Final Position paper
October 2012

Nanomaterials safety and legislation

Background

In October 2011, the European Commission adopted the following, general definition of nanomaterials. "*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".* These nanomaterials are not intrinsically hazardous. The purpose of the definition is to identify materials for which there may be a need to take into account specific considerations in their risk assessment. The definition will be reviewed in 2014.

The Commission adopted on October 3, 2012, a Communication on the regulatory approach to nanomaterials, and will soon adopt a Communication on the application of the REACH Regulation that will, inter alia, consider the application of that Regulation to nanomaterials.

In addition to REACH, there are also regulatory provisions relating to the use of substances for specific purposes, and these will, or do already, cover the use of nanomaterials. In particular:

- The Cosmetics Regulation
- The Novel Foods Directive
- The Biocides Regulation
- The Food Contact Materials Regulation
- The Pharmaceuticals Regulations

The above definition will help to ensure that nanomaterials are properly assessed in the regulatory framework comprising the framework regulation of substances under REACH and the regulation of specific uses to which substances might be put.

Introduction

The EU definition of "nanomaterial" is broad enough to capture a wide range of materials. Some are naturally occurring (eg smoke, soot, dust, sand) while others have been in use for many years (eg carbon black and silica, which have been used since the late 19th century). The common, defining characteristic is that the substance is made up of very small particles. Some are specially designed for their size and properties.

The catch-all term "nano-" does not mean that a nanomaterial poses a particular hazard to consumers or the environment. Indeed, there is little or no evidence that nanomaterials in current use pose any hazard at all. The forthcoming 2nd Regulatory review is not so much concerned with known materials, as with the need to assess the possibility of hazards associated with any new materials that might be developed in the future.

There are more and more illustrations of how modern nanomaterials can be used to improve the performance of products as different as solar panels, cancer treatments, and sun block. Nano-technologies are seen as "key enabling technologies" that will drive innovation and growth in the European economy. However, as with any innovation, it will be necessary to

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consider not only the benefits but also the possibility of unintended and adverse consequences of their use. The material question is whether the regulatory framework is able to establish whether there are any risks associated with the new product and, if so, to guard against them.

The EU Regulatory Framework

Under EU Law the producer of a new substance is required to research potential risks and ensure that products are safe for their intended use. Nanomaterials are no different from any other substances in this regard and, insofar as no hazard is specifically or specially associated with nanomaterials, there are no grounds for treating them any differently. Although nanomaterials have been subject to numerous safety studies, no "nano-effect" has been identified, and risk assessment methodologies currently used for assessing chemical safety, are equally applicable to nanomaterials.

In this regard, the REACH Regulation requires that a substance, including a nanomaterial, should only be put on the market if it has been satisfactorily demonstrated that its use does not constitute a risk to health or the environment. Two issues have been raised with regard to the application of REACH to nanomaterials:

- An analysis of dossiers submitted under REACH suggested that in the first round of submissions it may not always have been clear whether the submission concerned nanomaterials. REACH is relatively new legislation and its implementation is complex, however, we recognise and accept that these dossiers should be clear, accurate and complete. Therefore, to help companies meet their obligations under REACH, we support a number of changes to the Annexes thereto, and the issuance of revised guidance notes clarifying the appropriate way to deal with nanomaterials in such dossiers.

- It has been suggested that the application of a *de minimis* threshold of 1 ton is inappropriate for nanomaterials. This argument misrepresents the purpose of this threshold, which was intended to avoid imposing an unnecessary regulatory burden on a great many small and medium sized enterprises, holding chemicals in amounts that do not pose any material risk to health or the environment. In this regard, nanomaterials are no different from any other chemical: and there are no grounds for the suggestion that small amounts of these materials pose any particular or exceptional hazard.

In addition to REACH, which regulates substances, EU legislation also governs particular uses of those substances. Thus, for example, authorisation is required for the use of substances in food and food contact materials, in pharmaceuticals, cosmetics and biocides. These Regulations and Directives automatically cover nanomaterials in these particular uses: however, as the legislation has been revised and updated, specific provisions have been introduced to clarify the position. The Biocides Regulation, the Cosmetics Regulation and the Novel Foods Directive all contain specific provisions governing their application to nanomaterials. The legislation governing waste, water and air quality is in the process of being reviewed.

Thus, the application of nanomaterials in sensitive uses, in particular those where the potential impact on human health is most obvious, is governed by specific legislation and this legislation is being methodically updated. Moreover, and insofar as it is relevant, this legislation does not contain any *de minimis* provisions and unauthorised substances may not be present in food, or cosmetics etc. regardless of any threshold.

Finally, and in addition to the authorisation procedures, there is also a requirement that the use of nanomaterials on some consumer products (eg in biocides and cosmetics) should be indicated on the label.

The question of additional requirements (such as a nano-inventory)

Some commentators have expressed a concern that the use of nanomaterials is unsupervised and have suggested that a special register or 'inventory' of products containing nanomaterials should be set up.

Considering the above outlined EU regulatory framework, such an inventory would provide no additional protection to human health or the environment, nor would it give the authorities any greater ability to regulate the use of nanomaterials than is already provided for under existing legislation. On the contrary, it would achieve nothing other than to stigmatise products and create confusion and uncertainty for consumers.

Such an inventory would be an additional and unnecessary regulatory procedure and a burden on industry. Moreover, the introduction of such inventories through individual national initiatives would not only lead to confusion and uncertainty for consumers, but also create barriers to trade and fragmentation of the single market.

Cefic is willing to contribute to the European Commission's proposed Impact Assessment on options for a potential European web platform with references to all relevant information sources.

Concluding remarks

The Regulatory framework, described above, ensures that a great deal is known about the possible implications before a product can be put onto the market and the authorities have the powers necessary to authorise or restrict the use of any substance – including any nanomaterial – and if necessary to prevent its use in sensitive applications, if certain criteria are met.

There will always be residual areas of uncertainty which may be exploited to promote speculative fears: however, where a proper evaluation has not revealed any material risk this speculation ought not to become a constraint on innovation.

In this context, and as mentioned above, Cefic supports a clarification of the requirements for nanomaterials in the existing regulatory framework, in particular in the context of the REACH Regulation, by means of:

- Some changes in the Annexes of the REACH Regulation that are relevant for nanomaterials; and
- Revised guidance notes clarifying the appropriate way to deal with nanomaterials in REACH dossiers.

Communication on such a consistent and comprehensive regulatory framework, and the fact that it covers nanomaterials, should be improved in order to avoid speculation and emotional fears.

We ask people to look beyond the hype surrounding nanomaterials and consider that:

- ***Nanotechnologies are key enabling technologies that will produce new materials and innovative products, thereby fueling economic growth and facilitating the switch to a low carbon economy.***
- ***Being new, some of these products naturally give rise to concerns about the possible implications of their use. These implications can and must be scientifically evaluated under existing regulatory procedures. These regulations are being methodically reviewed to ensure that, where risks are identified, the authorities have the powers needed to ensure the protection of people and the environment.***