

*Proposed REACH Projects
Way Forward
November 2008*

I. Background:

- ⇒ The EHS Management Committee and Groups (SOG, MPPG, GEHS) identified medium and long-term challenges and trends with a view to respond and anticipate needed action/projects to address the challenges and the resources needs.
- ⇒ Many of the projects identified relate to the implementation of REACH, namely
 - o Interpretation and guidance on authorisation, evaluation, restriction, CSR etc.
 - o Use of the metals specific guidance on risk assessment and translation of the concept in official guidance (RIPs)
 - o Classification & labelling (and its downstream consequences)
 - o Risk assessment guidance for alloys
 - o Preparation of exposure scenarios
 - o Assessment of emerging issues such as nanos, mixtures
 - o Development of an alternative for the PBT approach
 - o Evaluation, authorisation, restriction and the related socio-economic analysis requirements

II. Executive Committee recommendation

The REACH projects are widely recognised by commodities and companies as being valuable and even indispensable for a sound implementation of REACH. They will however be of value to more than the EM and even commodities members as they will be used by the consortia which membership is wider.

The Executive Committee therefore recommended that the financing of the projects should be supported by a wider share of those who will benefit from it that is by the consortia. As Eurometaux's members are the commodities, the proposal is to invoice the commodities that will invoice the consortia. As the management of the projects require extra personnel, the cost of such human resource support is to be added to the overall project costs. It also recommended that training activities be self-financing, i.e. against fees.

III. REACH-related projects

III.1. Development of a metal specific guidance for Socio-economic analysis (SEA) for substances subject to restriction and authorisation.

- ⇒ REACH authorisation procedure is potentially of concern to all CMR (substances classified as carcinogens, mutagens or toxic to reproduction) substances and restriction for all metals potentially.
- ⇒ Aim: Capacity building on SEA with a view to providing guidance to companies and consortia on how to prepare a SEA for substances subject to authorisation/restriction.

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- ⇒ Multi-year joint project with ICMM (scoping study foreseen in 2009).
- ⇒ Budget: € 29.000 in 2009 and 30.000 in 2010 (ICMM share: € 25.000 in 2009) + communication.
- ⇒ Benefit: provide guidance towards consistent and sound SEA for metals industry
- ⇒ Risk: ban of substances; restrictions/authorisation

III.2. REACH Implementation and Communication towards a cost-efficient and harmonised implementation of REACH

- ⇒ Aim: Information sharing, legal advices, advocacy (workshops, trainings will be paying)
- ⇒ Budget: € 10.000 in 2009 and € 5.000 in 2010
- ⇒ Benefit: multi-metallic and cost-effective approach if carried out at EM level rather than at commodities level
- ⇒ Risk: less cost and time efficient approach by individual consortia.

III.3. Downstream consequences of classification & labelling under GHS (global harmonised system)

- ⇒ The draft CLP regulation requires that all substances, regardless of their status under REACH, be assessed for classification and notified to the CLP inventory by Dec 2010. To date most bulk products such as ores, minerals and concentrates have not really been subject to Dir EC 67/548, as they all came under generic EINECS numbers
- ⇒ Aim: Provide the industry with the needed analysis for implementation and argumentation for advocacy towards cost-effective consequences and provide metals specific guidance as to the necessary changes to be applied e.g. transport, Seveso directive. Advocacy, analysis and communication are part of the exercise.
- ⇒ Budget: € 15.000 in 2009 and € 15.000 in 2010
- ⇒ Benefit: avoid excessive cost for the implementation of classification requirements especially for bulk materials that are so far not subject to the classification requirements.
- ⇒ Risk: costs, new requirements (e.g. waste storage facilities becoming Seveso sites).

III.4. Translation of the present risk assessment concepts into the EU REACH Implementation projects (EU guidance on REACH implementation-RIPs)

- ⇒ As the HERAG/MERAG (human health and environment risk assessment methodologies for metals) are scientific reference work, they have to be translated into possible regional applications.
- ⇒ Aim: ensure that the data gathering can be used for risk management by different interested parties. The project includes communication to members and authorities.
- ⇒ Budget: € 15.000 in 2009.
- ⇒ Benefit: sound use and recognition of the metals specific concepts for risk assessment by authorities.
- ⇒ Risk: inappropriate risk assessment concepts validated in EU official guidance for the implementation of REACH. Potential high costs for the industry.

III.5. GHS joint project (Global Harmonised System)

- ⇒ REACH does not include classification requirements as it links with GHS (and the EU version CLP)
- ⇒ Aim: Translation of GHS in the EU guidance on REACH implementation on classification & labelling, including improvement to new critical endpoints (e.g. bioavailability).
- ⇒ Follow-up on the OECD GHS and UN-GHS bi-annual programme to ensure sound follow-

- up. Includes communication, training and guidance to members.
- ⇒ Budget: € 20.000 in 2009 - € 10.000 in 2010 - € 5.000 in 2010.
- ⇒ Joint project with ICMM.
- ⇒ Benefit: sound translation of the GHS for REACH implementation and hence avoid costly implications of ill classification.
- ⇒ Risk: ill classification of metals with potential implications on transport, sites and market access.

III.6. Finalise and update hazard/risk assessment guidance on alloys (MERAG/HERAG)

- ⇒ HERAG/MERAG are useful references for RA of substances but they do not include guidance for alloys.
- ⇒ Aim: Finalise generic scientific/technical guidance on alloys classification and risk assessment for environment/human health toxicity endpoints. Including guidance on read-across. Includes training (budget not included) and communication with industry and the regulators.
- ⇒ Continue updating and develop new MERAG/HERAG fact sheets to anticipate new challenges.
- ⇒ Budget: € 20.000 in 2009 - € 10.000 in 2010 -
- ⇒ Partly financed by ICMM and commodities.
- ⇒ Benefit: provide authorities and industry with a sound and internationally recognised methodology for the risk assessment of metals.
- ⇒ Risk: ill risk assessment of alloys under REACH.

III.7 Tool to facilitate data gathering under REACH and development of exposure assessment tools

- ⇒ Chemicals legislations like REACH require extensive exposure data gathering. In the absence of data, one needs to model exposure (environment, workers). There is no appropriate human inhalation model at the moment for metals.
- ⇒ Aim: contribute to an ongoing project carried out by a series of research institutes to develop a metals-appropriate model to assess inhalation. The model shall be available on a software platform in 2010 but a beta version shall be available in June 2009.
- ⇒ Budget: €30.000 in 2009.
- ⇒ Benefit: ensure the use of a sound tool to assess workers' exposure in the framework of the implementation of REACH.
- ⇒ Risk: wrong estimates of exposure in exposure scenarios. Moreover, there is a possibility that authorities use modelling in the evaluation phase and in particular the model developed by these research institutes. If there is no metals input in the model that is developed the exposure estimates that will be generated will be unrealistic overestimates and label workplaces at risk

III.8 MERAG and HERAG training and updates

- ⇒ MERAG and HERAG are sound and widely recognised scientific references for metals risk assessment but in order to ensure that the guidances remain references and are not quickly outdated, they need to be updated regularly.
- ⇒ Aim: Practical training in risk assessment of metals for the environment/human health (not in budget – self-financing). Promote use and acceptance of MERAG/HERAG at international/regional/national and industry levels through training and communication activities.
- ⇒ Aim: Ensure that the guidances remain up-to-date and hence a sound reference through regular updates.

⇒ Budget: € 10.000 in 2009 - € 10.000 in 2010 - € 10.000 in 2011

III.9. Unit World Model (UWM) - PBT (persistent bio-accumulative - toxic substances)

- ⇒ The metals industry is temporarily exempted from the PBT principle under REACH and is challenged to develop a new alternative. The Unit World Model is an alternative approach to the PBT criteria as the latter are recognised as not applicable to metals.
- ⇒ Aim: translate (consultancy) and advocate the UWM as a sound alternative to PBT. It may prevent metals entering authorisation for environmental reasons.
- ⇒ Budget: € 20.000 for 2009 - € 20.000 for 2010
- ⇒ ICMM is requested for support in 2010.
- ⇒ Benefit: ensure appropriate methodology for assessment and classification of metals hazards.
- ⇒ Risk: ill classification of metals as hazardous with potential significant impact on market access and costs, application of traditional PBT approach to metals during REACH authorisation phase if no alternative is proposed.

III.10. Methodology and strategy to assess and manage the risks from inorganic particles

- ⇒ The size, shape and form of inorganic particles may imply different chemical properties that will need to be assessed under REACH.
- ⇒ Aim: understand the influence of the form, shape, size and mineralogy when assessing hazard and risk of inorganic particles and develop a strategy on how to assess the risks from inorganic particles.
- ⇒ Budget: € 5.000 for scoping study in 2009 – later budget to be defined according to needs/relevance.
- ⇒ Benefit: gain knowledge on the risk management of particles and provide authorities with a sound assessment of the issue before they regulate it.
- ⇒ Risk: classification of inorganic particles for effects caused by inhalation with potential restrictions, bans...

Project	2009	€	2010	€	2011	€
1. SEA	29.000		30.000			
2. REACH implementation & communication	10.000		5.000			
3. Downstream consequences of classification & labelling under GHS	15.000		15.000			
4. Translation of RA concepts into RIPs	15.000					
5. GHS	20.000		10.000		5.000	
6. HERAG/MERAG Alloys	20.000		10.000			
7. Tools to facilitate data gathering + exposure assessment tools	30.000					
8. MERAG/HERAG training and updates	10.000		10.000		10.000	
9. Unit World Model - PBT	20.000		20.000			

10. Methodology to assess and manage inorganic particles	5.000	Tbd	Tbd
TOTAL REACH projects	174.000	100.000	15.000
Cost of one-man equivalent	75.000	75.000	75.000 (tbc)
TOTAL	249.000	175.000	90.000

IV. Cost estimates

As all consortia will need the vast majority of the information, tools and methodologies to be generated by the above projects, sharing the cost of the project should be done on a global basis (no project based financing).

Considering the below consortia (22)

Al – As – As – B – Bi – Be – CASI/Si – CaC2 – Cd – Cr – Co – Cu – Mg – Mn – Mo – Ni – Pb – PGM – Sb – Sn – V – W – Zn

And considering that out of 22, some 17 would like to fund and benefit from the projects, the following cost could be invoiced to each commodity (to be confirmed according to the real number of commodities supporting the projects).

2009	2010	2011
€ 249.000	€ 175.000	€ 90.000
Divided by 17 the cost per commodity would be		
€ 14.650	€ 10.295	€ 5.295

Considering the number of consortia for each metal and the number of members in each consortium, it is assessed that the extra cost per company would be very limited for the number of projects.

V. Way Forward

Each commodity is asked to commit itself in the written form for the payment of the above amount for 2009 and 2010.

The management of the projects will be ensured by Eurometaux.

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