

Chemicals management of Nickel

(Risk Assessment-OECD outcome-
Risk Reduction Strategy-GHS)

A status report

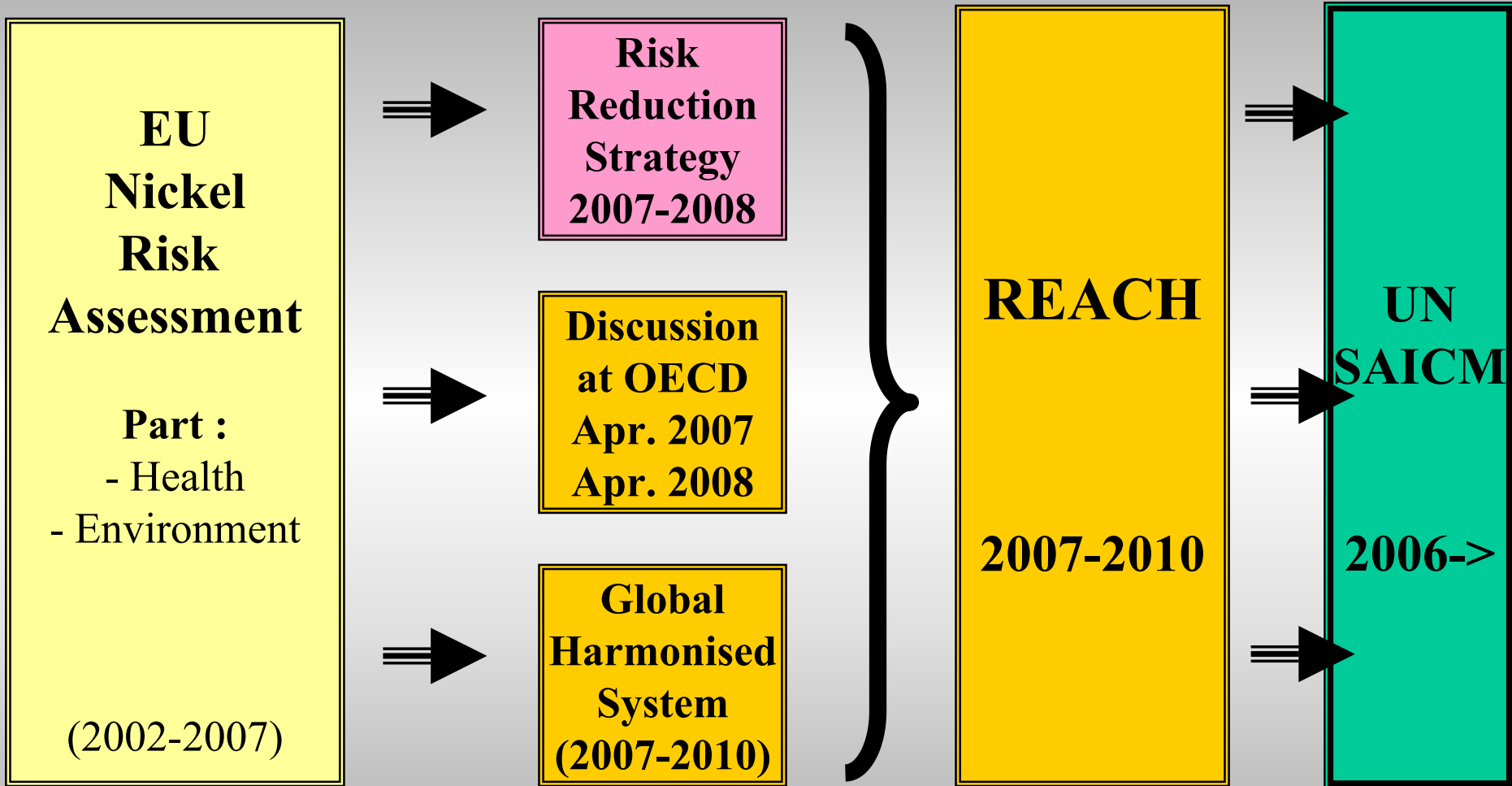
Steve Barnett (President NI)

Hugo Waeterschoot (Secretary General ENIA)

Content

- An overview perspective of CHEMICALS MANAGEMENT as a refresher
- Status EU RISK ASSESSMENT and OECD Ni review
- EU RISK REDUCTION STRATEGY
- GHS for Ni and Ni compounds

The *EU chemicals management agenda* for Nickel



2006-2008 will be characterised by intensive
Chemicals management activity on Nickel



Objectives of Ni Risk Assessment

<ul style="list-style-type: none"> LOCAL 	<p>Safe production of Ni</p>	<p>Workers Receiving Environment Local Public Health</p>
<ul style="list-style-type: none"> REGIONAL 		<p>(country level) rs</p>
<ul style="list-style-type: none"> 		<p>Health</p>

Level of interest at OECD / UN

Ni-RA : EUROPE



- **Health part** : finished in 2006
- **Environment** : major recent progress
 - Acceptance of BIOAVAILABILITY (soil, water, ...)
 - Acceptance of ECOREGION
 - Discussions expected to finish end of 2007

CONCLUSIONS Environmental RA on Ni :

- MAJOR *improvement in assessing Ni (metal)* in a better way!
- Improves assessment for Ni production sites and use applications, very considerably and
- Allows *higher env. standards* while safeguarding protection level
- Opens the way for use new techniques in *other jurisdictions*

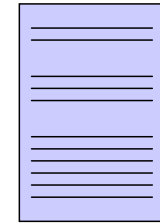
Role of the OECD review



- 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 extent the “*Risk Characterisation*” conclusions.
- *Exposure assessment* is not reviewed assuming use & exposure being potentially different across 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
- OECD provides recommendations for MS which are usually seen as a valuable contribution

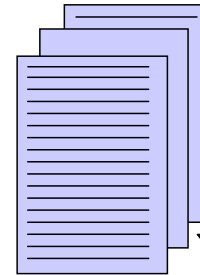
Documents considered at a SIAM

SIDS Profile (SIAP)



One to two-page 'Executive Summary' of the SIAR, along with conclusions and recommendations of the SIAM and their justification.

SIDS Initial Assessment Report (SIAR)



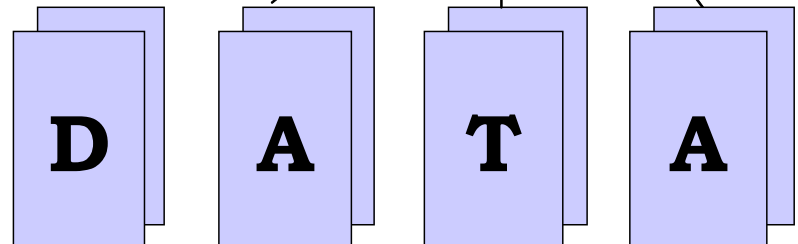
Presents and assesses key information relevant to hazards. The basic document reviewed at a SIAM.

IUCLID Data base



Basic reference that cites all available, relevant information, and contains the individual Robust Study Summaries of key data.

Study Data



Executive summary incl. recommendations for OECD MS's Published by OECD and UN

RA background of info for any other interested country (= copy EU RA- effects section only)

Basic data set used as reference WW (Mutual acceptance obligation)

**OECD review :
the document flow**
ENIA

Ni-RA : OECD



- **HEALTH** section :
=>discussed at SIAM 24 and **SIAP finalised !!!!**
- **ENVIRONMENT** :
=> presentation of methods/concepts to OECD

Next steps :

- HH publication of the SIAP
- ENV. : SIAM 26 in April 2008

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Environmental Risk Assessment of Nickel:
*Concepts and latest methodological RA
developments for metals*

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Hugo Waeterschoot, ENIA
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ENIA

Nickel
INSTITUTE

INSTITUTE
knowledge for a brighter future

ENIA

Ni-RA : OECD



Outcome SIAP debate on Ni-Health :

- Balanced wording and recommendations
- Different as in EU RA
- Balanced compromise on mention of uncertainty related to NiCO₃ read across (can be changed in the future, pending new tests)
- Elimination of all references to “Read Across” for carcinogenicity likelihood of all Ni compounds
- Elimination of references to Risk Reduction (e.g. welding)
- Addition of nickel particle size as an influencing factor

Outcome :better than expected

Ni-RA OECD



SIAP recommendations related to Health

Suggestions for OECD Member States

- Take note of the conclusions and recommendations of the *OECD Health Nickel review*
- Consider the *Ni RA health data base as a robust and high quality reference data set* recommended for national/regional assessments
- Take note of the *new RA concepts and methodologies presented for the env. RA of Nickel* and other metals
- *Support the review of the Environmental RA* on Nickel in April 2008
- Consider *GHS hazard classification & labelling proposals* as a recommendation for national reference / implementation

The Ni Industry would welcome discussing the outcome of OECD with INSG members

Hazard classification

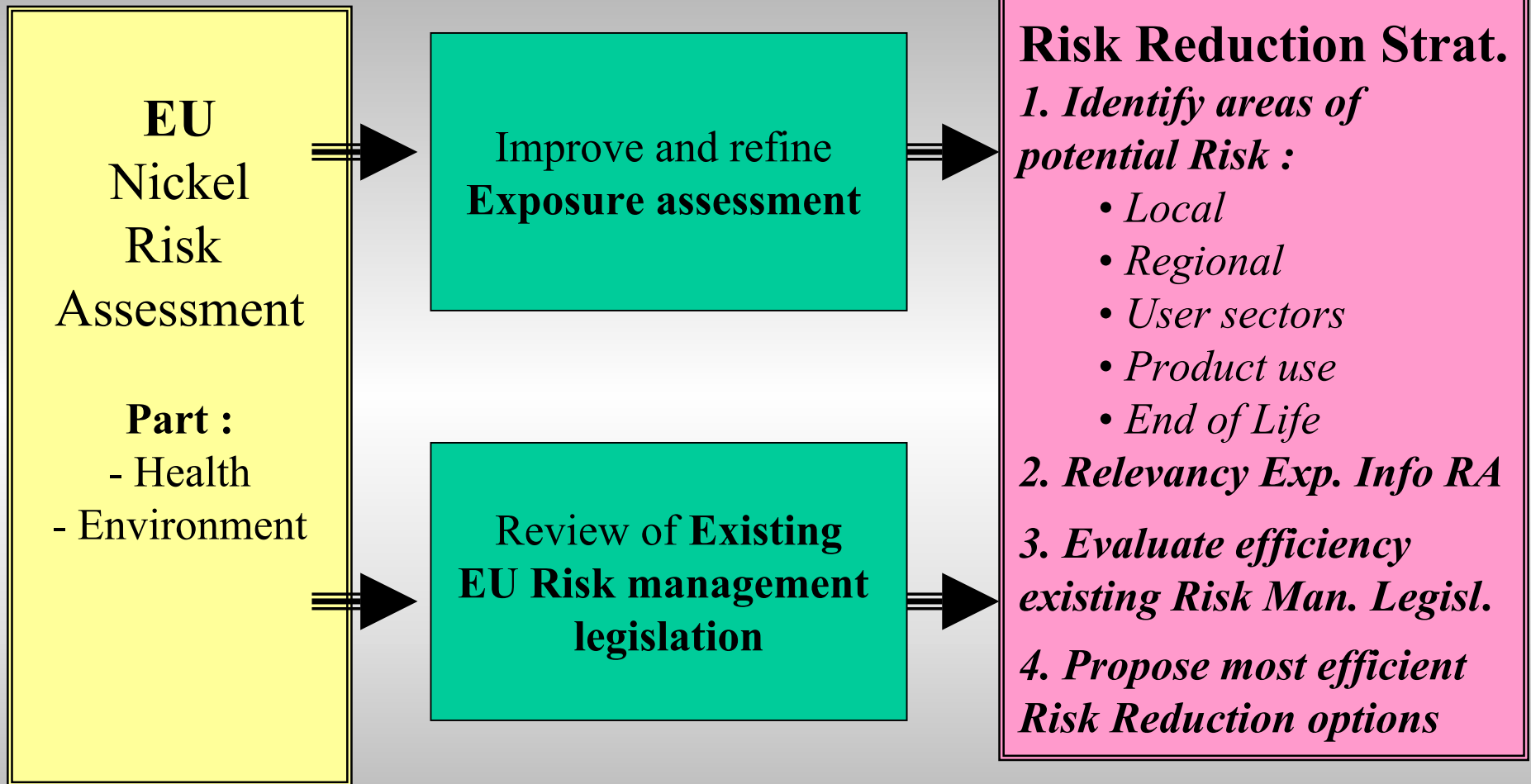
EU Hazard classification :

- **On Ni and 5 Ni RA compounds :**
 - finished.
 - GHS proposals will be forwarded to OECD
- EU Proposal to **similarly classify 150 additional Ni compounds !**
 - Based on “read across” concept of “solubility for most 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 are scrutinised and may be restricted in consumer applications in the EU
- Serious precedent for all other metals

Risk Reduction : *the next step*



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

Risk Reduction Strategy on Nickel

- *Draft Nickel Risk reduction recommendations* for Health part, be discussed by EU on 11 May !!
- In general *recommendations are minor and reasonably relevant*
- Draft *recommendations* of Denmark:
 - Need for OEL for Nickel
 - Need for restriction of Ni additives to food
 - Need for EU policy on Hyper sensitised persons (to Ni)
 - Need for Risk reduction strategy for welding process

Nickel industry supports these considerations IF assessment and Risk Reduction Suggestions are based on sound science

GHS Hazard Classification System

UN- Global Harmonised system

- Worldwide system
- Aiming for harmonisation o
- Focussing on “Hazard assessment”, “Classification” and “labelling”
- Countries around the globe are implementing GHS :
 - Japan, Australia, South Africa, EU, US, ...
- Biannual review by UN



GHS Ni classification proposals

- **Voluntary OECD program** requesting MS / Industry to submit UN-GHS proposals to OECD in preparation of international review workshop
- Aims : *Outreach knowledge and experience* on GHS implementation using real cases
- **Relevance for Nickel ?**
 - First metal reviewed under GHS
 - Demonstration on different classification for “massive” vs “powders”
 - Included most updated science info overruling some of the old info used by EU in its 2005 review
 - Industry provided Denmark and interested MS’s with GHS Ni classification proposals
 - Worldwide reference

GHS for Ni

Industry

- Requested *independent consultant* to update & review Ni RA hazard data set
- Made *GHS profiles available* for Denmark and interested OECD MS's (Australia, Canada, ...)
- GHS profiles available for Ni metal (massive and powder), Ni chloride, Ni nitrate and Ni sulphate

Industry invites **INSG members** to take full profit from independent work done and take full note of GHS profiles when implementing GHS in own countries