

Dear Pre-Registrant

As informed to you by earlier E-mail, the **Nickel REACH Consortia (Ni Cs)** is acting for VALE INCO as the **Pre-SIEF Facilitator** for **nickel monoxide** (EINECS No. 215-215-7) and **nickel oxide** (EINECS No. 234-323-5)

A member company of the Nickel REACH consortium is prepared to undertake the obligations of Lead Registrant and to act as the SIEF Formation Facilitator for **nickel (mon)oxide** for the purposes of preparing and submitting the Registration Dossier, and where agreed the Chemical Safety Report (CSR), pursuant to REACH Article 11.

Ni Cs was launched on 1 January 2007 and formed on 1 September 2007 for the sole purpose of assisting industry to comply with REACH. It is an initiative of the Nickel Institute. The Consortium is comprised of the major EU manufacturers, major non-EU manufacturers, EU importers and traders, and their respective Affiliates.

Nickel Consortium is focusing on generating and compiling necessary data for the Registration Dossier (see below). Ni Cs has already dedicated substantial financial and personnel resources to this effort, and is progressing well. Ni Cs also benefits from the Ni Risk Assessment undertaken under the previous chemical policy. This was officially quoted by authorities at EU and OECD level as the best Risk Assessment ever done. Its members are committed to achieving submission of the Registration Dossier for **nickel (mon)oxide** before the first registration deadline of 1 December 2010.

The Consortium is undertaking to compile and assess all relevant existing studies and data necessary to prepare the Registration Dossier for **nickel (mon)oxide**. We will, as SIEF facilitator, collect information from the SIEF members as well as from sources outside the SIEF.

As mentioned above, Nickel Institute has already conducted an extensive Risk Assessment on Ni and Ni compounds. We are also working to develop read-across approaches, develop hazard classification and labelling proposals, identify and evaluate downstream uses [and exposure scenarios], and prepare the CSRs. Nickel Institute is providing human resources and administrative support to coordinate these efforts. Finally, the Consortium is well versed in the SIEF obligations, and has been developing strategies and systems to manage the SIEF process.

Access to the Registration Dossier

Ni Cs will ensure that all **nickel (mon)oxide** SIEF members intending to Register have timely access to the Registration Dossier for that substance to enable them to register with ECHA by the earliest deadline. In complying with REACH, we are seeking to balance sound science with responsible resource management. We are committed to making access to the Registration Dossier available on fair, reasonable and non-discriminatory terms. Interested companies will have two basic options to obtain the necessary access to information:

- Companies that plan to register in the highest tonnage band and/or companies wishing to provide resources and expertise to contribute to the development of the Registration Dossier **are encouraged to join the Consortium**. This will provide companies full access to all information and data developed by the Consortium. It is expected that joining the Consortium will be the most cost effective option for the active participants and companies in the higher tonnage bands.
- SIEF members who do not wish to join the Consortium will be able to obtain the Registration Dossier via a Letter of Access or License to use. The Consortium is currently assessing the likely cost for access to the Registration Dossier. The cost will highly depend on the number

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of companies intending to register **nickel (mon)oxide** and will be established on a fair, reasonable and non-discriminatory basis to include all of the costs (including administrative and scientific) associated with the preparation of the necessary information.

Next Steps

The first task is to move ahead with the Pre-SIEF activity i.e. to agree 'sameness of substance'. You will soon receive an E-mail with a link to a brief Pre-SIEF Questionnaire for you to complete and submit.

After evaluation of the Questionnaire responses, Ni Cs will then facilitate:

- the grouping together of all those pre-registrants that consider they do have the same substance, and they will enter into the SIEF for that substance.
- The grouping together of those pre-registrants that consider they do not have the same substance, for further discussion and potential entry into sub-SIEFs or another SIEF.

Ni Cs will also contact you again shortly with more details about:

the option to join the Consortium

the option to not join the Consortium, remain in the SIEF and fulfill your REACH Registration obligations by means of a Letter of Access to or License to use the Registration Dossier on fair, reasonable and non-discriminatory terms.

With kind regards,

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