

# **Chemicals management of Nickel** (Risk Assessment-Risk Reduction-GHS-REACH) **a status report**

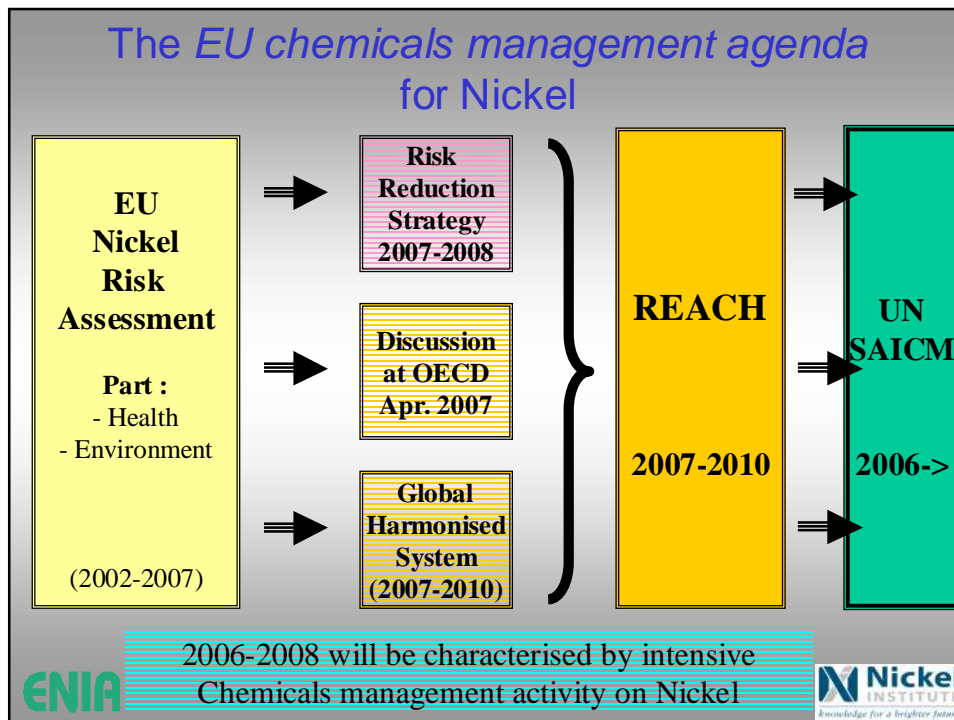
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Secretary General  
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## **Content**

- An overview perspective of CHEMICALS MANAGEMENT
- Global Harmonised System (GHS)
- Status EU RISK ASSESSMENT
- RISK REDUCTION STRATEGY
- REACH and RIP's





## GHS

- Result of **UN Rio SD** world summit 1992
- Worldwide **harmonised UN recommendation**
- **Scope** :
  - HAZARD assessment and
  - RISK communication
- **Impact** :
  - General harmonisation (although not complete)
  - Change in classification, packaging, labeling, SDS,  
...

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## GHS (2)

- GHS **updated** every 2 years
- Most **countries prepare implementation** :
  - EU : draft regulation open for comments
  - US : draft text open for comments
  - SA : ready
  - Au : draft text open for comments
  - Russia and China : evaluating how to implement
  - .... And many, many others ....

**BUT :**

- Implementation is different between “blocks”
- Unclear yet how Ni will be classified in other regions
- WW Influence expected from OECD discussion !



## Objectives of Risk Assessment

LEVEL	AIM :	SCOPE
• LOCAL	Safe production of Ni	Workers Receiving Environment Local Public Health
• REGIONAL	Safe use of Ni	Environment (country level) Workers in user sectors Product use safety
• CONTINENTAL	Safe use of Ni	Environment General Public health



## Status of EU Nickel Risk Assessment

SECTION	Status Health part	Status Env. part
• Hazard id	FINISHED (2004)	FINISHED (April 2005)
• Exposure assessm.	FINISHED (2004)	FINISHED (Jan. 2006)
• Effects assessm.	FINISHED (2004)	<b>ONGOING</b> (June-Sept.'06)
• Risk Characterisation	FINISHED* (2004)	<b>ONGOING</b> (Sept.-Dec.'06)
• Conclu. i) R&D.	ONGOING (2007)	FINISHED

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## Status of EU Nickel Risk Assessment

(1)

- Env. Risk Assessment on Ni **under finalisation**
- Contains several significant **new concepts** improving metals Risk Assessments :
  - Correction for **Bioavailability**
  - How to handle **large data sets**
  - **Ecoregion concept** recognising the variability of natural conditions
  - ....

**Industries objective on RA:** proactive support of activities based on sound science, and weight of evidence approach

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## Status of EU Nickel Risk Assessment (2)

### Ni env. RA will be benchmark for :

- Safe production and use at *local* and *regional* level
- Environmental quality standard setting
- Worldwide level : Effects data sets and Risk assessment methodology

Several non EU countries already indicated RA activities in the field of chemicals management: *US, Japan, Australia, ...*



## Hazard classification

### Hazard classification :

- On Ni and 5 Ni RA compounds :
  - finished.
  - GHS proposals will be forwarded to OECD
- Proposal to **similarly classify 150 additional Ni compounds !**
  - Based on “read across” concept of “solubility for all toxicity endpoints”
  - Lacking Science basis for Read across

### Risk of wrong Read Across application :

- Stigmatisation of Ni and Ni compounds
- Market restrictions since CMR substances may not be used in consumer applications in the EU
- Serious precedent



## Role of the OECD review

- OECD reviews internationalize national/regional substance RA's (HPVC program)
  - HVPC : High Volume Product Chemicals Program
- OECD reviews limited to “*effects part*” and to a lesser extend the “*Risk Characterisation*” conclusions.
- *Exposure assessment* is not reviewed assuming use & exposure being potentially different between OECD MS's
- OECD reviews follow a strict procedure and dossiers are submitted by a *Rapporteur country* (Denmark)
- The final outcome of the OECD review is published under the auspices of the UN



## Legal status OECD reviews

- *OECD* produces guidance documents for OECD & UN memberstates and international institutions
- **NO LEGAL requirement** for OECD MS's to adopt/implement the data sets **BUT** :
  - Most OECD/UN MS's accept data sets since too cumbersome to redo the overall assessment at national level
  - UN and other int. agencies use “*OECD reviews*” as reference
  - Approved data sets fall under the “*mutual data acceptance rule*”
  - GHS classification recommendations are strong reference source for countries/producers and users Worldwide, implementing GHS

OECD reviews & GHS recommendation become therefore in practice a primary reference source for national, regional or international Env., Workplace or Consumer legislation



## Expected Timing of OECD review on Nickel

### Timing milestones :

- Development by Denmark of:
  - The IUCLID file on Human Health (HH) : March-June 06
  - The IUCLID file on Environment (ENV): 2nd Sem. '06
  - SIAP HH / ENV : 2nd Sem. '06
  - GHS classification statement 2nd Sem. '06 (by DK tbc)
- Deadline for submission SIAP & IUCLID : 21 Jan'07
- Electronic Discussion Forum (EDF): End of Jan-March 2007
- Review SIAP by DK Rapporteur : Beginning of April 2007
- OECD SIAM 24 : 3th wk April-2007



## Why is Ni RA discussion at OECD so important ?

- Effects assessment is **most extensive** metal file ever
- Took for the first time all **MERAG concepts** in consideration going much beyond what was done in previous metal RA's so far (Cd, Zn, ...)
- **New concepts** will be applied in other metal files (Cu, Pb, ...)
- Introduces **Environmental Classification** accordingly to GHS recommendations (*distinctive classification for massive and powder form !*)

The Ni **OECD** discussion will **set a (unique) milestone** for metals RA and the **benchmark for Ni worldwide**



## Ni Risk Assessment General Conclusions

### Suggestions :

Industry would appreciate IF :

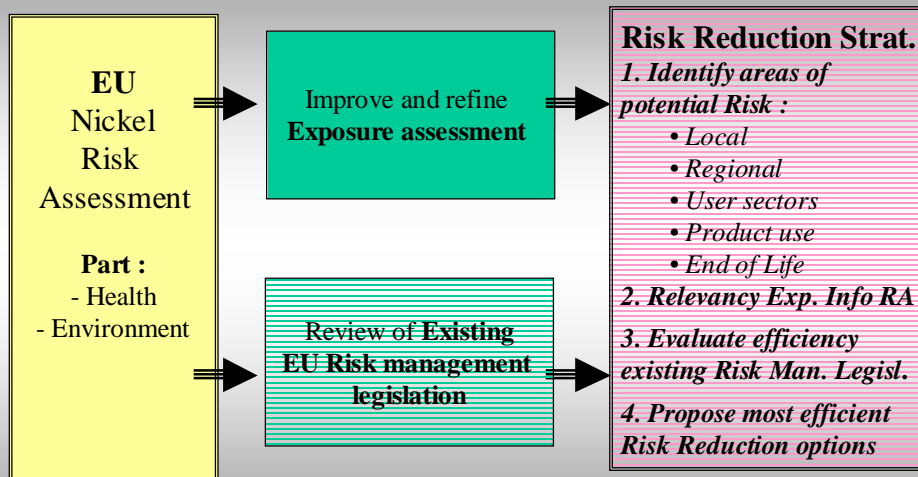
- In general
  - Countries could consider **relevancy of new concepts** for metal risk assessments
- For Nickel
  - Countries could **familiarise themselves** with new concepts
  - **Review the Ni RA** in detail when released in Jan. 2007

Industry would be most willing to provide any further background on this subject if needed

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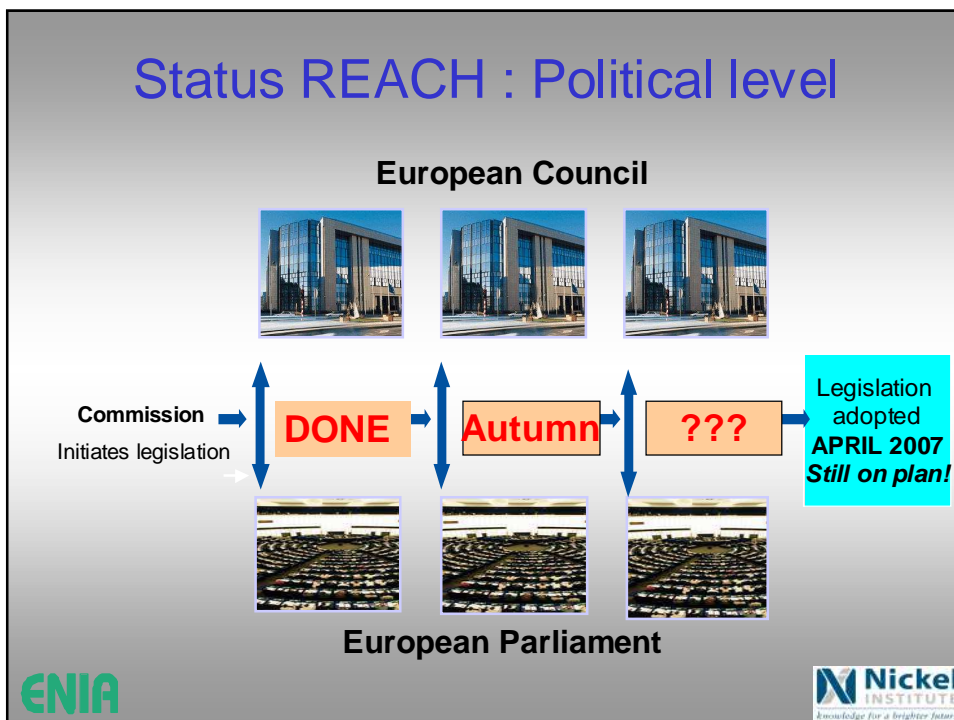
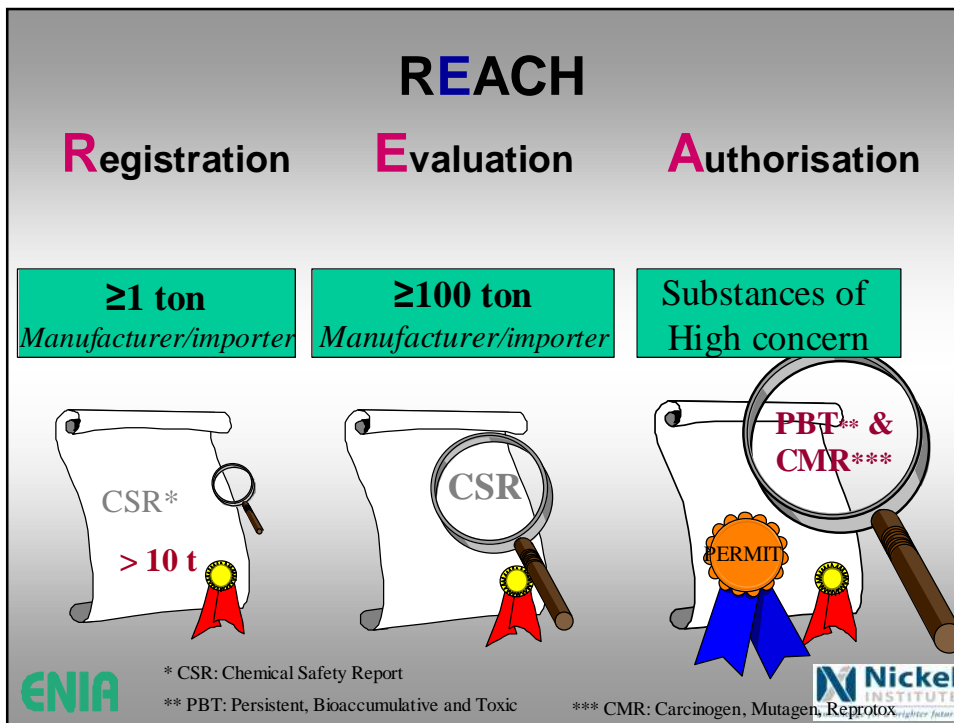
## Risk Reduction : *the next step*



Industry started **anticipative actions** in preparing for the Risk Reduction phase

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## REACH main outstanding policy issues for the metals and mining industry (incl. Ni)

### Most **critical issues** for Ni associated with **AUTHORISATION part or REACH**

- Minerals, ores and concentrates are excluded from REGISTRATION but NOT from AUTHORISATION
  - Most will fall under authorisation due to natural impurities !!!
- High focus on SUBSTITUTION without recognition of Sustainability considerations
  - Leading to non risk/SD based solutions
- Limited validity of the Authorisation granting
  - Discriminative for industries with long product lifetime/development



## Status REACH : Political level

### Timing

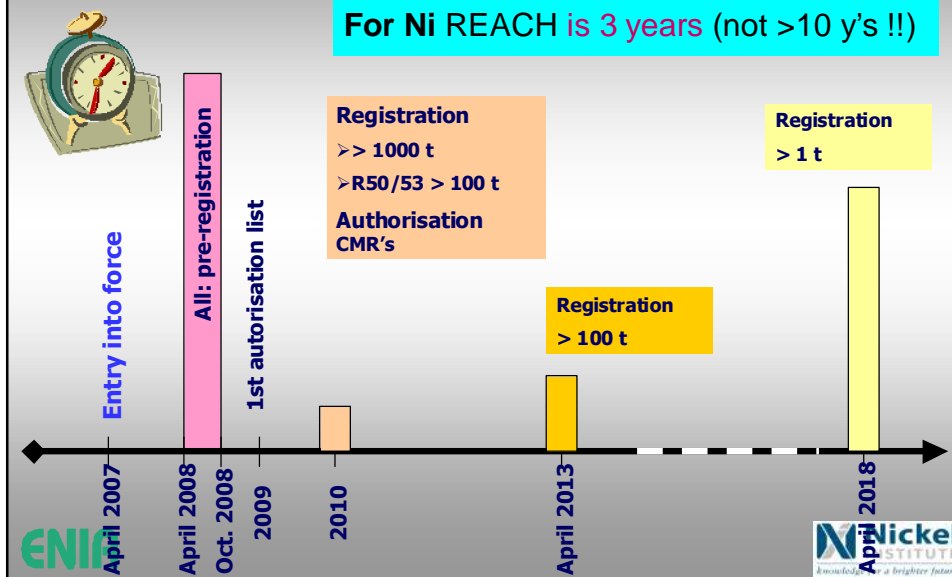
- 3 Oct. '06: Discussion in EP Environm. Com.
- 10 or 20 Oct.'06: Vote in EP Environm. Committee
- **14 Nov. '06: Plenary Vote in EP**
- 4 Dec. '06: Expected vote in Competitiveness Council and possible final approval of REACH (Second reading).

Entry into Force still foreseen for April 2007



## REACH Implementation timeline

For Ni REACH is 3 years (not >10 y's !!)



## EU RIP program

RIP = very large EU program preparing tools and instruments to implement REACH

### Importance for metals and Ni :

- Recognition of Hazard and RA methodologies (link with MERAG and HERAG)
- Will determine "read across" rules (to avoid testing)
- Will determine prioritisation tools for Authorisation, Evaluation and Restriction
- ...

OECD and other non EU countries are involved in the RIP drafting and review

RIP's are a worldwide relevant project for metals & Ni industry

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## EU RIP program

### Key program areas for NI for 2007 :

- RIP 3.2 & 3.3 : on testing methodologies / requirements, and rules for Read Across and Exposure scenario's
- RIP 3.4 : Pre-registration and data sharing
- RIP 4.3 : On prioritisation for Authorisation/Evaluation
- RIP 3.1 : Integration of CSR-Evaluation-Authorisation
- RIP 3.9 : Socio Economic analysis

Collaborative action with **Eurometaux/Eurofer**  
NI focussing on RIP's of specific relevance/importance for Ni  
Demonstrate leadership on REACH implementation

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## Ni response to REACH : *build on Ni RA !*

### PRE- REGISTRATION – REGISTRATION - EVALUATION



### AUTHORISATION



**Conclusion** : key steps clear except for Authorisation

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## NI industry response to REACH and RIP's

- Very **active involvement of Ni** industry experts in **RIP drafting groups** (coordinated by Eurometaux)
- Nickel Institute started **REACH implementation preparation** already
- “D-day” start REACH implementation Consortia : 23 Jan '07
- **Nickel Institute REACH Consortia** :
  - Will guide Ni industry to implement REACH (2007-2010) (Pre-registration – Registration – Authorisation)
  - Open for all Ni producers and importers world wide



## NI industry response to REACH

- 11 Steps approach:

– Step 1: Clarify issues of interpretation related to REACH scope	
– Step 2: Clarify status of Ni primary materials	
– Step 3: Organisation/Management aspects	2006-2007
– Step 4: Members approval of REACH implementation plan	
– Step 5: Anticipate critical Pre-Registration, Registration and Authorisation	
– Step 6: Pre-Registration phase	April 2007-2008
– Step 7: Planning Registrations	
– Step 8: CSR on Ni and Ni Compounds	April 2008-2010
– Step 9: CSR for primary materials and intermediates	
– Step 10: Authorisation phase	2007-....
– Step 11: Consortia in Authorisation	2009??



## Conclusions

As a responsible industry NI believes in the principles of **proper Chemicals management** and will **provide proactive support** to the Ni production and import industry **to increase their knowledge and comply with REACH**

