

ECHA/NA/12/29

ECHA and MSCAs pave the way for further assessment of nanomaterials under REACH

In a two day workshop, ECHA shared experiences with Member State Competent Authorities, the European Commission and Accredited Stakeholders in evaluating registration dossiers containing nanomaterials and proposed the initiation of an ECHA working group on nanomaterials. Best practices, collected from registrants that have already registered nanomaterials, will be disseminated in the near future aiming to help those registrants that need to register nanomaterials by 31 May 2013. In its assessment of substances in the nano-form, ECHA will use the EU recommendation on the nano-definition as the benchmark.

Helsinki, 8 June 2012 - ECHA organised a workshop concerning its first experiences with nanomaterials under REACH with an emphasis on the Evaluation process. In the two day event ECHA, MSCAs, Accredited Stakeholders and the European Commission discussed how nanomaterials in general have been characterised in registration dossiers. Currently, the scope of the registration (i.e. whether and how many nano-forms are included) is often unclear and the level of nano-specific information provided (e.g. substance characterisation, hazards, exposure and risks) shows significant room for improvement. Over 50 expert participants from the MSCAs discussed the scientific and technical challenges as well as the regulatory processes that REACH offers to address safety aspects of nanomaterials.

ECHA agreed with MSCA representatives on a common approach to addressing the current information requirements in nanomaterial dossiers taking into account the scientific uncertainties and legislative framework provided by REACH. The workshop provided recommendations on how to proceed with nanomaterial substances under Evaluation in the near future, paving the way for ECHA to continue further dossier evaluation activities on these dossiers. ECHA will implement the European Commission recommendation on the definition of a nanomaterial as a benchmark in assessing substances and invites registrants to proactively characterise their substances in light of this definition. ECHA's first aim is to provide clarity on the physico-chemical characteristics of nanomaterials and will use the available REACH instruments to obtain available data or request new data to be generated. The workshop confirmed that such a gradual approach combined with a collaborative and constructive interaction with registrants would be the first step towards future safety assessments of nanomaterials under REACH.

The plan to set up a working group on nanomaterials that would provide advice on scientific and technical principles related to nanomaterials under REACH was discussed and supported at the workshop. The working group on nanomaterials would act independently but report to the

relevant ECHA committees (similar to the already existing PBT working group). The mandate of this working group will be further consolidated with the MSCAs.

ECHA intends to disseminate the best practices that are currently collected from relevant stakeholders that registered nanomaterials and which were discussed in the first GAARN (Group Assessing Already Registered Nanomaterials) meeting prior to the workshop. Based on the practical challenges and successful experiences shared at this meeting, and with the support of the recently updated guidance concerning nanomaterials, the Agency hopes to facilitate the work of those registrants that intend to register their nanomaterials at the next registration deadline. These best practices will be published on ECHA's website by this summer.

Further information:

Nanomaterials report:

<http://ec.europa.eu/environment/chemicals/nanotech/index.htm>

Guidance on information requirements and chemical safety assessment for nanomaterials:

<http://echa.europa.eu/web/guest/guidance-documents/guidance-on-information-requirements-and-chemical-safety-assessment>

