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Nanomaterials, risk and regulation

There is a concern that the unique properties of nanomaterials may have side-effects in the form of unique risks for health and the environment. Nanomaterials are diverse, and we can expect great variation in terms of hazard, exposure and in our understanding. Regulations must be in place that stimulate the generation of knowledge, and ensure control where it is needed.

This policy brief focuses on health and environmental risks of engineered nanomaterials, as opposite to materials that occur naturally, or unintentionally, on the nanoscale. We mainly focus on applications within the consumer market and industry, including chemicals, electronics, textiles, cosmetics and construction materials. However, the discussion is also relevant to applications within food and medicine. The report describes risk and management at different stages in product life cycles, from challenges within industry, to questions regarding use and disposal.

What are nanomaterials?

A central topic within nanotechnology is to develop nanomaterials. These are materials whose structures measure between 0,1 and 100 nanometers, and that have unique properties related to their size. Nanotechnology is based on our increasing abilities to modify and build structures on the atomic and molecular level, and to control the properties that appear.

Categories

Traditionally, substances are identified by their chemical structure. To categorize nanomaterials, however, it is also necessary to differentiate between geometrical structures. There are four general categories:

1. Materials where all three dimensions are on the nanoscale (true particles)
2. Materials where two dimensions are on the nanoscale (tubes and wires)
3. Materials where one dimension is on the nanoscale (surfaces, coatings)
4. Bulk materials that have an inner structure on the nanoscale, e.g. materials with nanosized pores

C60-fullerenes and carbon nanotubes (CNT) are examples of nanomaterials belonging to category 1 and 2. Both are based on carbon, but have different geometrical structures. In the first case, a grid of carbon atoms forms a ball; in the latter, a similar grid of carbon atoms forms a tube. Category 1 also includes particles based on metal oxides such as titanium dioxide, and metals such as silver and iron. Categories 1 and 2 have several similarities in relation to risk, and in this report we therefore allow both categories to fall under the term "nanoparticles".

Applications

Nanoparticles are generally used in combination with other materials. In addition to their geometrical and chemical structure, nanoparticles can therefore also be categorised according to their substrate; whether they are in gas phase, suspended in liquid, bound to surfaces or integrated into solid structures (composites). Materials can change form and therefore the particles may fall into several categories during their lifetime.

Composites reinforced with CNTs allow for rough uses such as cars and sports equipment. Some types of CNTs conduct electricity, or they may be applied as semi-conductors in electronics. Nanoparticles of titanium dioxide are used in sunscreen to protect against UV-light, while platinum is applied in catalysers in cars. Nanoporous structures (category 4) may contribute to insulation or to filtration of water or air.

Health and environmental concerns

Research on risks related to nanomaterials has primarily been focused on health effects, and there is some evidence of harm. However, the knowledge is scarce, especially related to long term effects and environmental impacts.

There is a general acknowledgement that nanoparticles are the primary concern compared to other categories of nanomaterials. The particle nature makes it possible to enter parts of the body and the environment that are otherwise protected. Furthermore, smaller structures have relatively more atoms on surfaces and edges where they can react and interact with other elements. This does not imply that all nanoparticles will do harm. Risk is a product of hazard and exposure.

Hazard

Animal tests where nanoparticles are inhaled or injected indicate that certain nanoparticles may translocate from airways and blood to organs like the liver and brain. Other tests indicate that some nanoparticles may oxidize and disturb organic structures and processes, for instance in cells. What implications this may ultimately have for human health is uncertain; though diseases in the airways, cardio vascular system, nerve system and cancer are possible scenarios.

Exposure

Release of nanoparticles will vary according to the nature and life cycle of the product. Particles are generally unable to escape from composites; however such escape may occur during manufacture or waste management. Products with free particles or where particles can be released through wear and tear attract special attention. Occupational settings are a major candidate for human exposure. Such professional exposure can occur at different stages of product life cycles, from laboratories and manufacture, to use and waste management. Consumers may be exposed where products are used on or close to the body, such as in food, cosmetics and in the indoor environment. For the short term, the use and release of most nanoparticles is considered to be so limited as not to give rise to harmful doses in the natural environment.

Some products can easily be classified as either low risk or high risk, based on whether nanoparticles can be released or not. Most often, however, we have limited knowledge about the product life cycle, for instance about wear and waste management. Will particles escape by themselves, or be bound to larger fragments? Will they remain as primary particles, form larger aggregates, or break down into smaller compartments? Such changes may affect their mobility and reactivity. We also lack understanding regarding how nanoparticles interact with other elements. For instance, nanoparticles may react with other elements, including toxics, and mobilize these.

Challenges for regulations

Nanomaterials fall under different regulations, depending on the type of application and the stage in the life cycle. Environmental release is regulated by the Pollution Control Act, while the Working Environment Act covers risks in occupational settings. Applications in medicine, food, cosmetics and pesticides are covered by distinct regulations, which may warrant risk assessment, permissions and product declarations. Applications in consumer products such as chemicals, textiles, toys, electronics and construction materials are covered by the Product Control Act. In general, Norway shares these regulations with the EU.

Possible approaches to regulation

It has been proposed that the challenges around nanoparticles are not properly addressed by existing regulations and that they require their own regulatory approach. To regulate nanomaterials under a unique regulation is, however, not fruitful as the materials and their applications are so diverse. To achieve consistency between the needs and the means of protection it is more fruitful to differentiate according to the type of application. This principle is already applied in the general structure of current regulations, which pose different requirements according to differences in risk profiles, from pesticides, through medicine, to consumer products. It is, however, necessary to assess whether these regulations address the uncertainties concerning nanomaterials. The crucial test is whether regulations stimulate understanding and ensure control where needed.

Triggers for risk assessment

Requirements to ensure knowledge and control vary. Food additives must pass different tests to qualify for a list of approved substances. Substances in consumer products require risk assessment only if they fulfil certain criteria. The information provided by such assessment is subsequently used to identify appropriate control measures. The requirement to perform a risk assessment is therefore critical to enable control. The criteria that trigger risk assessment must be adapted to nanomaterials, in particular this relates to threshold values and how substances are identified.

Mass thresholds are not sufficient

Thresholds in current regulations are generally based on mass. For example, commitments to register a substance according to the REACH directive only apply to substances that are produced or marketed in quantities above 1 ton. Such mass-based thresholds are insufficient for nanomaterials as they do not capture increased mobility, reactivity and eventual risks that may appear when materials are modified to smaller structures with increased particle numbers and aggregate surface.

The identity of substances

A report from the Nordic Council¹ refers to a review of eleven products that were claimed to contain CNTs. In most cases the CNTs were reported to belong to the substance graphite, and implicitly, risks were also supposed to be similar. The report emphasizes that CNTs have unique characteristics, and questions if it is valid to identify CNTs as graphite.

To identify CNTs as graphite is mistaken – though even if it wasn't, it should not formally revoke the requirement to obtain information about the unique properties of CNTs. Risk assessment should in general also consider the different risks that may arise from different forms and uses of a substance. The example above indicates that this requirement is not precise, and may easily fall prey of misinterpretations.

So far, it is unclear which nanomaterials should be classified as unique substances with their own unique risk assessment. Alternatively, if a nanomaterial is identified as a new form or use of an existing substance, how do we satisfy the need for knowledge?

Monitoring product life cycles

The form and properties of nanomaterials are influenced by how they are used. To shed light to this, regulations commit actors in the value chain to exchange information. Such information shall, *inter alia*, enable actors to learn from experience and provide for adequate management through the different stages of the life cycle. To achieve a comprehensive overview of nanomaterials' fate, however, it is also necessary that authorities monitor these value chains. To realize this, the authorities may seek out information or, alternatively, impose mandatory registration. The Norwegian Product Registry would be an obvious candidate to enforce mandatory registration.

Research and methodologies

The Scientific Committee on Emerging and Newly Identified Health Risks in the EU, SCENIHR, has evaluated current approaches for assessing risks related to human health, and found that the general principles of these approaches are also appropriate for nanomaterials. However, uncertainties remain, both concerning the nanomaterials' properties, mechanisms of damage to health and the environment, and test methodologies. As a consequence, more research is needed. The OECD has taken the initiative to coordinate research on risks associated with nanomaterials. Norway should participate by appointing topics where Norwegian researchers take a lead.

Precaution and participation

Industry's commitment to risk assessment and public risk research will bring about increased understanding, but cannot eliminate uncertainty. The precautionary principle emphasizes that the absence of full scientific certainty shall not be used as a reason to postpone measures to reduce a potential hazard if the suspicion is sufficiently severe. The degree of certainty necessary to legitimate measures is a political question.

Recommendations from the expert group

Nanomaterials do not reward a separate regulation. Rather, regulation of nanomaterials should be based on current regulatory approaches concerning health and the environment.

It is necessary to investigate the properties of nanomaterials. To commit the industry towards this, authorities must amend the triggers for risk assessment. Mass-based thresholds must be supplemented by other values, such as aggregate surface area or particle numbers. In occasions where nanomaterials are considered as new forms of existing substances, this should not be taken to reduce the commitment towards risk assessment. Risk assessment should also consider how properties may change during the life cycle.

It is necessary to monitor the use of nanomaterials. Mandatory registration in the Norwegian Product Register should be expanded to include all products where nanoparticles are added.

¹ <http://www.norden.org/pub/sk/showpub.asp?pubnr=2007:581>

Systems for extended producer responsibility should be considered for more product types than today. Such systems imply that producers are put in charge of waste management and can stimulate life cycle perspectives already at the point of product development.

Employers must amend their EHS-approaches according to new knowledge. They must reconsider protective equipment and routines in occupational settings, and methods to manage waste and discharge.

A mandatory labelling scheme for products with nanomaterials is of little value. Rather than expecting consumers to take a position on whether to approach or avoid such products, consumers should expect that authorities ensure sufficient control and require consumer guidance where needed.

The lack of knowledge concerning nanomaterials should be met by research on health and environmental effects, as well as development of methodologies.

The government should appoint research institutes with a responsibility to stay up to date on international research. Further, they should consider establishing a scientific committee for risk assessment of materials and products, including nanomaterials.

Managing nanomaterials require a trade-off between benefits and burdens. Such dilemmas are political topics that should be negotiated in open dialogue with both research, industry, organisations and the public.

This abstract is based on the report “Nanomaterialer, risiko og regulering” (in Norwegian). The report and recommendations have been developed in an expert group involving the following members:

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