Listing & Authorisation

ANSES MEETING (Paris, 2 July 2012)

Background

On Wednesday 27 June 2012, the ANSES (French agency for food, environmental and occupational health safety - http://www.anses.fr/), in charge of drafting of Annex XV proposals to be selected by the French Authorities, contacted us. The ANSES is still working on nickel salts which have been registered under REACH and on potential Risk Management Options which need to be put in place at EU level. They would like to solicit the Nickel Institute and the Lead Registrants to obtain detailed technical information on uses and related tonnages of some nickel salts). A meeting has been organized on Monday 2nd July 2012, in Paris, between the ANSES and the NI to:

- Allow the ANSES to explain the context and objectives of this request
- Discuss how the ANSES, the NI, the Lead Registrants and the downstream users can collaborate, taking into account the confidentiality issues related to the requested information
- Decide on a way forward to ensure the best collaboration between the different bodies.

Report of the meeting with ANSES

Participants:

- Nickel Institute: France Capon and Isaline de Baré
- ANSES: Arnaud Lagriffoul (Scientific Project Manager) and Karine Fiore (Socio-Economic Projects Manager)

Mr. Lagriffoul started the meeting reminding the work done by the ANSES in the past years on the nickel containing chemicals, focused mainly on nickel hydroxycarbonate, nickel sulphate, nickel dinitrate and nickel chloride in the context of the French pre-consultation. He explained also clearly the role of the ANSES: this is a separate independent agency providing technical and scientific support to the French authorities in food, environment and occupational health safety. This agency has no decision power nor political role in the REACH process. They have a neutral and separate role from the Ministry of Environment (the REACH competent authority).

Mr. Lagriffoul explained us that the Ministry of Environment has renegotiated the mandate that they gave to the ANSES regarding the assessment of chemicals in the context of the Authorisation. Following the last workshop between ECHA, Commission and Competent Authorities, it has been decided to give more weight to the Risk Management Option (RMO) analysis and to perform it as upstream as possible before deciding which RMO could be needed for chemicals (e.g.: No action, Authorisation, Restriction, OELs, classification or Substance Evaluation). An informal group has been created to discuss this issue: the “RIM”. ECHA drafted a template to perform this RMO analysis but which is not publicly available so far.

The ANSES has been requested to perform a RMO analysis on nickel containing chemicals and confirmed (at least) with ECHA that they will take the lead on the RMO analysis of nickel containing chemicals.

The ANSES followed the following reasoning to identify the substances that they would like to assess:

- In December 2010, 19 Ni salts from the 138 listed in the 1st ATP have been registered.

- They excluded 5 substances registered only as intermediates dossiers and 2 substances registered as full dossiers but with intermediates uses *a priori*.
- They preselected for further assessment 6 Ni salts of potential interest (the driver was mainly the types of uses) amongst the 12 remaining substances. However, the 6 remaining are currently not excluded from a potential further appraisal.

The 6 substances of interest are:

- 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) (NOT INCLUDED IN THE NICKEL REACH CONSORTIA)

The 6 other substances which could be considered for further appraisal:

- Nickel dihydroxide (CAS 12054-48-7)
- Nickel sulfide (CAS 16812-54-7)
- Nickel subsulfide (CAS 12035-72-2)
- Nickel sulfamate (CAS 13770-89-3)
- Nickel diacetate (CAS 373-02-4)
- Nickel difluoride (CAS 10028-18-9) (NOT INCLUDED IN THE NICKEL REACH CONSORTIA)

To perform the RMO analysis, the ANSES needs the following information on each substance:

- Existing regulatory context
- Objectives and reasons of potential RMO
- Details on existing RMO and RMM and their efficiency
- Hazard data, emission and exposure data
- Detailed uses (including description process to assess the intermediate uses) and related tonnages
- Analysis of alternatives including R&D
- Costs-benefits information for SEA

The ANSES would like to collaborate with the NI, the Lead Registrants and the downstream users to gather this information to ensure that a proper RMO analysis can be performed using reliable data. The ANSES will keep confidential ALL the data and only share with the French Ministry of Environment and the other Competent Authorities the conclusions of the RMO analysis.

The RMO analysis must be finalized by August 2013.

France presented to the ANSES the Nickel Institute and the Nickel REACH Consortia explaining the mandate and responsibilities of these bodies. She confirmed to the ANSES that since the first French pre-consultations, the Nickel Institute put in place a Listing & Authorisation Workplan in collaboration with the Nickel Consortia Members and downstream users. She presented the main projects on analysis alternatives, SEA case study and database on consumption of nickel salts in EU. The projects conducted now since two years by the Nickel Institute in collaboration with key stakeholders could already fill some data gaps identified by the ANSES in the context of the RMO analysis.

We agreed that:

- The ANSES will contact the Lead Registrants of the different substances to make a formal proposal of collaboration
- The Nickel Institute will play the role of coordinator and main interlocutor of the ANSES except, of course, if confidential data should be provided directly to the ANSES
- The Nickel Institute will check over summer the position of the different stakeholders involved in the NI projects.
- In September, the Nickel Institute will provide the ANSES with a formal reply of our future collaboration and a meeting will be organized to set up the practical aspects.

Next steps and actions

- **ASAP:** The stakeholders involved in the different NI project are invited to react to the ANSES proposal
- **July:** The Nickel Institute will perform a data gaps analysis: information needed versus information available in the Authorisation projects
- **July:** the Nickel Institute in collaboration with the consultants will prepare a detailed mapping of the participants to the different NI projects
- **August-beginning of September:** the Nickel Institute will contact individually the stakeholders to have a formal agreement on the data sharing with the ANSES: conclusions, full reports or raw data provided by the companies. The recommendation at a first stage is the share the non-confidential reports and to assess on a case-by-case basis which confidential information could be shared with the ANSES.
- **August:** assessment of the data gaps to be filled in Q3-Q4 2012 to address ANSES questions
- **September:** finalization of the practical aspects of the data sharing with the ANSES and meeting with the ANSES.
- **Q3-Q4:** fill in the major data gaps
- **Q4 2012-Q2 2013:** perform, in parallel to the ANSES, an internal RMO analysis on nickel containing chemicals

Conclusions

The Nickel Institute is happy to see that the ANSES decided to contact us upon recommendation of the French Ministry of Environment. **This is a big step forward in the collaboration and dialog with the authorities. This means that all the efforts put in the follow-up of the 2011 French pre-consultation are now paying back.** This significant and positive change in the attitude of the ANSES and the Member States in general is also due to the case of the listing of the cobalt in the Authorisation process. **We have now achieved a high level of credibility and trust with the French authorities. Therefore, we strongly encourage all the stakeholders involved in the different NI Authorisation projects to accept to share (at least) non-confidential data and conclusions of the work done in the past years.**