



THE IMPLICATIONS OF “READ-ACROSS” CLASSIFICATION FOR NICKEL COMPOUNDS

This first INSG Insight in the series focuses on the implications of introducing “read-across” classification for nickel within the framework of REACH (the EU’s new chemicals policy) in the European Union. It analyses and assesses the issue of classification of nickel compounds by analogy that arose during the October meeting of the International Nickel Study Group and considers the wider implications of such a move.

INSG estimates for 2006 indicated that stainless steel accounted for two-thirds of primary nickel consumption. Nickel compounds that are the subject of potential read-across account for 6 percent of nickel usage. However, read-across classification has the potential to impact both total nickel usage and international trade.

Denmark, the EU nickel risk assessment reporting country, has proposed using one nickel compound, nickel carbonate (Ni CO_3), as a point of analogical reference for 150 other nickel compounds that it deemed to have similar chemical structure. The crucial point is that during the nickel risk assessment NiCO_3 was classified as a category 1 (proven) carcinogenic substance. If fully adopted read-across would mean that one in every ten of the substances that are considered to be of very high concern in REACH will be nickel compounds.

The fact that so many nickel compounds may be classified this way makes it likely that nickel metal could face substantial damage to its image and reputation. In turn this could damage its usage as an alloy in stainless steel.

Interest is being shown by World Trade Organisation (WTO) members on what is essentially a nickel technical and scientific issue prior to WTO’s next meeting on Technical Barriers to Trade (TBT). However, the effect of read-across could be wide-reaching not only for nickel but for other metal compounds. Member country representatives are invited to share this paper with their government and industry colleagues, and are also invited to suggest further topics to the Secretariat on which similar Briefing Papers might be prepared.

Comments or Questions

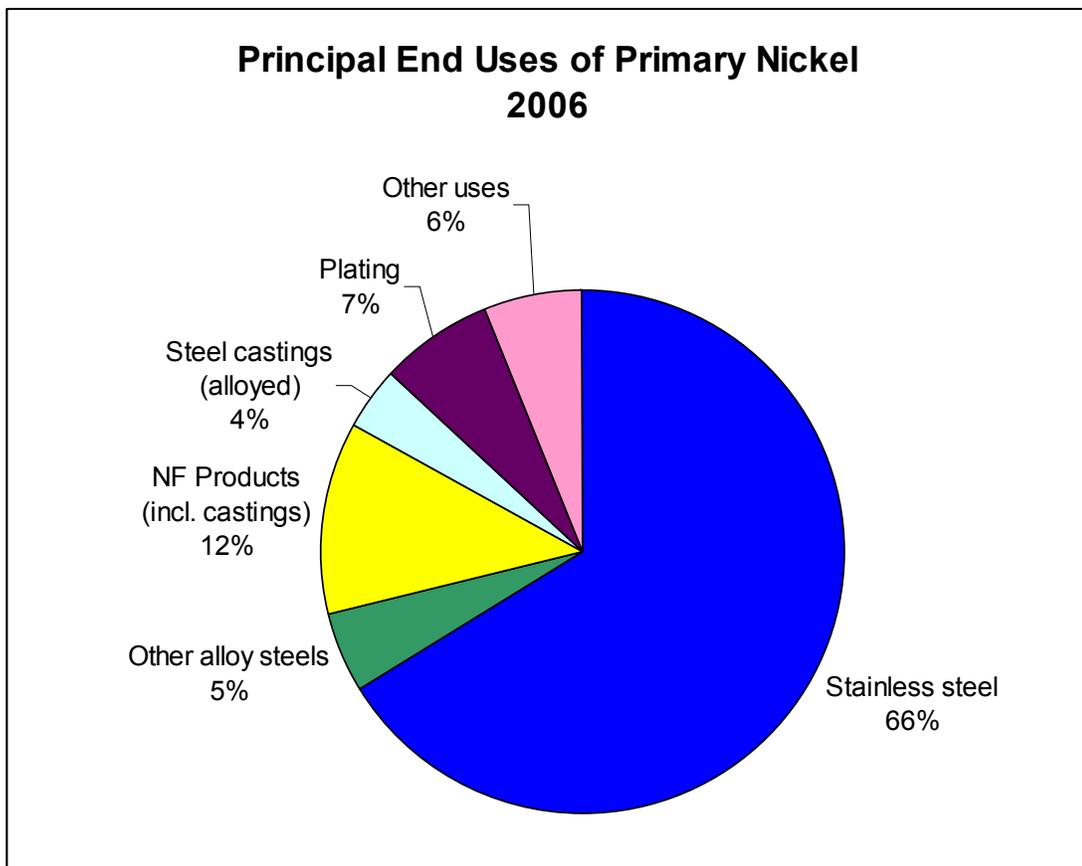
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The Implications of “Read-Across” Classification for Nickel Compounds

Introduction

Primary nickel usage is dominated by the stainless steel industry. INSG estimates for 2006 indicated that stainless steel accounted for two-thirds of primary nickel consumption. The next most significant market was nickel used in non-ferrous products, including castings, which accounted for about 12 percent of usage. Plating, steel castings and other alloy steels collectively accounted for 16 per cent of usage. Other uses, including the compounds which are referred to later in this “INSG Insight”, account for the remaining 6 percent of nickel usage. However, they are significant in that they are used by the nickel-battery industry.

Chart 1



Source: INSG

In 2002 the European Union began a risk assessment of nickel that has examined the effects of nickel production and usage by the sectors shown in Chart 1 on human health and the environment. Denmark assumed the role of “Rapporteur” country. The part of the human health nickel risk assessment relating to hazard identification, exposure assessment, effects assessment, and risk classification concluded in 2004. The environmental nickel risk assessment covering the same categories concluded in 2007. Although the compartment relating to hazard

classification covered five nickel compounds, as early as 2006 the Danish “Rapporteur” was proposing to similarly classify another 150 nickel compounds. This classification by analogy has become known as “read-across”.

Read-Across

In common with the risk assessments undertaken in the EU for cadmium and zinc, the nickel risk assessment process, which has lasted five years, proved to be longer than had been anticipated by both Denmark (the “Rapporteur” country) and the international nickel industry. To speed up the conclusion of the risk assessment the Danes proposed using one nickel compound, nickel carbonate (NiCO₃), as a point of analogical reference for 150 other nickel compounds that they deemed to have similar chemical structure. The crucial point is that during the nickel risk assessment NiCO₃ was classified as a category 1 (proven) carcinogenic substance, as category 2 (potentially) harmful to reproduction, and as category 3 (suspected) mutagenic.

This serious classification of NiCO₃ places it firmly within the group of substances that are regarded as most harmful and dangerous to the environment. To extend this classification by analogy, and as industry claims without data confirming proven effects on humans, to another 150 nickel compounds has two consequences within the European Union:

- It potentially stigmatises the entire nickel industry as producing an environmentally bad metal
- It places nickel firmly within the first wave of substances of very high concern that will be considered in the first process for authorisation and restriction of chemicals under REACH (the EU’s newly adopted Chemicals Policy).

REACH – the EU’s new Chemicals Policy

The EU’s new chemicals policy introducing a single system for existing substances (placed on the market before 1981) and new substances (thought to number 2,700) called **REACH** (Registration, Evaluation, Authorisation and Restriction of Chemicals) entered into force on 1 June 2007. Some 30,000 substances are to be assessed through the REACH process. It is expected that up to 1,500 substances that are considered to be of very high concern will be subject to authorisation. These substances fall into three broad categories:

- Substances that are carcinogenic, mutagenic or toxic to reproduction (CMRs)
- Persistent, bio-accumulative and toxic substances (PBTs)
- Substances that are very persistent and very bio-accumulative (vPvBs)

Once these substances are listed in Annex XIV, the manufacture and use of these substances will only be possible on the basis of an authorisation granted by the Commission in accordance with very strict conditions set out in the Regulation. The conditions include the submission of an analysis of the risk of alternative substances and their technical and economic feasibility as substitutes and of a substitution plan where suitable alternatives are available.

If the proposed read-across is fully implemented one in every ten of the substances that are considered to be of very high concern will be nickel compounds.

The cornerstone of REACH is the reversal of the burden of proof from the authorities to industry for testing and risk assessment of chemicals. Companies producing or importing more than one tonne of nickel compounds will therefore be expected to submit basic information about them to a central database held at the newly created European Chemicals Agency (ECHA) in Helsinki. Since metals are classed as high volume chemicals (and hence REACH priority substances) the nickel industry will have three years (instead of 11 years for lower volume chemicals) to comply with REACH requirements. The Nickel Institute estimates that assembling the data necessary to ensure the correct scientific classification of nickel compounds will cost in the region of €20 million. However, imposition of read-across will effectively render this data gathering phase inconsequential.

The International Repercussions of “Read-Across”

Industry argues that although the issue of read-across for nickel compounds may appear an internal EU matter it has wider international implications involving members of the World Trade Organisation (WTO). In February 2007 the EU convened its 30th Adaptation to Technical Progress (ATP) meeting that considered the adoption of the five risk assessed nickel substances, including NiCO₃ and a political decision was taken to adopt the risk assessment classification and to inform the WTO’s Technical Meeting on Barriers to Trade (TBT) that is due to convene in November 2007. Formal implementation of the 30th ATP decision on the risk assessed nickel compounds has been delayed until after this WTO meeting.

The European Commission has announced that the 31st ATP, that is due to meet in early 2008, will take a political vote on the adoption of read-across to the other 150 nickel compounds that have been targeted. In advance of this meeting a number of WTO member states, including Australia, Brazil, Canada, China, Japan, South Africa and the United States have lodged comments to the TBT and have requested that the European Commission provide data relating to NiCO₃. Separately the Russian Federation (not a member of WTO) has written to the European Commission to voice its concern on the read-across issue. These countries view the implementation of read-across to 150 nickel compounds as a potential technical barrier to trade imposed without sound scientific data. It is argued that at stake is not only international trade in nickel, but also trade in nickel containing alloys such as stainless steel.

The European Commission will reply formally to the comments and requests for clarification lodged by WTO members at the November TBT meeting at the WTO. Only after these comments have been answered will the decision of the 30th ATP to formally adopt the risk assessed classification of the first five nickel compounds be implemented.

The Nickel Industry's Position

The nickel industry welcomes the EU risk assessment process for nickel compounds as a means of using sound science to address a range of environmental and health issues within the nickel industry and beyond. The industry has also reacted positively to the nickel risk management phase that follows risk assessment since there is widespread agreement that it represents a chance to set a worldwide benchmark for safe production, environmental quality setting and the international adoption of effects data sets and risk assessment methodology for nickel and nickel compounds. Industry's concerns are focused on differences in opinion over hazard classification, which arise from the implementation of read-across.

There are two broad areas where the nickel industry has expressed its concern to the Danish "Rapporteur" arguing that

- The premise that read-across can be made from NiCO₃ to other nickel compounds is flawed
- Denmark has not followed the correct nine step procedure for read-across to be applied and industry has not been given enough time to formally respond.

To support its first claim the nickel industry launched two studies to disprove the Danish assumption that nickel hydroxycarbonate and nickel hydroxide had a similar chemical structure, resulting in Ni(OH)₂ being assigned the same classification as NiCO₃. The first study, recently completed, revealed "diverse chemical structure" between the three compounds, which they argue therefore appears to confirm that there should not be read-across from one to another. The results of a second study are expected before the end of the year.

Turning to the procedural question, industry has pointed out that OECD Guidance on Chemical categories (read-across of nine steps, imposing testing for scientific validation of read-across) is being unilaterally changed by Denmark. Industry is concerned that Denmark is trying to insert read-across into future guidance for REACH within REACH Implementation Plan (RIP) 3.3.2 which focuses on alternatives to testing. All the RIPs have yet to be finalised and stakeholder expert groups will have a chance to make their concerns known to the consultant contracted to complete each RIP for the European Commission at the end of December 2007. However, if adopted in its current form, using RIP 3.3.2 in this way would, in practice, allow straight read-across without some testing for scientific validation not only for nickel but for other compounds.

The point about the relevance of the OECD guidelines is very significant for countries beyond Europe. Not only does the Danish two-step proposal challenge the status quo but it also has implications for the introduction of the UN-sponsored Globally Harmonised System (GHS) that is intended to harmonize hazard classification and risk communication of chemical substances. In the EU it is expected that GHS regulation will be implemented in the middle of 2008. All accepted EU classifications (including those arrived at through read-across) would then be grouped together as an Annex to GHS. Such an annex would likely influence the implementation of GHS in other regional blocs of the world and could

conceivably quickly widen the impact of read-across of nickel compounds to a global scale.

Conclusions

The read-across question is nearing a crucial stage driven by Denmark's push to have the result of the EU's 30th ATP meeting implemented. This would entail the immediate classification of the five risk-assessed nickel compounds. It would also prepare the way for NiCO₃ to be used to read-across to a further 150 nickel compounds.

The full implementation of read-across for all these nickel compounds could have a significant impact on the nickel industry well beyond the nickel chemicals specifically targeted. All nickel compounds would be classified as Category 1 (proven) carcinogens without the need for corroborating data. As a consequence nickel compounds would be likely to be among the substances of very high concern that will be considered in the first process for authorisation and restriction of chemicals under REACH.

It has been argued the fact that so many nickel compounds may be classified this way makes it likely that nickel metal could face substantial damage to its image and reputation. In turn this could damage its usage as an alloy in stainless steel.

Interest is being shown by WTO members on what is essentially a nickel technical and scientific issue prior to the organisation's next meeting on Technical Barriers to Trade (TBT). However, the effect of read-across could be wide-reaching not only for nickel but for other metal compounds.

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