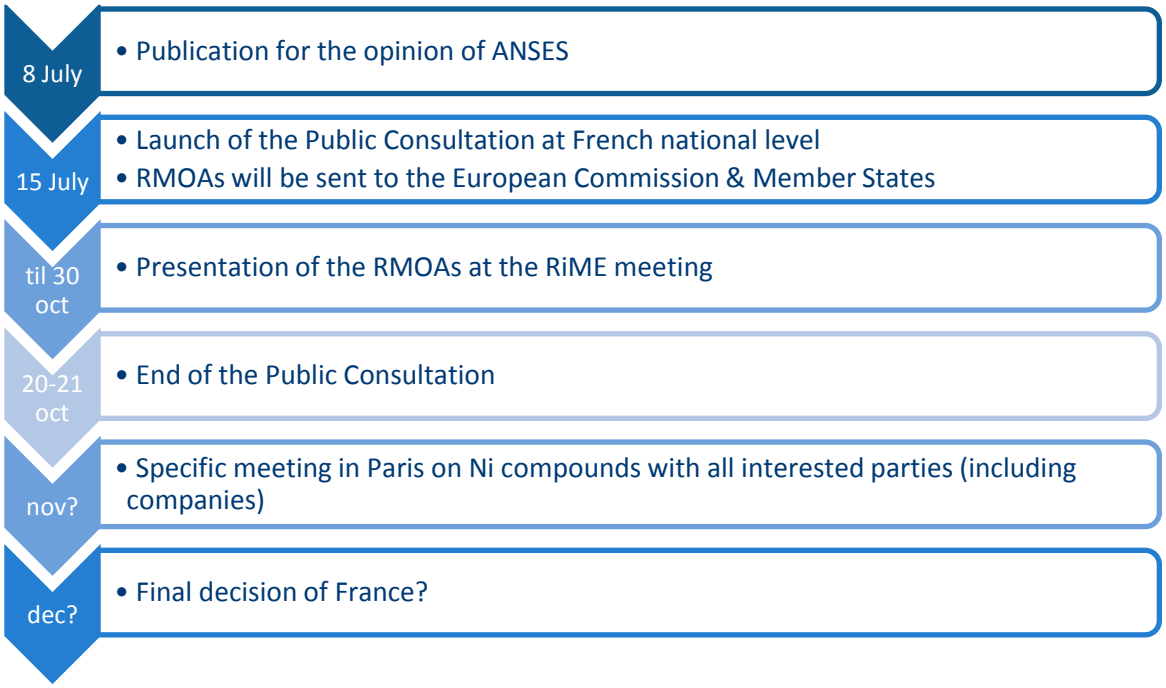
« GROUPE MIROIR » MEETING - 30 JUNE 2014

SUMMARY

The French authorities believe that OELs are the best risk management option, but they said that they couldn't accept any value above the SCOEL value (0.01 mg/m3 inhalable) as according to them, such a value would not be protective enough for the workers. A binding OEL is preferable above an indicative OEL.

TIMELINE



PRESENTATION OF THE RMOAS BY ANSES

ANSES presented their «analysis of the best risk management option » for nickel sulphate and nickel oxide (cf. ANSES presentation.

- For nickel sulphate, they do not include 2 GES because of sufficient information about these uses. For NiO, there are 4 GES that are not included.

- The use tonnages are very different depending on the source used (Eurostat, NI, REACH). ANSES considers that the figures from the NI are the most realistic.
- For NiSO4 they estimate that 40% of the use if intermediate, for NiO 90%.
- In their evaluation, ANSES has focused on workers as the consumer is not exposed to these compounds.

ANSES specified that there are a number of uncertainties regarding the exposure scenarios & an update is necessary. Under these conditions, they feel that the risk is not sufficiently managed & that the current DNEL is not protective enough. For the risk management, they believe that it is necessary to go for a BOEL of 0.01mg/m3 (inhalable fraction).

They gave an overview of the 3 main risk management options: i) OELs (CMD or CAD), 2) Restrictions & 3) Authorisation. However, Authorization only covers the uses of the substances whereas OELs & restrictions would cover the whole value chain.

1. Analysing the IOELs versus the BOELs, ANSES believes that the IOELs may not be sufficient for several reasons:
    i. possibility of different implementation across the EU;
    ii. the Member States may adopt values that are higher than the SCOEL value; relying on the willingness of industry to implement.
2. With respect to Restrictions, an « unacceptable » risk should be present. ANSES has shown that for NiSO4 there is a risk for all of the current inhalation scenarios in all uses. For NiO the risks are under control in a few uses (catalysts, glass). The options for a Restriction could include setting a protective DNEL, closed or automated systems, PPE,… but in general it seems that there is an overlap with the workplace legislation.
3. With respect to Authorisation, ANSES believes that it goes beyond the objective (management of the worker's exposure), it doesn't cover all uses as intermediate uses are exempt. Moreover, substitution is not an argument in this case as for nickel compounds it appears that there is no possibility to substitute them in the medium to long term, in most of the uses.

The analyses of alternatives from the NI have not been reviewed critically but they found that the data were of sufficient quality.
Finally, ANSES presented the socio-economic impacts, highlighting that this is based on reports from industry, which have not been 'challenged' so far, so they need to be taken with precaution. ANSES felt that not all indirect costs have been taken into account; hence the health benefits may be underestimated.

DISCUSSION

Sylvie Drugeon highlights that this is the first exchange, as they have not yet spoken about these RMOAs at European level.
The RMOAs have been written in English and are currently being reviewed to ensure that everything confidential is removed from the reports. ANSES will publish their advice on the 8th of July. The RMOAs will be published on the 15th of July on which date the national consultation in France will be launched. The RMOAs will then also be sent to the other Member States & the European Commission.

Initially it was foreseen that the national consultation would last until the 30th of September but at the request of GIFAS who feels that this timing was too short to allow industry to generate more data, Mrs Drugeon accepted to extend the timeline until the 30th of October.
Mrs Drugeon said that OELs are the most appropriate option & the consultation will be around the following questions:

- (Technical & economical & possibly, timeline for compliance) feasibility of the SCOEL value for the companies. She did highlight that if the OEL is above the SCOEL, this would not be sufficiently protective of the workers & they will feel obliged to look at other risk management options (such as Restrictions or Authorisation?);
- Justification of the DNEL from the NI;
- More information about tonnage for certain applications;
- Risks of relocation – comparison of the European production with the global industry.

The final decision will be taken in the autumn.

We indicated that we already started to work on improving & refining the exposure scenarios & we asked whether the refinement of these exposure scenarios could be integrated in the process at a later stage (taking this into account, there is a need to choose an “adaptable” RMO). There was not a clear answer but it was mentioned that we are at an early stage of the process & the choice of the best RMO will be made at the end of the year.

ADDITIONNAL INFORMATION

Mr Lagriffoul informed us in private that he will be leaving ANSES on 9th July to join a company active in the biocides sector. Mrs. Catherine Gourlay-France, his superior at ANSES will take over the dossier.

We had a long discussion with him on Wednesday 2nd July 2014 that allowed is to get some more input or clarifications on some of the points raised at the Groupe Miroir meeting:

- It is of the utmost importance to participate in the national Public Consultation as it will be the last occasion where Industry will be in a position to contribute data susceptible to influence the process at an early stage of the decision-making.
- ANSES considers that the DNEL as set in the registration files, i.e. 0,05 mg/m3, has at this stage of the debate to be considered as rejected. Any effort to try and contest the SCOEL value by advocating another value should happen outside the current discussion, which is about managing risks that have been established. Thus the chances of shifting the DNEL (OEL) back to the value set by industry should be considered as extremely slim, at this stage. However, were the public consultation to reveal that Industry considers the OEL values as proposed by SCOEL as unworkable from a technical or economic point of view, the French authorities or another Member State may decide for another risk management measure, which might be either a Restrictions or, more likely, Authorisation. Risks having been identified, it is unlikely that no action will be taken.
- It is estimated unlikely that the French ministry may be prepared to ask for a re-evaluation of the DNEL value were the ACSH to recommend another value than the one proposed by SCOEL.
- It is important that the registration files be updated, in particular to address their weak point i.e. the monitoring data and the exposure scenarios. This might be very useful in the discussions that will follow. With the current values, even high performance PPEs such as respirators (APF 40) are insufficiently protective.
- It is important that Industry provides more accurate data on the tonnages used so as to avoid the default use of worst-case figures. This may become critical in the discussions on the choice of RMO, up to prioritisation for authorisation.
- Industry is advised to seek inspiration in the work and discussions the cobalt industry is engaged into for the establishment of an OEL.
- The ministry will decide, early 2015, how it will address the other nickel salts. The choice might be to read-across the conclusions on sulphate and oxide or to perform ad-hoc studies if their uses appear to be sufficiently different to warrant a specific examination.