ECHA
EUROPEAN CHEMICALS AGENCY

# Best practices on physicochemical and substance identity information for nanomaterials

**1st GAARN meeting**
**Helsinki, 29 May 2012**

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**Best practices – 1st GAARN meeting**

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# 1. Objectives

The purpose of the Group Assessing Already Registered Nanomaterials (GAARN) is to build a consensus in an informal setting on *best practices* in assessing and managing the safety of nanomaterials under the REACH Regulation, and thereby to increase confidence and mutual understanding among stakeholders so that nanomaterials can be sustainably developed. The GAARN group consists of several experts from Member States, the European Commission, ECHA and industry. The group has selected three registration dossiers that include nanoforms/nanomaterials, and aims to review and exchange views on how these registration dossiers meet the REACH information requirements in the areas of physicochemical properties and substance identity (SID), human health and environmental endpoints, specifically for the nanoforms. GAARN aims to discuss best practices for each selected registered nanomaterial and to develop recommendations on how to fill potential information gaps.

The purpose of this report is to highlight the outcomes of the first GAARN meeting, out of the three meetings foreseen to be held during this project. The meeting was held in Helsinki on 29 May 2012, and this first meeting concentrated on discussing the challenges faced when registering substances under REACH, and on the information requirements for substance identification and physicochemical properties only.

# 2. Summary

Prior to the meeting, ECHA and the participating lead registrants (LRs) for the three selected registered substances exchanged a number of questions related to substance identity and physicochemical properties. ECHA sent a selection of questions related to their registration dossier to the registrants, and two out of the three LRs sent questions to ECHA. The aim of this exchange of questions was to provide a basis for discussion at the meeting and make both parties (ECHA and LRs) aware of their concerns and limitations related to physicochemical and substance identification concepts relevant for addressing nanoforms under REACH, and also to focus the discussion on how the nanoforms have been addressed in the respective dossiers.

The GAARN plenary sessions included the presentations by the three LR representatives, each followed by ECHA's responses to the questions received from the corresponding LRs.

# 3. Best practices

Best practices on what type of physicochemical and substance identity information should be reported in a registration dossier registering nanoforms are reported below.

- Registrants registering nanoforms should consider updating their REACH dossier as soon as possible. When the scope of the registered substance involves both nanoforms and bulk forms, it is recommended that if the registrants of >1000 t/y substances are aware of deficiencies in their dossier, they should provide an updated dossier as soon as possible, and not wait until the REACH registration deadline for substances under lower tonnage bands (<1000 t/y). Registrants should take this into consideration even if the fraction of nanoforms in the registered dossier is below this threshold and only the total tonnage band (for bulk and nanoforms) is >1000 t/y. Note that according to Article 22 of REACH, registrants shall be responsible, on their own initiative, for updating their registration without undue delay.

- In relation to the recommendation for the definition of nanomaterials, although it is not legally binding, it is a source of information to be legitimately taken into consideration by ECHA, the institutions, Member State competent authorities (MSCA) and registrants. The Commission has made a commitment to assist in the development of standardised methods to determine particle size and distribution specifically for the EU recommendation. However, it is important to keep in mind that the absence of a mandated standardised method need not be considered as a deficiency of the definition. ECHA does accept data generated by non-standard methods, provided the conditions of Annex XI are met. Specifically for physicochemical data, Annex XI 1.1.1. allows registrants to use data generated using non-GLP methods or other test methods than those referred to in Article 13(3), as long as the information provided is adequate. Indeed, if the particle size is relevant for the technical specifications of the product placed on market, then the use of non-standardised methods for measuring granulometry might be accepted by ECHA, provided these methods are clearly described. With regard to the methodologies used for measuring particle size distribution of nanoforms, it should be noted that although REACH requires the removal of solvents from the substances registered, there are a number of analytical techniques that require the samples to be in dispersion for their proper analysis (such as chromatographic and spectra data) and the solvent does not need to be removed. Characterising the physical and chemical properties of nanoforms is likely to require a multi-method approach.
- It is generally recommended that registrants provide a detailed description of the sample preparation for (eco)toxicological assays, even if it goes beyond the information required in the standard OECD guidelines. The OECD guidance on sample preparation and dosimetry does not aim to be conclusive due to the diversity of types of nanomaterials. As stated by the OECD[1], *"This guidance notes is susceptible to change until the test methods for nanomaterials are established, so it is important to note that this document, Preliminary Guidance Notes on Sample Preparation and Dosimetry for the Safety Testing of Manufactured Nanomaterials, is a "living document" and as such, it will be updated and amended in an iterative manner based upon knowledge accumulation, evolving communication and as experience is gained with the testing of nanomaterials."*
- Guidance for nanomaterial testing and characterisation will be developed as the field develops and more experience is gained. It would be difficult to come up with guidance that would cover all situations, though industry is encouraged to come up with characterisation standards for their specific substances.

# 4. Conclusions

The Commission, MSCAs and ECHA indicated that the current nanomaterial definition (2011/696/EU) is a benchmark that should help registrants to know whether the substance they register falls within the scope of the definition. The definition also aims to cover several regulatory frameworks.

The inclusion of the definition on its own may not bring new obligations to the registration dossier. It would simply define what is considered to be a nanomaterial under REACH. It is not yet known whether additional specific provisions for nanomaterials will be included in any

[1] OECD - Preliminary Guidance Notes on Sample Preparation and Dosimetry for the Safety Testing of Manufactured Nanomaterials
http://search.oecd.org/officialdocuments/publicdisplaydocumentpdf/?cote=ENV/JM/MONO(2010)25&docLanguage=En

revision of REACH. However, registrants are obliged to update their dossier with any new information available.

The recommendation for a nanomaterial definition defines nanoform as the size of the smallest constituent particle. However, while a substance may be a nanomaterial, this does not imply the substance is more hazardous and does not necessarily impose new testing for (eco)toxicological endpoints. If registrants are able to show (by measurement and documentation) that particles form strong aggregates that will not leach out nanoparticles during the lifecycle of the substance, then this may be an exposure-based argument that no further testing (beyond size) is necessary.

It was stressed by the registrants that there are several analytical techniques that can provide information on primary particle size distribution, as well as aggregate size distribution. However, the results obtained will depend on the analytical technique used and sample preparation, which leads to a number of assumptions on whether the substance falls within the scope of the current definition for nanomaterials. Based on the lack of standardised or validated techniques, it was also unclear at which stage of the production process the particle size distribution should be quantified (powder/suspension stage vs. end-product). The registrants also stressed the need to consider the elevated costs of a detailed physicochemical characterisation, if such characterisation was needed at several stages.

ECHA and the MSCAs stressed that the use of several analytical techniques for characterising nanoforms (multi-method approach) was favoured. With current knowledge and the limitations of current analytical techniques, there is no single method that can provide sufficient information on all the physicochemical parameters necessary to characterise nanoforms. Furthermore, bias from one technique could be minimised by the use of multiple techniques, providing new and more detailed information. At the very least, it would be expected that the method employed to measure a specific parameter should be identified and reported in the registration dossier.

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