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Considerations on the EU definition of a nanomaterial: Science to support policy making

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ABSTRACT

In recent years, an increasing number of applications and products containing or using nanomaterials have become available. This has raised concerns that some of these materials may introduce new risks for humans or the environment. A clear definition to discriminate nanomaterials from other materials is prerequisite to include provisions for nanomaterials in legislation. In October 2011 the European Commission published the 'Recommendation on the definition of a nanomaterial', primarily intended to provide unambiguous criteria to identify materials for which special regulatory provisions might apply, but also to promote consistency on the interpretation of the term 'nanomaterial'. In this paper, the current status of various regulatory frameworks of the European Union with regard to nanomaterials is described, and major issues relevant for regulation of nanomaterials are discussed. This will contribute to better understanding the implications of the choices policy makers have to make in further regulation of nanomaterials. Potential issues that need to be addressed and areas of research in which science can contribute are indicated. These issues include awareness on situations in which nano-related risks may occur for materials that fall outside the definition, guidance and further development of measurement techniques, and dealing with changes during the life cycle.

1. Introduction

Nanotechnologies are booming business. It is now evident that nanotechnologies are becoming a substantial part of society and indeed already a multitude of nanotechnology products, or at least products with a nano-based claim, are commercially available (PEN, 2005). Nanotechnologies include the development and production of nanosized engineered particles, fibres, coatings, etc., collectively referred to as nanomaterials. Similar to other chemical substances, society, governments and industry alike want to assure that these new products can be used safely. In case risk assessments indicate the unacceptable probability of adverse effects, risk management measures should be taken to protect the environment and human health.

Risks of conventional chemicals are regulated in existing national and international regulatory frameworks. Nanomaterials are often praised for their "new and unique" properties. However, because of these new properties, nanomaterials are also likely to differ from their conventional chemical equivalents with respect to their behaviour in the environment and their kinetic and toxic properties. This raises concerns in connection to their widespread use, as this leads to an increase of exposure to these nanomaterials for humans as well as the environment. As legislation lags behind technological developments (Choi et al., 2009), additional (data) requirements for risk assessment of nanomaterials are yet to be formulated in existing regulatory frameworks. In case regulatory risk assessment procedures are adapted for nanomaterials, it is required that nanomaterials can be clearly and unambiguously identified.

Some countries outside of Europe already have published definitions, not necessarily in a regulatory framework but as working definition (Australia; NICNAS, 2010), policy statement (Health Canada, 2011) or presented as a general description in guidance (US-FDA, 2011). The Scientific Committee on Emerging and Newly Identified Health Risks (SCENIHR) of the European Commission has published the scientific basis for the definition of the term nanomaterial (SCENIHR, 2010). In October 2011 the definition of a nanomaterial by the European Commission was published

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(EU, 2011a). It should be noted that the Commission published its definition of a nanomaterial as a Recommendation. This definition will only become legally binding, when it is incorporated into legislation. In case it becomes part of legislation, then guidance to that legislation should be developed to indicate how requirements can be fulfilled. With its definition, the Commission solely intends to identify substances within a specific size range and explicitly does not aim to classify nanomaterials as inherently hazardous. More details on the definition are provided in Section 2 of this paper.

Research is ongoing to assess potential risks and risk assessment procedures of nanomaterials. For example, within the OECD Working Party on Manufactured Nanomaterials the Sponsorship Programme for the Testing of Manufactured Nanomaterials (OECD, 2007) was established to evaluate whether the existing OECD test guidelines developed for chemicals may also be useful for the safety evaluation and risk assessment of nanomaterials. For testing, nanomaterials were chosen that are already in use or will be in the near future, including fullerenes, single-wall and multi-wall carbon nanotubes, metals and metal oxides. These key nanomaterials are being tested for their physicochemical properties, environmental degradation and accumulation, kinetic properties, environmental and mammalian toxicology.

In this paper we elaborate on the interpretation of the (recommended) definition of the European Commission and the current status of various European regulatory frameworks with regard to nanomaterials. Potential issues that need to be addressed and areas of research in which science can contribute are indicated and discussed. Ultimately, this will contribute to understanding the implications of the choices policy makers have to make in further regulation of nanomaterials.

2. The EU recommendation for a definition of a nanomaterial

The European Commission based its recommended definition mainly on a reference report by the European Commission Joint Research Centre (JRC) (Lövestam et al., 2010) and a scientific opinion by the SCENIHR (SCENIHR, 2010). Inevitably, the final wording and especially the thresholds comprise political compromises as well. In its Recommendation (EU, 2011a) the European Commission states that:

> *'Nanomaterial' means a natural, incidental or manufactured material containing particles, in an unbound state or as an aggregate or as an agglomerate and where, for 50% or more of the particles in the number size distribution, one or more external dimensions is in the size range 1 nm–100 nm.*
>
> *In specific cases and where warranted by concerns for the environment, health, safety or competitiveness the number size distribution threshold of 50% may be replaced by a threshold between 1% and 50%.*

Alternatively, it is stated that a material should be considered as falling under the definition where the specific surface area by volume of the material is greater than 60 m^2/cm^3. The Recommendation also includes definitions for 'particle', 'agglomerate' and 'aggregate'. The Commission foresees a review of the definition by December 2014, particularly focusing on the appropriateness of the 50% limit.

The recommendation contains a rather broad description of the term nanomaterial. It includes all kinds of nanomaterials/nanoparticles irrespective of their origin. The definition thus also covers natural nanoparticles, such as volcanic ashes, as well as incidental nanomaterials like nanoparticles originating from human activity such as exhaust of combustion processes, and the intentionally manufactured nanomaterials/nanoparticles by industry as they may be used in various industrial processes and consumer products. With the definition the Commission solely aims to identify substances within a specific size range and explicitly does not aim to classify nanomaterials as intrinsically hazardous. For this purpose it is appropriate to use a broad description, especially since no distinction can be made on the origin of the particle when only size is measured. However, as with other materials, distinctions between natural, incidental or manufactured materials need to be made in the specific areas of legislation since the need for such a distinction will be related to the purpose of that legislation.

The Commission states that the definition should be used as a reference for identifying nanomaterials for legislative and policy purposes in the European Union. However, whether defining a material as nanomaterial has regulatory consequences should be decided on in the specific regulatory frameworks. It is also indicated that for certain regulatory frameworks deviations may in some cases be necessary, either to exclude materials that fall within the definition or to include materials that are beyond the definition. For this reason, the option is given by the Commission to adjust the number size distribution threshold to a value between 1% and 50%.

3. Why is there a need for a definition?

Similar to conventional substances, it is now recognised that some nanomaterials may be hazardous and some may not be hazardous (SCENIHR, 2010). As indicated before, the small size can be accompanied by specific physicochemical properties and may result in an increased potential for crossing biological barriers. This may result in differences in behaviour and (internal) exposure to the nanomaterial that do not occur with larger sized conventional materials or dissolved molecules. Different behaviour in combination with widespread application of nanomaterials has raised concerns that some of these materials may introduce new risks when e.g. workers, consumers, patients or the environment are exposed. Therefore, special provisions for nanomaterials have been considered in various regulatory frameworks. In case adaptation of legislation would be appropriate, there is a need for a definition to distinguish nanomaterials from conventional chemical substances, particularly from other substances with the same chemical composition (e.g. nanosilver and metallic silver; carbon nanotubes and black carbon; titanium dioxide powder and titanium dioxide nanoparticles). Hence, a definition is required to distinguish which materials need closer inspection related to the small size and different characteristics of the nanomaterials. Also for notification purposes (e.g. listing of ingredients) a definition is required to provide consumers sufficient information to choose a certain product, either with or without nanomaterial ingredients.

A clear example of nano-specific behaviour arises from the colloidal nature of nano-particulate matter. While current risk assessment methodologies adequately account for partitioning of chemicals between dissolved and particulate states, typical colloidal processes of aggregation and subsequent sedimentation are not considered, and thus results of colloidal interactions for exposure and intake doses are not accounted for.

In line with the indicated need for a definition, the Commission primarily intends the 'Recommendation on the definition of a nanomaterial' to provide clear and precise criteria to identify materials that can subsequently be used in specific regulatory provisions. The Commission further states that another purpose of the definition is to promote consistency in the interpretation of the term 'nanomaterial' in regulatory frameworks. Also for notification and labelling, for which transparency for consumers is used as a rationale (i.e. cosmetics, food), it is imperative to unequivocally know what defines a nanomaterial.