

EC nickel classifications

A non scientific methodology not meeting the strict data requirements of the Dangerous Substances Directive and that may be applied to all substances under REACH

Lisbon, 6 October 2008

Introduction

Aims

- Nickel Consortia under REACH
- To update INSG on 30th and 31st ATP developments
- To ask for support in challenging the nickel entries in 31st ATP

Nickel Consortia

- 3 Consortia in Operation
 - Risk Assessed Substances
 - Intermediates
 - High volume substances not in RA
- Pre-registration by December 1
 - Over 250 metal legal entities pre-registered
- Nickel di-oxide on preliminary priority list
 - Removed
 - Other Nickel substances expected in next round
 - Will require eventual substitution.
 - 9 nickel substances on NGO Substitute it Now (SIN) list

ATPs

Nickel Institute Objectives

1. Ensure good science underpins regulation
2. Have nickel carbonates re-classification reversed
3. Prevent the 31st ATP with ~120 nickel substances being adopted with classifications as CMR category 1 and 2 without data
4. Prevent the duplication of error-based EU classifications to other regions
5. Provide an environment in which nickel metal future classification will not be adversely impacted
6. Regulatory decisions based on sound science

Update - 30th ATP

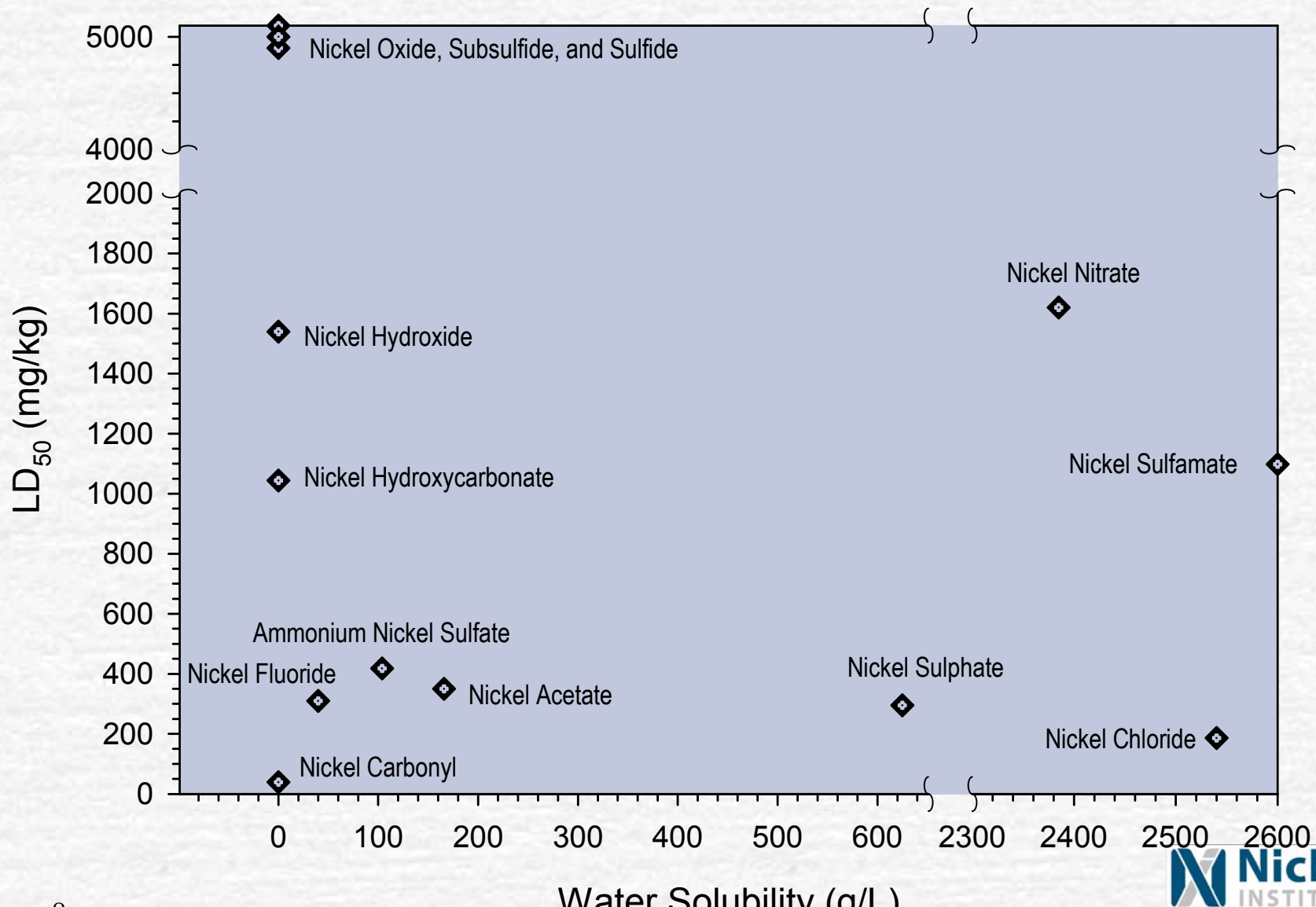
- Classifies 5 nickel substances
 - Concern: nickel carbonates based on derogation statement - worst case assignment of nickel sulphate properties
- Finally published 15 September 2008
- Came into force 5 October 2008
- Ombudsman complaint ongoing
- Legal action being prepared
 - Letter Before Action sent to UK HSE on 18 September
- Transfer of classifications into new CLP Regulation?

31st ATP

Background - 31st ATP

- Proposal to classify ~120 nickel compounds based on water-solubility read-across method
 - Without any data (even water solubility)
 - Method is not OECD compliant
 - If these classifications are approved, it will be impossible to modify them, even on the basis of new data (for CMR)
 - Scientific alternative (with data) exists
- Method deemed to be used as a precedent under REACH for all other metal substances
- Industry believe Classifications not legally or scientifically sound and more trade restrictive than necessary

Water Solubility vs. Oral LD₅₀ for nickel compounds



Consequences

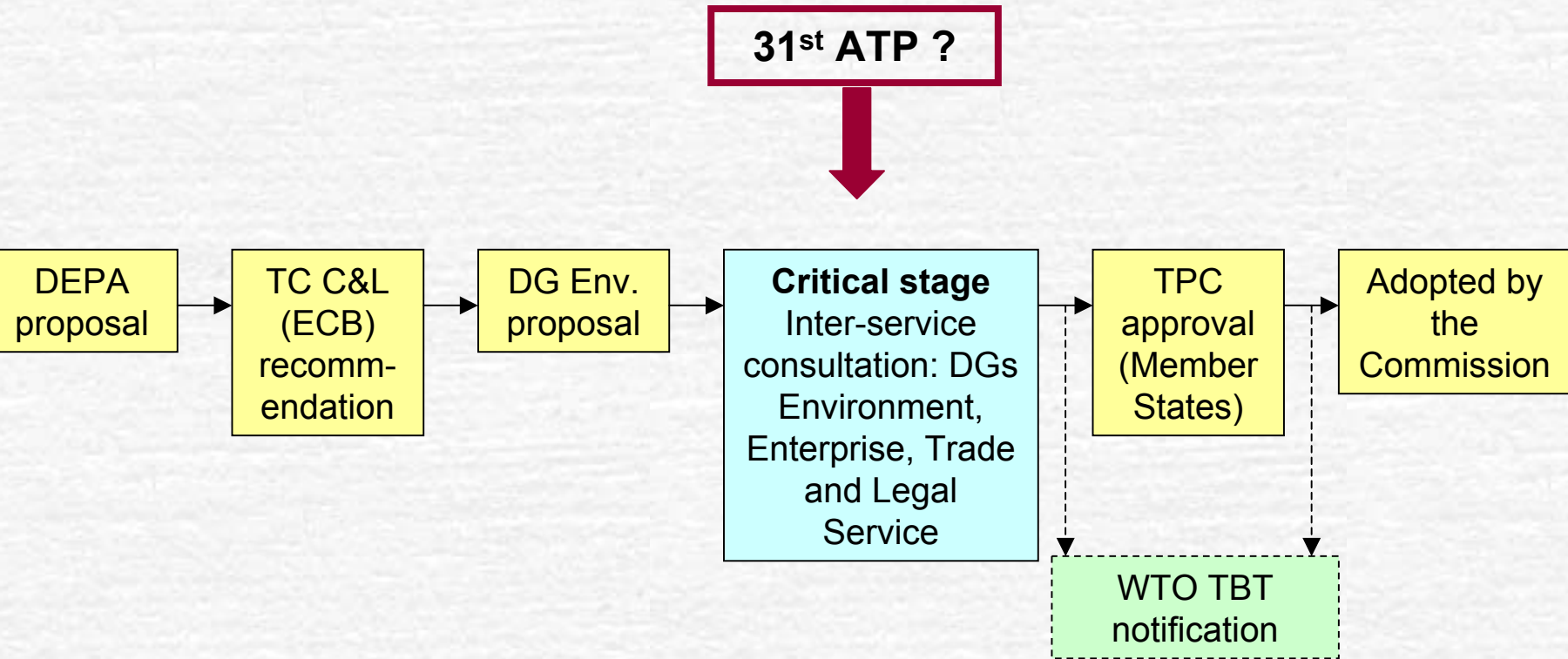
Europe

- REACH
 - Substances of Very High Concern (SVHCs)
 - May be subject to authorization and substitution
 - Method without data to be applied to other substances
- Significant downstream regulatory consequences:
 - Worker H&S measures
 - Restrictions on investments - Seveso
 - Impact on green uses / procurement

Worldwide

- Nickel to appear the most hazardous of all metals
- Stigmatization effect to provoke a drastic downsizing of nickel use in metal applications (e.g. stainless steel)
- Domino effect in other regions of the world
- Unjustified impact on maritime transport, making it practically impossible

Procedure for adopting 31st ATP



Update 31st ATP

- Intensive advocacy efforts with other Commission services resulted in:
 - Negative Opinion from DG Enterprise
 - DG Trade and Legal Service raising important concerns
- Extraordinary meeting of MS experts held on 29 September to discuss 31st ATP nickel classifications
- WTO TBT meeting on 5 November

Meeting 29 September

- Discuss classifications
- Examine
 - Scientific basis of the water solubility methodology
 - Whether legal criteria for classification were respected
 - Two scientific studies questioning the methodology
 - Independent experts (commissioned by Industry)
 - Australian Ministry of Health
- Industry delegation limited to 2 persons ...
- Australian delegation limited to 1 person ...
- ... and only for the morning session

Meeting 29 September

Morning Session

- Presentations from Australia (NICNAS), Eurometaux and Nickel Institute
- Constructive and positive discussion

Afternoon Session

- Only with Member States experts
- Discussion on DG ENV's written questions
- 7 Member States expressed doubts about the carcinogenic classification (proven effects on human)

Next Steps

- By 10 October :
Comments on the DG ENV written questions awaited from MS experts and Industry
- Week of 13 October :
EC InterService Group to convene in order to decide on whether and which nickel inclusions in the 31st ATP
- 5 November : WTO TBT meeting
- **Depending on the outcome of the WTO mtg, DG ENV could then reconsider the nickel entries**
- 10 November :
Official vote of the Member States on the 31st ATP as a whole
- Immediately after :
Notification of the 31st ATP to the European Parliament for a month (“droit de regard”)
- End December :
Official vote of the Commission on the 31st ATP

WTO Meeting : 5 November

DG ENV's plan is to adopt the 31st ATP just after the WTO meeting, i.e. without taking its views into account

...

.. because DG ENV is keen to adopt the 31st ATP with the nickel entries before the adoption of the Global Harmonised System on Cl. And Labelling

- At that point, the only remaining opportunity to stop the proposal is a very clear and strong opposition by the WTO

Current Actions

- **Member States**
express their doubts on the methodology (especially carcinogenicity) during the consultation ending on 10 October
- **WTO countries**
express their opposition to the methodology used for nickel entries in the 31st ATP
- **All : Request the withdrawal of the nickel entries**
 - REACH makes it mandatory to propose classifications on the basis of data, with strict rules on potential test waiving

Thank you !