

March 24, 2010

## ROOM DOCUMENT FROM CANADA

### NICKEL

- Canada has numerous concerns relating to the EC's classification of over 130 nickel-containing substances as carcinogenic and dangerous under the first adaptation to technical progress (ATP). These classifications may negatively impact Canadian exports of nickel containing substances to the EU worth some \$5.4 billion Canadian dollars.
- The following is a summary of Canada's concerns for which we request a response.

#### **Classification of Nickel-containing Substances**

- Canadian industry still has significant concerns regarding the scientific validity of the classifications of the nickel compounds that were adopted by the 1<sup>st</sup> ATP to the Regulation on classification, labelling and packaging (CLP).
- Most recently industry has brought to our attention that they are generating data as part of the REACH registration process that puts in question the EU's assumption that a wide range of toxicological effects in the human body can be accurately predicted by grouping nickel containing substances on the basis of water solubility alone. This assumption provided the basis upon which the EU applied the read across methodology to classify the majority of nickel compounds that were adopted by the 1<sup>st</sup> ATP to the CLP.
- Canada seeks assurances from the EU that it will give serious consideration to the data industry is producing as part of the REACH registration process as well as other relevant, sound scientific information.
- Moreover, we seek assurances that in light of this information the EC will review its classifications of nickel in a transparent and objective manner. To this end, we request information on the transparency, oversight and peer review measures that will be put in place to ensure data submitted by industry under REACH is adequately considered.

#### **Downstream Consequences of the Classifications**

- The EC has characterized the nickel classifications contained in the 1<sup>st</sup> ATP to the CLP as 'mere labelling requirements', but we remain very concerned about their potential downstream impacts.

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- For instance, on the basis of these classifications, nickel substances have been added to the so-called "Substitute it now!" (Sin) list drawn up by a coalition of environmental campaign groups. The list has been drawn up by an umbrella group called the International chemical secretariat (ChemSec) and is aimed at "speeding up implementation of REACH."
- Canada had previously commented on challenges being faced by industry as a result of reference to these classifications in the EU Toy Safety Directive. We now note with some satisfaction that the Commission has considered the risk associated with the use of nickel in stainless steel and created an exception for this use in toys.
- However, most recently through the TBT notification process we became aware (via G/TBT/N/EEC/297) that the EU intends to add over 100 nickel compounds to Annex XVII of REACH (via its Proposal to amend Annex XVII of Regulation 1907/2006 ('REACH')). This proposed amendment would ban the sale to the general public of substances classified as category 1 or 2 CMR in Regulation 790/2009 (the '1<sup>st</sup> ATP'), and mixtures containing them at above certain concentrations. Such substances and mixtures must also be labelled: 'Restricted to professional users'.
- Canadian industry stakeholders have expressed concern that the EU has not properly assessed the addition of these nickel compounds to Annex XVII against the legal requirements of REACH.
- Canada understands that the legal basis for the Proposal is Article 68(2) of REACH which allows a substance that, "meets the criteria for classification as carcinogenic, mutagenic or toxic to reproduction, category 1 or 2, and [that] could be used by consumers and for which restrictions to consumer use are proposed by the Commission" to be added to Annex XVII of REACH (emphasis added).
- While Canada understands that the Commission has made considerable efforts to understand the consumer uses and potential risks posed by other substances in the Proposal, such as borates (see recitals 4, 5 and 6 of the proposed EC regulation), Canada has received reports from industry stakeholders indicating that the same work has not been done for nickel substances.
- Moreover, industry has also informed us that very few of the nickel substances contained in the 1<sup>st</sup> ATP to the CLP are used by consumers. The legal text of REACH suggests that the Commission has to show that the nickel compounds (and mixtures containing them) could be used by consumers in a way that could create a risk in order for them to be added to Annex XVII.
- The EC has assured the TBT Committee on several occasions that the consequence of classification is limited to labelling. However, the current

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proposal is clear evidence that classification has other far-reaching consequences.

- While Canada supports the objectives of protecting human health and the environment, as well as the principle of restricting consumer exposure to products containing carcinogenic, mutagenic or toxic to reproduction (CMR) substances, Canada is concerned that imposing a ban on the sale of the nickel compounds to consumers without first assessing whether consumers are even at risk, is more trade restrictive than necessary and does not appear to take into account the risks non-fulfilment would create, contrary to Article 2.2 of the TBT Agreement.
- We would appreciate receiving information on:
  - What information the EU has on how nickel compounds in the proposal “*could be used by consumers*”?;
  - What steps the EU has taken to assess the potential risks to consumers from the use of these nickel compounds?; and
  - Whether the EU has or will conduct an impact assessment on the effect of its classification of nickel substances?
- As Canada has stated previously, given their potential to negatively impact nickel producers and exporters, it is essential that any classifications of substances be based on transparent, sound science. Similarly any measures that rely on these classifications must be developed in a transparent manner and must be proportionate to the specific risks posed.

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