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## **ECOS on standards for nanotechnologies – Ideas and demands of the environmental community as input into EC standardisation mandate M/409**

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*ECOS, the European Environmental Citizens' Organisation for Standardisation, is an association of NGOs active in the field of environmental protection, which together have more than 26 million individual members. ECOS was created in 2001 as a non-profit association under Belgian law to enhance the voice of the environment within the European standardisation system. Apart from standardisation, it represents the environmental movement in the implementation process of the EU-Directive for the Eco-design of Energy using Products (EuP). ECOS is supported by the European Commission and EFTA. Its secretariat is based in Brussels. [www.ecostandard.org](http://www.ecostandard.org)*

The European Commission (EC) has released a programming mandate (M/409 Nanotechnology) addressing CEN, CENELEC and ETSI in order to elaborate a work programme for the development of required standards in the area of nanotechnology and nanomaterials.<sup>1</sup>

The mandate “for the elaboration of a programme of standards to take into account the specific properties of nanotechnologies and nanomaterials” aims to promote the development and application of nanotechnology and to assure the competitiveness of the European high-tech industry in the rapidly developing field of science, technology and innovation.

### **Present standardisation activities**

So far, standardisation activities in the field of nanotechnology are taking place at the international and EU levels. The ISO/Technical Committee (TC) 229 on nanotechnologies established in November 2005 is divided into three working groups (WGs). WG 1 ‘Terminology and Nomenclature’, WG 2 ‘Measurement & Characterisation’ and WG 3 ‘Health, Safety & Environmental Aspects of Nanotechnology’ are working on a number of technical specifications and technical reports, which, similar to pre-standards, allow more flexibility in developing nanotechnology. Although CEN (with the support of some Member States) is apparently making steps forward towards participating and taking the lead in documents that will touch environmental and consumer questions, several important standardisation topics for nanomaterials have been and are still being decided at ISO-level.

In Europe, some Member States are reluctant to push standardisation at the EU level mainly with the argument of avoiding duplication of work. Additionally, certain industry representatives mentioned that some industries hesitate to engage in the nanotechnology standardisation process because the proposals aim to standardise substances instead of products, which is normally not the focus of standards. The needs and specifications for substances are so far dealt with and assured by negotiations between trading partners.

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<sup>1</sup> The work programme can address the need for new standards, technical specifications or technical reports as well as the need for a revision of existing sector-specific standards and the identification of stakeholders for involvement in the standards development process.

## Approaches on how to govern nanotechnologies

The environmental community is of the opinion that the regulatory framework thus far does not adequately address the specific properties of nanomaterials and nanoparticles. It should be a clear priority of the EC to establish mandatory risk assessment at national and EU levels. ECOS thinks that compliance with mandatory risk assessment can, as the EC states, be demonstrated using standards; however, the risk assessment should be as detailed as possible, leave as few topics to standards as possible (see the proposals below) and foresee involvement of the public, which should have access to vital environmental safety and human health data.

Testing methods and guidelines to assess (eco-) toxicology of nanomaterials and nanoparticles should be rather elaborate and published by the OECD because this is traditionally its responsibility. ISO/TC 229/WG 3 on 'Health, Safety & Environmental Aspects of Nanotechnology' is currently working on several documents. Though ISO/TC 229 and the OECD are exchanging experts and have established a 'Memorandum of Understanding', this situation may create inconsistent developments.

Besides, the expected technical report of ISO/TC 229/WG 3 on 'Health, Safety & Environmental Aspects of Nanotechnology' on 'Health and Safety Practices in Occupational Settings Relevant to Nanotechnology', as well as the draft standard on 'Endotoxin test on nanomaterial samples for in vitro systems' should undergo a wide and open scientific discussion that should not be restricted to standardisation bodies.

As far as labelling is concerned, it is questionable whether this should be dealt with through the use of standards. The proposed CEN-work item 'Format for reporting the engineered nanomaterials content of products' could turn out to be relevant for consumers, provided that the reporting also concerns the final product. The reporting within the production chain is very useful, undoubtedly, so that every company has relevant information, e.g. on how to properly bag, transport and dispose of the product. **However, a format for labelling in order to give informed choice to the consumer should be developed in an open process involving a broad range of stakeholders and possibly the public.** Maybe, labelling will turn out to be desirable only for special product groups such as personal care products, cosmetics and food and has to be legally regulated. **In any case labelling should in no way be seen as a substitute for higher-level regulatory tools, e.g. legislation.**

## Ideas and demands of the environmental community on standards for nanotechnology

There are some topics in the area of nanotechnology that may possibly only be addressed by using standards. **ECOS strongly supports an ambitious and quick standardisation programme** which provides real progress in terms of risk assessment and measurement of nanomaterials, especially manufactured ones. "Quick" does not mean that fast-track deliverables with limited consensus and public enquiry requirements should be privileged. However, ECOS sees a clear urgency for standards in this field.

- Terminology and definitions of nanoparticles and nanomaterials should be carefully worked out taking into account the requirements for toxicological assessment. Generally terminology and definitions should be elaborated in cooperation with toxicologists and material scientists.

**The definition of the particle size in particular might need to be expanded because of toxicological concerns.** When defining specific production processes, the particle size of a substance should be defined within a narrow range if the toxicological profile of different sized nanoparticles varies. Toxicologically relevant parameters for different exposure routes should be defined within the general terminology and definitions, such as particle concentration and particle size distribution.

- Terminology and definitions should provide taxonomy for all different kinds of nanoparticles and nanotechnology as a basis for specific standards on how to test the impact of the different types of nanoparticles arising from different applications and production processes.
- Terminology and definitions should clarify the naturally occurring and diffuse exposure by nanoparticles in order to define acute exposure by specific applications.

- **The development of measurement methods is necessary and urgent in order to better assess the exposure and thus possible risks of nanomaterials and nanoparticles.** The measurement methods should be validated and at best address any measurement uncertainty as well as the limitations of the methods.<sup>2</sup> Reporting schemes on measurement results should be standardised as well. This could be covered in a general document or by a separate paragraph in each measurement standard.
- The development of standardised laboratory procedures, biomarkers and analytical methods for the detection of nanoparticles in biological samples should be enforced to allow for assessment of risks to health and the environment.
- If there are different approaches for the measurement of a specific nanoparticle and thus different standards are available for measuring certain aspects, such as its concentration, a scheme for comparability should be provided.
- A focus should be on measurement methods and defined requirements to assess exposure. Requirements and definitions are needed to be able to compare exposure scenarios.
- Sampling schemes are an important issue that should be addressed as well by the measurement standards or as a separate standard.
- At best, measurement of a given nanoparticle in different environments should be provided in order to make environmental monitoring possible.
- Standards on the production or processing of nanomaterials and nanoparticles should address contained use or minimised environmental release unless the safety of the nanoparticle or nanomaterial is proven.
- If standards cover single substances as nanoparticles, the range of size should be defined as narrowly as possible. Packaging, transport and proper disposal should be addressed as well.
- **In terms of priority products to be targeted, ECOS gives priority to food, food packaging and personal care products.**
- **Another focus should be on products that are used by lay people in their private households such as varnishes, paints, household cleaning agents etc. because of the possibility of uncontrolled release into the environment.**

**As long as the regulatory framework for a specific risk assessment as well as the above-mentioned standards on definitions and testing methods are not available, ECOS members call for a precautionary approach and prefer to restrict the uncontrolled release of nanoparticles. Products containing nanoparticles already on the market (e.g. cosmetics) should be clearly marked.**

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<sup>2</sup> CEN/TC 352 has not yet made a decision on the new work item "Guide to nanoparticle measurement methods and their limitations" that will result in a technical report. It remains to be seen whether a state-of-the-art guide providing levels of uncertainty, resolution, accuracy and reproducibility in measuring parameters under different regimes and environments will be sufficient in this complex and fast developing technological field.