GHEMIGALWATCH

Communication tools for nanomaterial products

Companies producing products that contain nanomaterials need to find tools that will allow them to transfer data and information about the risk management of such materials down the supply chain.

Christoph Meili offers his thoughts on one way this could be done.

Nano inside? – A crucial question!

Consumers want to know what they buy, retailers have to know what they sell and processors and recyclers need to know what they handle. This applies to ordinary materials but also to products which contain engineered nanomaterials. However, the relevant nano-specific information does not reach these actors in the value chain. This is either because there are no clear rules for the transfer of nanospecific information along the value chain, or because the existing tools, such as material safety data sheets, do not explicitly contain nano-specific information. Engineered nanomaterials could therefore easily become "black boxes" in terms of safety data and information flow or, even worse, "unguided missiles" in relation to consumer acceptance and potential risks to health and the environment. There is an urgent need for downstream users and even for authorities and regulators to be informed about the structure and the characteristics of materials and products containing engineered nanomaterials. Tools to adequately handle information transfer about manufactured nanomaterials like MSDSs are available but have to be adapted to take such materials into account. The second issue which has to be addressed is whether consumer product declarations and labels in regard to nanomaterials are needed to prevent a GMO-like backlash against nanotechnology.

REACH in principle applies...

The European Commission has recently stated that REACH does in principle cover nanomaterials. REACH clearly shifts responsibility for ensuring that products are safe from the authorities to manufacturers

and those who put them on the market. However, there are key issues which have to be discussed at an early stage. For example, REACH's registration requirements only apply to substances produced or imported in quantities above one tonne per year, and only require a chemical safety assessment to be produced for substances above ten tonnes per year. Some nanomaterials may fall below this threshold and could be of concern.



Meili: urgent need to inform downstream users about nanomaterials' properties

The other concern is the registration schedule. Phase-in substances at the nanoscale between 1 and 100 tonnes do not have to be registered until 1 June 2018, eight years from now. This seems an eternity for nanotechnology which was not known six years ago. Last summer the European Parliament clearly disagreed with the European Commission's opinion that the existing regulatory framework is suitable for nanomaterials. The Parliament unequivocally stated in its report on the regulatory aspects of nanomaterials that the REACH principle of "no data, no market" should also apply to nanomaterials. MEPs said they wanted manufactured nanomaterials to be treated as new substances, requiring more extensive safety testing and mandatory labelling, and that

the Commission should review all relevant legislation during the next two years. This work is now under way.

... but nanotech has problems

Consumer organisations have been calling for mandatory product labels and declarations for engineered nanomaterials since the beginning of the nano debate some years ago. In the meantime, the issue has appeared in EU legislation. The new European cosmetics Regulation requires industry to declare engineered nanoparticles in cosmetics in the form of "substance name(nano)" from 2013 onwards. This makes cosmetics the first product category to have mandatory "nano-branded" requirements. Similarly, in the updating of the Novel Foods Regulation (Regulation (EC) No 258/97), the declaration of engineered nanomaterials in foods as well as safety data requirements were clearly addressed. It is likely that this process will continue and especially consumer-near goods containing engineered nanomaterials will have to be labelled sooner or later due to growing political pressure. However, it remains unclear whether nano-labelling of consumer goods will actually enable consumers to make informed choices. There are reasonable concerns from the industry that nano-labelling as such could be misunderstood as an indication of hazard, thereby raising new and potentially unnecessary fears among consumers. Therefore the purpose of a nano-labelling or declaration system should be determined in advance (eg pure informational purpose, instructions for use or precautionary guidelines). Transparent and proactive communication is necessary to prevent the mixing of safety relevant data needs (eg. in the value chain) and nano-labelling (eg. in consumer product declarations).

Nano information pyramid

Along the value chain it seems clear that the information needs of downstream users have to be satisfied by appropriate means, and that the information and data requirements must be communicated to upstream players as well.

This implies the following challenges:

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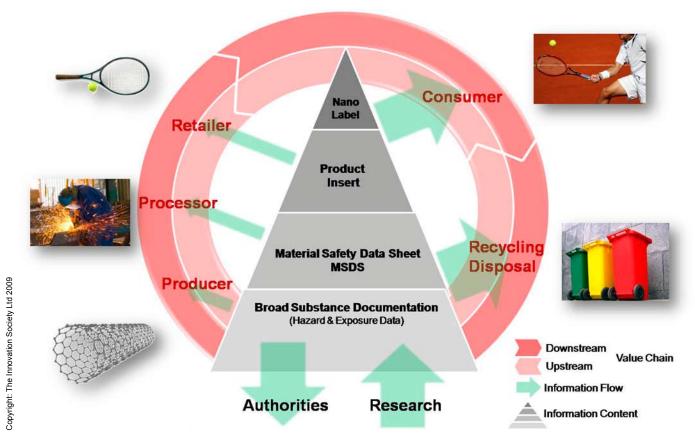


Fig 1: The nano information pyramid concept

- * Finding/adapting appropriate and trustworthy tools to transfer data and information along the value chain
- * Ensuring that the information flow (up and downstream) is not interrupted
- * Allocating costs and responsibilities to the accountable stakeholders

We suggest that adopting the concept of a "nano information pyramid" would provide a framework for information exchange and could be used to illustrate and satisfy the needs of different stakeholders along the value chain. The pyramid also addresses consumer-relevant issues of labelling and declaration. It combines different recipient-specific tools in a constitutive system which takes into account not only the calls for more information on nanomaterials along the value chain, but also hazard profiles of the substances (if necessary).

At the bottom of the pyramid there is the safety data which is provided to authorities and regulators by the industry in a **broad substance documentation** (REACH and beyond). This serves as a database to regulators and authorities for registration or documentation purposes, and for considering intellectual property and confidentiality issues. Lower Mass and

volume thresholds of nanomaterials have to be taken into account, subject to hazard and exposure potential of the substances (adaptation of REACH).

On the second level, the **MSDS** should contain user-specific information on

A "nano information pyramid" would provide a framework for information exchange and could illustrate and satisfy the needs of different stakeholders along the value chain

substances' nano-specific properties. Because MSDSs contains expert information and address experts, they should be the tool of choice for transferring information along the value chain from producers to processors, and possibly even further to recyclers. However, as widely recognised, the MSDS need to be adapted to cover the specific properties of engineered nanomaterials. Several organisations are already working on the nano-specific adaptation, and the Swiss government's Secretariat for Economic Affairs (SECO) is developing guidance on the integration of nano-specific information in the MSDS.

On the third level we recommend **product inserts**, which could provide user-specific information on the properties of the materials and products (directions for use, properties, hazard recommendations for waste treatment, recycling, etc.) and address potential questions of users. Such inserts could be useful both for consumer products such as textiles and sports goods, and industrial products such as plastics, paints and surface coatings that contain engineered nanomaterials. Products inserts should be aimed at the general public (non-academic-users) if they are used in consumer or industrial products

On the fourth level **nano-labels** could be applied. These would refer to product properties. Product labelling seems to be

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particularly useful to indicate in a very concentrated manner certain quality features or environmental, health and safety properties of a product containing engineered nanomaterials (eg. a tennis racket containing carbon nanotubes). They could be useful for consumers and provide information for waste treatment or the recycling of potentially hazardous materials

Figure 2 gives an overview of the tools of the nano information pyramid regarding the steps of the value chain, indicating the information flow and the interfaces between the downstream user. It also shows the tools that could be applied at each step and the issues concerning the exchange of information between the different elements.

Risk management

Companies which produce or handle engineered nanomaterials have to apply appropriate safety measures, and are expected to provide safety relevant data to their customers. To prevent liability claims they should use appropriate risk

management tools. Apart from conventional risk management systems there is also a nano-specific risk

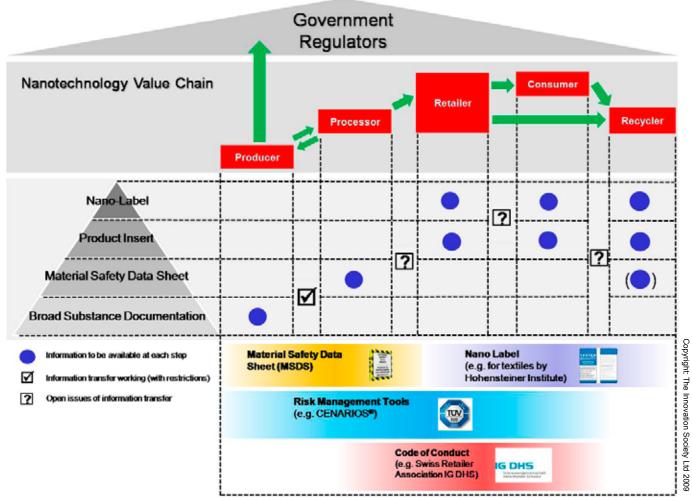
Companies producing or handling nanomaterials should use appropriate risk management tools to prevent liability claims

management system called CENARIOS (Certifiable Nano-specific Risk management and Monitoring System) (www.cenarios.eu), which has been developed by the German consulting and certification company TÜV SÜD.

Currently, this is the only comprehensive standard for a nano-specific safety label which is approved by an accredited third party organisation, and which can be communicated along the value chain. The certificate asserts that the company's risk management system is based on the latest scientific and technical knowledge regarding the risks of engineered nanomaterials, and the relevant data can also be transferred to downstream users and to the broader public. This creates safety in the value chain and trust on the consumer side.

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Fig 2: How the nano information pyramid relates to the value chain



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