production) CTPHT use in the manufacture of coke electrodes for the aluminium industry (ECHA Q&A)
Authorisation should not apply to constituents of **UVCBs** but to UVCBs as such
Assess the possible **intermediate status** for metals/metal compounds used as scavenger/collector in the refining of metals
Consider **longer review periods** for REACH Authorisation
Extend the waste phase so that the first or more steps of the recycling fall under the waste legislation

COM Proposal to update Authorisation list

- Draft Commission proposal contains 12 substances
- All substances from ECHA's 6th list except the "Borates" and one additional substance from the 5th list
- No critical substance for PMC in that list
- RCFs and Borates "postponed for the moment"
- Awaiting adoption by REACH Committee (Q4 2016)

1	1-Bromopropane (n-propyl bromide)	Reprotox 1B	6th list
2	Diisopentylphthalate	Reprotox 1B	6th list
3	1,2-Benzenedicarboxylic acid, di-C6-8-branched alkyl esters, C7 rich	Reprotox 1B	6th list
4	1,2-Benzenedicarboxylic acid, di-C7-11-branched and linear alkyl esters	Reprotox 1B	6th list
5	1,2-Benzenedicarboxylic acid,dipentylester, branched and linear	Reprotox 1B	6th list
6	Bis(2-methoxyethyl) phthalate	Reprotox 1B	6th list
7	Dipentylphthalate	Reprotox 1B	6th list
8	N-pentyl-isopentylphthalate	Reprotox 1B	6th list
9	Anthracene oil	Carc 1B, PBT, vPvB	6th list
10	CTP HT	Carc 1B, PBT, vPvB	6th list
11	4-Nonylphenol, branched and linear, Ethoxylated	ED for the environment	6th list
12	4-(1,1,3,3-Tetramethylbutyl)phenol, ethoxylated	ED for the environment	5th list

ECHA's 7th Draft Recommendation list



- 11 substances including **PbO** and three other Pb compounds (orange lead, and two Pb sulphates)
- Only uses covered by RoHS and ELV are proposed for possible exemption under Art 58.2 of REACH (risks already controlled based on other existing substance-specific legislation)
- Approved by MSC but **without consensus**– several member states opposed or abstained inclusion of substances!
- **Proportionality, effectiveness concerns**
- Next steps:
  - ECHA's final opinion to be issued (end Oct)
  - Commission to issue its legislative proposal amending Annex XIV and to submit it to the REACH Committee (Feb 2017)
  - Inclusion in Annex XIV **not before summer 2017**

PbO

- PMC uses (as such or in a mixture)
  - fire assaying
  - frits production
  - PM refining
- Useful clarifications by MSC
  - use in fire assaying below 1t/y: outside the scope of Authorisation!
  - Use in frits production: intermediate use, outside the scope of Authorisation!
- Implications for PMC
  - As things stand, a few PMC members may have to submit AfAs may have to be submitted for use in fire assaying above 1t/y, and specific use in PM refining
- Advocacy on Art 58.2
  - Eurometaux will initiate action to support exemption of all workplace uses based on OSH legislation/binding OEL for lead

Preparation of ECHA's 8th list

- Based on « scoring » of SVHCs
- 8th list discussions postponed from Sept 2016 to April 2017
- Results from previous scoring - goes from 1 (lowest priority) to 45 (highest priority)

Substance identified as relevant by at least 1 member	PM relevant use	Scoring
Nitrobenzene	PM refining	20
Hydrazine	PM refining	15
Lead dinitrate	Used in gold cyanidation and in catalysts; additive for galvanic baths	13
Trilead bis(carbonate)dihydroxide	PM refining	9

Update on borates

- Inclusion „postponed for the moment“ due to workload concerns
- PMC uses:
  - Laboratory chemical for chemical extraction, analytics
  - PM smelting (makes the slag more fluid and easier to pour)
  - Production of brazing fluxes
  - Use in many electroplating solutions like gold, silver, nickel and palladium
  - R&D

  → **Apparently, no intermediate uses**

  → **Except R&D and lab use below 1t, ALL uses likely to fall in the scope of Authorisation!**
- PMC joined Borates Downstream User coalition. Low profile recommended.
- Proposed actions:
  - Monitoring
  - Build on Eurometaux activities on capacity building for AfAs

Update on RCFs

- Inclusion in Authorisation „postponed for the moment“
  - Limited number uses falling in the scope of REACH Authorisation (most RCFs transformed into articles at production site)
- Binding OEL proposed at – 0,3f/ml
  - Adoption expected end 2017 / + 2 years transition period
- PMC uses:

  1/ High temperature heating systems
  - Insulator in high temperature oven
  - Refractory insulator in high temperature industrial furnace operating above 900˚C, up to 1.600˚C,
  - Sealing between refractory and steel kettles, valves, …,
  - Fillings /compensation of thermal stress (expansion) in induction furnace,
  - Thermal insulation of electric equipment linked to furnaces in industrial processes

  2/Automotive catalysts
  - wrapping/ packaging material for autocatalyst substrates
  - structural enhancer/thermic stabilizer for autocatalyst substrates
- Proposed actions:
  - Clarify scope of uses that may fall in the scope of Authorisation
  - Monitor substance/article discussions

Update on Hydrazine

- Hydrazine will be part of the scoring exercise for the 8th list
- In parallel, EU binding OEL proposed for Hydrazine at 0.013 mg/m^3 (=DNEL)
- Hydrazine Consortium launched survey on:
  - Uses
  - Tonnages
  - Concentrations of Hydrazine
- Objective: refine information in the registration dossier to make sure Hydrazine gets right scoring
- Members using Hydrazine must have received a questionnaire from their supplier
- Use as reducing agent – use where more clarification is needed!

Current Exposure scenario

- Use as reducing agent for metal-based chemicals in closed industrial systems under controlled conditions	
Environmental release category:	ERC 4: Industrial use of processing aids in processes and products, not becoming part of articles ERC 6b: Industrial use of reactive processing aids
Process category:	PROC 1: Use in closed process, no likelihood of exposure PROC 3: Use in closed batch process (synthesis or formulation) PROC 8b: Transfer of substance or preparation (charging/discharging) from/to vessels/large containers at dedicated facilities
Product category used:	PC 0: Other: UCN R0500/R05100 (reduction agents)
Sector of end use:	SU 14: Manufacture of basic metals, including alloys
Substance supplied to that use in form of:	As such In a mixture
Subsequent service life relevant for that use:	no

Update on Hydrazine

- Beyond individual companies‘ input, opportunity for PMC to contribute to improving registration dossier
- PMC has gathered monitoring data : Occupational exposure report (October 2015)
- PMC has conducted an initial „ Authorisation scoping report“ (March 2013) followed by a more detailed AoA (March 2014)
- PMC Recommendation
  - Share Occ. report to see if ES can be updated on this basis
  - Conduct a short survey on volumes of Hydrazine in PMs -> updated tonnage estimation for the sector
  - Complement information with most relevant information from AoA/scoping report (e.g. number of plants)

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6. Workplan and Budget

Workplan and Budget

- Key tasks 2017
  - Monitoring of SVHC Roadmap implementation (substance, policy issues)
  - Follow up on critical substances/policy issues (advocacy, improvement of registration dossiers)
  - Capacity building on AfAs

- Budget
  - 2016 budget (30 000 EUR) not spent so far, will be carried over to 2017
  - HR 2017: 0,5 FTE
  - Similar forecast also for 2018, 2019 budgets

	PMC 2017 Budget *to be spent*	PMC 2017 Budget *to be invoiced*	PMC 2017 HR	PMC 2018 Budget *to be spent*	PMC 2018 Budget *to be invoiced*	PMC 2018 HR	PMC 2019 Budget *to be spent*	PMC 2019 Budget *to be invoiced*	PMC 2019 HR
2.8 SVHC Roadmap-specific costs	*91.250 €*	*61.250 €*	*0,5*	*91.964 €*	*91.964 €*	*0,5*	*92.250 €*	*92.250 €*	*0,5*
2.8.1 Authorisation work programme	20.000 €	0 €		20.000 €	20.000 €		20.000 €	20.000 €	
2.8.2 Monitoring and advocacy	0 €	0 €		0 €	0 €		0 €	0 €	
2.8.3 Prioritization on authorisation	10.000 €	0 €		10.000 €	10.000 €		10.000 €	10.000 €	
2.8.4 Internal Regulatory Affairs Manager	61.250 €	61.250 €		61.964 €	61.964 €		62.250 €	62.250 €	

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7. AOB, Next meeting, Closing remarks

THANK YOU

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