

ECHA strategy on substances in nanoforms

48th Meeting of the Management Board 14-15 December 2017

Key messages

The Management Board is asked to take note of the progress made by ECHA Secretariat in implementing the workplan on nanomaterials.

The possibility for using dossier and substance evaluation under the current legal text of REACH to verify safe use of nanomaterials on the EU market has become increasingly challenging and resource intensive, following recent rulings of the Board of Appeal. The lack of information on hazardous properties of nanomaterials hampers not only the identification of specific concerns but also the assessment of whether additional risk management measures are needed. The revision of REACH Annexes is therefore even more urgent than before. These developments, however, do not eliminate the responsibility of industry in ensuring the safe use of substances, in whatever form.

Following recent scientific developments, ECHA will increase the investment in working together with Member States to amend OECD Test Guidelines to ensure they are applicable also to nanomaterials.

Background

ECHA Secretariat introduced its work plan on nanomaterials (for years 2016-2018) to the Management Board in September 2015¹. The plan contained the following main elements:

1. Clarification of ECHA guidance for nanomaterials;
2. Promote improvement of data quality for nanomaterials to ensure their safe use;
3. Identify and address nanomaterials of concern;
4. Ensure synergies via international activities and links with research projects; and
5. Contribute to transparency about nanomaterials on the market.

ECHA has implemented this work plan for two years now with the ambition of ensuring the applicability of REACH and CLP to substances in nanoform without any explicit legal information requirements in any of the regulations. This has partly been successful. However, the Board of Appeal issued two decisions on nanomaterials earlier this year that had a significant impact on ECHA's ability to continue its evaluation activities, and in particular compliance checks. At the same time, scientific developments have led to a need to invest more in systematic review and amendment of OECD test guidelines to ensure their applicability for substances in nanoform.

Meanwhile, the discussion has started in the REACH Committee on the proposal prepared by the Commission to revise the technical information requirements in REACH Annexes specifically for nanomaterials. In parallel, the EC Recommendation for a definition of a nanomaterial is also undergoing a review, which has been delayed. The uncertainty on whether changes to the current definition will be introduced further complicates the identification of these materials under legal frameworks.

¹ [MB/41/2015](#)

This document, therefore, informs the Board on status of ECHA's nanomaterial activities, and how these are impacted by the recent developments.

Rationale

Guidance activities

ECHA completed the development of new, and update of existing, REACH guidance in May 2017 to mirror latest scientific progress made, resulting in:

- New practical guide: How to prepare registration dossiers that cover nanoforms;
- New guidance on grouping and read-across between nanoforms; and
- Nano specific Appendices to the guidance on information requirements and chemicals safety assessment, covering:
 - Update of the information requirements for human health and for the environment;
 - New guidance for read-across and grouping between nanoforms.

The differences of views among stakeholders in terms of how REACH should be implemented for nanomaterials was also visible in the guidance update process. More than 2000 comments were received on the draft guidance updates. All guidance updates were, however, available one year ahead of REACH 2018 registration deadline. It is nonetheless unlikely that the new guidance will generate updated registration dossiers with new nanospecific information before the legal text has been amended.

Under the work programme for 2018 ECHA is prepared to start another round of guidance revision, as soon as the discussion on revision of REACH Annexes have resulted in a stable legal text.

Evaluation activities

In March 2017, the Board of Appeal (BoA) published the first² of two important decisions on a substance identity targeted dossier compliance check done in 2014. The request from ECHA was for the registrants to transparently report what forms of the substance (titanium dioxide) were covered in the registration. This is the starting point for any evaluation to ensure that the hazard data in the dossier is representative for all forms of the substance as registered and put on the market. However, BoA ruled that requesting this specific information (including what nanoforms and surface treatments are covered), without an explicit requirement for the relevant additional parameters in the legal text³, is outside ECHA's competence. Consequently, without a proper verification of the scope of the registration, designing a compliance check decision requesting hazard information covering all different nanoforms in the dossier in a targeted and proportionate way, has now become very challenging and complex.

In July 2017, in a second⁴ ruling on a substance evaluation decision (of synthetic amorphous silica, 'SAS') done in 2015, the BoA partly annulled and partly upheld the ECHA decision requesting sub-chronic inhalation studies for four pyrogenic SAS forms. In line with the previous rulings on substance evaluation, the BoA stated that lack of hazard data *per se* is not a justified concern and, therefore, also the lack of information on a specific nanoform is not a legitimate reason for generation of new hazard data either. Such a request would need to be based on concern related to specific evidence on the substance.

If the scope of the registration cannot be clarified, then the potential data gaps cannot properly be assessed and the basic hazard data cannot be effectively requested. Unless the registrant

² A-004-2016

³ Under section 2 in Annex VI of REACH

⁴ A-015-2015

voluntarily gives the relevant information on substance identity as well as transparently reports test materials used to generate the submitted data, there are significant limitations in requesting additional information using the current legal text of REACH. This results in complication also in substance evaluations where fulfilling the standard information requirements for nanofoms would be the best way to identify the substance specific potential concern. While evidence from scientific literature can also be used as evidence, it should be noted that also there information on toxicological properties of nanomaterials is scarce. In any case, ECHA will continue to support the Member States in their efforts in conducting substance evaluations. On the latest CoRAP list, dated March 2017, there are nine cases where it is likely that nanofoms will be included in the assessment.

The above does not eliminate the responsibility of industry in ensuring the safe use of substances, in whatever form. However, in the current situation ECHA cannot effectively and systematically verify whether safe use of nanomaterials in the supply chain is demonstrated, and whether additional regulatory risk management measures are needed. This in turn emphasises, once again, the urgent need to amend the REACH Annexes.

Scientific developments

To enable generation of reliable hazard data to underpin all aspects of implementation of REACH, CLP and BPR, the OECD test guidelines are an important foundation. As further progress has been made in regulatory science about nanomaterials, concerns have been raised about the applicability of the existing test guidelines for their testing. With a better understanding of the specific challenges, a clear need has been recently identified to systematically evaluate and to amend several of the existing test guidelines to be applicable also for nanomaterials.

ECHA has already supported the work at OECD level by participating in the revision of the inhalation toxicity and several environmental test guidelines, but significant further work is needed. The involvement of ECHA's Nanomaterials Expert Group (NMEG) has been instrumental in this. It facilitated an agreement of priorities among test guidelines needed especially for REACH. In addition, it also created the conditions to effectively mobilise the Member States at political level under the lead of Germany. ECHA prepares to contribute to this work starting 2018, as part of the nanomaterials work plan implementation.

Improving the transparency around the risk and safe use of nanomaterials

In December 2016, ECHA was officially mandated to set up, via a delegation, a new EU initiative: European Observatory for Nanomaterials (EUON)⁵. The initiative was as a result of an impact assessment done by the Commission of measures to increase the transparency of nanomaterials on the EU market. The Commission identified the observatory as the best option in balancing cost for both industry as well as regulators whilst still addressing the current (perceived) lack of information.

The EUON was launch as planned in mid-June 2017 and was well received, however noting the critical views of some stakeholders towards the relevance of the observatory. A stakeholder dialogue was organised in June to capture the views from external users and the event was supported by a survey in advance. The EUON will continue to be developed over the years to come, not only in terms of added content but also by incorporating several external sources of information (eNanoMapper and NanoDATA) and implementing a more user-friendly interphase. In these developments a close cooperation with ECHA's partners and stakeholders will remain of fundamental importance to ensure that objectivity and relevance of EUON's content is safeguarded.

⁵ euon.echa.europa.eu

Working together with Member States and Stakeholders

The NMEG has been meeting twice yearly and had this autumn its 10th meeting. The group was originally set up to allow for technical discussion between ECHA, Member States, NGO and industry representative on issues surrounding the implementation of REACH, CLP and BPR. The group's importance has kept increasing over the years as demonstrated by the high interest among Member States and in particular stakeholders. The NMEG has become the focal point for discussion of regulatory science issues of nanomaterials at EU level. It has supported ECHA's work and also created opportunities for exchange of views among industry, NGOs and regulators on issues of importance. Despite the very slow progress in the revision of REACH Annexes for nanomaterials, the NMEG has shown a capacity to progress on the technical issues and has supported ECHA's and member states work on finding solution for reporting in IUCLID, guidance updates and best practices.

Alternative options

ECHA could continue dossier evaluation activities on nanomaterials as in previous years. However, the work on nanomaterials remains not only technically and legally challenging, but also resource intensive. The work on finding solutions under the current legal text has involved numerous legal as well as scientific experts in ECHA and at Member State level. Despite these efforts, the uncertainties have remained, decisions have been appealed and ECHA's competence in requesting information under REACH, has been more narrowly defined. However, ECHA will seek opportunities to work together with proactive companies that are willing to invest in the safety of nanomaterials despite the legal uncertainties.

Drawbacks

In 2012, Commission stated in their communication on the second regulatory review on nanomaterials: "REACH sets the best possible framework for the risk management of nanomaterials when they occur as substances or mixtures". After years of significant efforts by ECHA and Member States, it has become clear that this framework does not work satisfactorily without the revision of REACH Annexes. In current situation, the authorities cannot verify whether registrants have demonstrated the safe use of nanomaterials throughout the supply chain or whether further regulatory risk management measures are needed. This may also have consequences in terms of market trust on nanomaterials. The realisation of the great opportunities that nanotechnology and nanomaterials may offer society, should go hand in hand with the transparent demonstration by industry of their safety and sustainability.

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