

Analysis of Risk Management Options Nickel Monoxide

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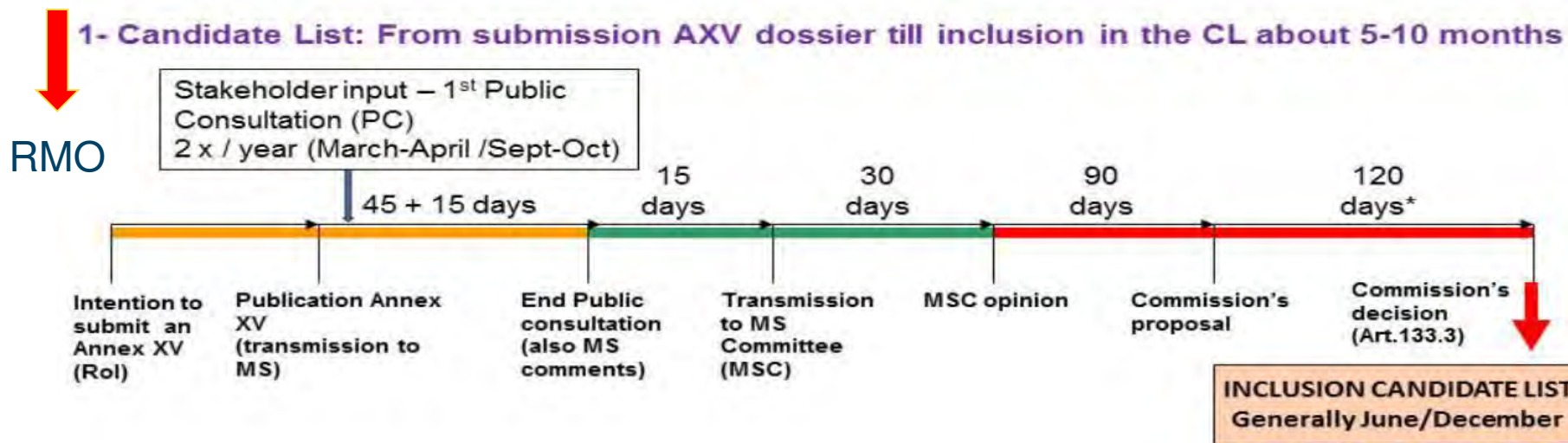
1.

What is an RMO?



Why an RMO?

- EU Member State analysis of risk management options
 - Identify concerns of risks
 - Identify and choose risk management option
 - Share with other MS (NB: voluntary)
 - Promote early discussion and lead to common understanding
 - Timing: before legal initiative is formally decided, e.g. Annex XV dossier



What does an RMO contain

- Summary of legal status
- Review of available information, e.g.:
 - Hazards, risks, uncertainties
 - Use, use conditions, compliance/ reality check
 - Analysis of Alternatives
 - Socio-economic considerations
- Identification of concerns
- Identification of possible RMO's
- Evaluation of suitability of RMO
- Conclusions

RMO – new template

- Does the substances fulfil Art. 57 criteria
- Uses of the substance
 - Art 58(2) Uses exempted from authorisation
 - Is the substance a potential substitute for another CL substance
- Evidence for unacceptable risks requiring immediate action and sufficient basis for initiating a restriction
- Policy reasons why authorisation is not the desired outcome
- Conclusions

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RMO on nickel monoxide (NiO)



Background

ANSES has selected the following substances to be considered:

- **Nickel sulphate (CAS 7786-81-4)**
- Nickel hydroxycarbonate (CAS 12607-70-4)
- Nickel dichloride (CAS 7718-54-9)
- Nickel dinitrate (CAS 13138-45-9)
- **Nickel monoxide (CAS 1313-99-1)**
- Nickel bis(dihydrogen) phosphate (CAS 18718-11-1) (i.e. not included in the nickel REACH Consortia)

Aim of the project

- Prepare systematic and fully justified RMOs on nickel oxide and nickel sulphate in 2013
- Report to be used in consultations with the French authorities and others

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Existing regulation



REACH

- Registration in 2010; and updated on yearly basis
- REACH, Annex XVII, 28:
 - Carc. 1A and 1B substances must not be contained in consumer products
 - Restriction on release of Ni from jewellery, etc.
- No ROI or Annex XV dossier on a nickel substance has been submitted by MS

CLP – Nickel Oxide, harmonised classification

Nickel monoxide (CAS No. 1313-99-1)

Skin Sens. 1 H317 - May cause an allergic skin reaction

Carc. 1A H350i - May cause cancer by inhalation

STOT RE 1 H372 ** - Causes damage to organs through prolonged or repeated exposure

Aquatic Chronic 4 H410 - Very toxic to aquatic life with long lasting effects

Directives of relevance to nickel oxide

Work environment

- Carcinogen and Mutagen Directive,
- Chemical Agents at Work Directive
 - Provisions for limit values for exposure (OEL)

- National OEL values do exist!
- DNEL Reg. dossier; long-term inhalation: 0.05 mg Ni/m³ *
- SCOEL recommendation (2011) long-term inhalation: 0.01 Ni/m³ *

* Inhalable fraction

Directives of relevance to nickel oxide

Exposure of humans via Environment

- Directive on Ambient Air Quality (20 ng Ni/m³)
- Drinking water Directive (0.020 mg Ni/L)

Directives of relevance to nickel oxide

Environmental regulation

- Establishment of EQS: 4 µg Ni/L (fresh), 8.6 µg Ni/L (marine).
- Groundwater directive (National limit values)
- Industrial Emission Directive (incl. BREF notes)
- Waste Framework Directive
- Mining Waste Directive

Other regulation of relevance

- Seveso III Directive (≥ 1 tpa nickel compounds, inhalable powder)
- Battery Directive (provisions on recycling, limits on Cd content with exemptions)
- Cosmetic regulation (nickel oxide is prohibited in cosmetics)
- Food contact materials (nothing on nickel substances)
- Food regulation (nothing on nickel substances)

Conclusion regarding existing regulation

- Nickel oxide is extensively regulated.
- Provisions in existing regulation cover:
 - REACH, adequate control of risks the entire life cycle + restrictions
 - CLP, communication of hazards
 - Work environment: MS OEL, recommendation from SCOEL
 - Environment regulation pertaining to water, air, waste
 - Industrial emissions (IED, BREF)
 - Consumer products: REACH, Annex XVII, 28; Cosmetics Directive

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Available information



Main uses of nickel oxide

Nickel oxide

Stainless, special steels and alloys

Nickel zirconium cores

Catalyst

Nickel powder

Electronic components

Enamel frits

Pigments

Glass

Available information, Overview

- Chemical Safety Assessment (registration dossiers)
- Uncertainty analysis of risk characterisation
- Analyses of Alternatives
- Socioeconomic analysis

Risk characterisation – Key points

Risk Characterisation,

- Long term inhalation: RCR is high in some exposure scenarios, e.g. handling of powder or cleaning and maintenance
- Uncertainty analysis point to:
 - long-term inhalation exposure of workers is not robust due to few measurements and use of Tier 1 exposure assessment tool.

NiO; Analysis of Alternatives

- production of catalysts and catalysts precursors
- production of pigments
- production of glass
- production of frits

NiO; Analysis of Alternatives, Catalysts

	Refinery	Hydrogen	Fertilizers	Bulk chemicals	Fine chemicals	Oleochemicals
Steam reforming/ Methanation	Red	Red	Red	Red	Grey	Grey
Hydrotreating (HDS, HDN, HDO)	Red	Red	Red	Red	Grey	Grey
Hydrocracking	Red	Grey	Grey	Grey	Grey	Grey
Hydrogenation	Red	Grey	Grey	Red	Red	Red
Amination	Grey	Grey	Grey	Red	Red	Grey
Sulfur trapping	Red	Red	Red	Red	Grey	Grey


 = nickel catalysts are being used

Table 1. Market/functionality matrix for nickel catalysts based on ECMA survey.

NiO; Analysis of Alternatives

Catalysts:

- There are only limited possibilities of substitution of nickel
- Consequences of substitution include:
 - increased capital and process costs, leading to increased price on oil products
 - inferior products and increased energy use (CO₂ emission)
 - less effective sulphur removal: increased sulphur in fuel and emissions to air
 - Depletion of alternative metals as ruthenium and platinum group metals

NiO; Analysis of Alternatives

Production of pigments:

- Where nickel is the main constituent there are currently no drop-in alternatives.
- For pigments where Nickel oxide is used as a modifier, the specific properties of colour tonality cannot be achieved with any other substance
- R&D is needed to find substitutes for pigments where Nickel oxide is used as a main constituent or modifier

NiO; Analysis of Alternatives

Production of glass:

- There is no drop-in alternatives to nickel oxide
- Crystal glass manufacturers have indicated that research is needed to identify alternatives to nickel oxide
- Erbium oxide, cobalt oxide and neodymium oxide are known to be decolouring agents, but not as global substitute to nickel oxide
- R&D is needed to find substitutes for pigments where Nickel oxide is used as a main constituent or modifier

NiO; Analysis of Alternatives

Production of frits :

- Possible alternatives to Nickel oxide in ground coat enamels includes a combination of metal oxides: cobalt oxide, manganese oxide, copper oxide and possibly antimony oxide
- For the moment none of these can replace nickel oxide as a colouring agent in glass colouring frits
- Further research and development would be needed.

Key observation – SEA;
Catalysts: NiO non-use scenario

Economic Impacts:

- Steam reforming and Hydrotreating catalysts application
 - Annual lost added value in EU27 of around 13-15 billion €
 - Investment costs related to application of CoMo catalysts, including R&D, are estimated in the range of 1 billion €.
 - Investment costs related to relocation range 7.5-8.3 billion €.

- Hydrogenation catalyst applications
 - Annual lost added value in EU27 of around 1.4 billion €

Key observation – SEA;
Catalysts: NiO non-use scenario

Human health impact: Monetised human health cost of cancer incidence range at 1.6 million €

Social impacts

- At least 150,000 jobs across the EU are shifted to jobs outside the EU
- Relocation of catalyst manufacturers and catalyst service companies may trigger relocation of research facilities

Key observation – SEA;
Catalysts: NiO non-use scenario

Wider economic impacts

- Loss of up to 0.14% of EU GDP due to net reduction in production value from steam reforming, hydrotreating and hydrogenation catalyst DU (16.5 billion €)

Key observation – SEA, pigments: NiO non-use scenario

Economic impact

- Manufacturers are concentrated in Spain, and the impacts will occur mainly in this region
- Investments and R&D costs are estimated at 335,000 EUR
- About 29% of manufacturers are planning to relocate to their facilities to outside the EU
- It is expected that EU suppliers may suffer losses of income of about 2.3 million euro.

Key observation – SEA, pigments: NiO non-use scenario

Social impacts

- Total employment in pigments manufacturers using Nickel oxide is estimated at roughly 1,800 jobs, 54 directly working with nickel oxide

Human health impact: cannot be estimated.

Key observation – SEA, Glass: NiO non-use scenario

Crystal glass

- **Investment costs** (22.2 million euro) and R&D costs (8.5 million euro) in total for around 22 companies.
- **Increased operating costs:** 0.5 – 17 .5 mill EUR depending on the alternative.
- **Social impacts:** It is estimated that maximum 25 companies, employing 11,000 people. The major part of manufacturers is confident to find and adopt an alternative
- **Human health impact:** Currently not possible to quantify

Key observation – SEA, Glass: NiO non-use scenario

Ophthalmic glass

- **Economic impact:** Due to relocation of production an annual loss of about 60 million euro is to be expected.
- **Social impacts:** Loss of employment for 350 people.
- **Human health impact:** Currently not possible to quantify

Key observation – SEA, Glass: NiO non-use scenario

Black Light Blue glass

- **Economic impact:** loss of production value is to be expected between 100,000 euro and 250,000 euro per year
- **Social impacts:** loss of 50 jobs in case of a refused authorisation.
- **Human health impact:** Currently not possible to quantify

Key observation – SEA, Frits: NiO non-use scenario

- **Economic impact**
 - R&D costs estimated at 2.6 million EUR
 - Increased operating costs : 1.1 Mill EUR + optional 1.3 mill EUR
 - relocation could potentially cause an annual loss of production value of around 0.7 million euro.
- **Social impacts:** no major social impacts, but relocation of about 90 jobs
- **Human health impact:** Currently not possible to quantify

Summary on the available information

Key points:

- Risk characterisation point to long-term inhalation as the main concern, often related to the handling of powder.
- For key applications of NiO, no alternatives are available
- Socioeconomic analyses identifies dramatic socioeconomic implications of non-use scenarios for NiO

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Objectives for possible further regulation of nickel oxide



Identified concerns

Long term exposure of workers by inhalation

- Some uses have relative high RCR
- Uncertainty analysis conclude the RCRs are not robust

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Analysis of RMO



Identified RMOs

- **RMO 1: Measures available in existing Community legislation**
- (RMO 2: Substance evaluation - not relevant)
- (RMO 3: (further) harmonised classification - not relevant)
- **RMO 4: Further restrictions under REACH Title VIII**
- **RMO 5: Authorisation under REACH Title VII**

Evaluation of RMO 1: Existing Community legislation

- The raised concern can be addressed through indicative OEL/ community OEL enforced at MS level.
- **Effectiveness:** National legal provisions for the work environment is in place and control and enforcement are well known. Effectiveness is **high**.

Proportionality:

- The cost effectiveness of using existing provision and control measures is **high**.
- Little additional administrative resources is needed to adopt new requirements.

Evaluation of RMO 1

Existing Community legislation

- **Practicality:** The obligations are well known to the operators of industrial sites. Division of roles and responsibilities is well known and monitorability **is high**.
- **Regulatory consistency:** Implementation across EU may vary because of differences in the legal implementation and enforcement. Regulatory consistency is **medium**.

Evaluation of RMO 4: Further restrictions under REACH Title VIII

- **Effectiveness:** A restriction seem less suitable. The raised concerns are related to very different industrial production processes and uses. There is no consumer exposure to NiO. The effectiveness is rated **low**

Proportionality:

- The cost effectiveness of a restriction depend on the scope but could be **high**.
- The administrative effort for preparing a restriction is high in the implementation phase and low thereafter because the provision are subject to existing inspection programs etc.

Evaluation of RMO 4: Further restrictions under REACH Title VIII

- **Practicality:** The clarity of new requirements implemented as restrictions of use is high. Division of roles and responsibilities is well known and monitorability **is high**.
- **Regulatory consistency:** A restriction under REACH is a community wide legislation and the regulatory consistency is therefore **high**.

Evaluation of RMO 5: Authorisation under REACH Title VII

Effectiveness: The concerns can be targeted efficiently by an authorisation of nickel oxide.

Proportionality:

- The cost effectiveness of an authorisation requirement is **low**.
 - Authorisation is very expensive for authorities and for industry.
 - Suitable alternatives are not available.
 - The socioeconomic consequences are high.

Evaluation of RMO 5: Authorisation under REACH Title VII

- **Practicality:** The clarity of an authorisation requirement is high as it targets the specific substance and its uses. Also division of responsibilities is clear and enforcement procedures available. The monitorability of the measure is **high**.
- **Regulatory consistency:** An authorisation is a community wide provision and the regulatory consistency is therefore **high**.

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Conclusions



Summary of evaluation of suitability

	RMO 1	RMO 2	RMO 3	RMO 4	RMO 5
	Existing legislation	Substance evaluation	Harmonised classification	Restriction	Authorisation
Effectiveness	High	-	-	Low	Low
Proportionality	High	-	-	High	Low
Practicality	High	-	-	High	High
Regulatory consistency	Medium	-	-	High	High

Conclusions

Recommended option:

- **RMO 1: Measures available in existing Community legislation**
 - Effective
 - Proportionate and Cost effective measure

Not recommended:

- **RMO 4: Further restrictions under REACH Title VIII**
 - measure seem not suitable
- **RMO 5: Authorisation under REACH Title VII**
 - Fails because of disproportional costs

Thank you

