AN increasing number of engineered nanomaterials (ENMs) are entering the market in everyday products spanning from healthcare and leisure to electronics, cosmetics, energy, agriculture, food and transport.

While for chemicals there are established regulatory frameworks dealing with the risk for consumers, workers and the environment, this is not the case for nanomaterials. The cause is precisely the reason for ENM use — the properties of matter at the nanoscale change and become dependent on the feature or particle size. Our understanding on how such nano-systems react with biological matter, such as cells and tissues, is far from complete and this brings about increasing levels of uncertainty in the research and development process.

It becomes increasingly clear that harmful properties of nanoforms often do not correlate with the toxicological profile of the bulk materials. One of the challenges there is the identification of the best metric for toxicological assessment. A related challenge is how a nanomaterial can be defined as there are several different definitions internationally.

In Europe, the concept of safe-by-design was established to help the development of nanomaterials minimising the risk at every stage of the research and development process in order to achieve long-term commercial potential and consumer acceptance. At the heart of safe-by-design lies the concept of substituting the question ‘Is the material safe?’ with ‘Can we engineer the nanoform to be safe?’.

What are the identifying methodologies?
An holistic view of the nano-hazard and the related process risk is crucial for successful integration of nanosafety aspects into the overall risk management methodology. Material properties, health effects, potential of release and occupational exposure are principal aspects for successful risk mitigation.

Traditional chemical risk assessment tools are based on the quantitative dose-response relationship, which is augmented by setting a threshold defining the no-effect levels, or occupational exposure limit (OEL). It is applicable in cases when sufficient toxicological and occupational exposure data are available. However, this is not the case for the majority of nanomaterials.

Additional challenges are the size and shape dependence of the toxic effects, which can be substantially modified by applied functionalisations or the interactions with the environment in the body. Therefore, the current expert opinion tends to agree that conventional risk assessment tools have limited applicability to nanomaterials. At present there is no regulatory agreement on OELs for nanomaterials, which slows down industrial acceptance of such materials and hampers consumer confidence.

Management must be based on grouping principles
Such identified gaps in understanding promote the view that the most promising approaches for the management of nano-related risk must be based on grouping principles. This brings the field’s attention to various risk and control-banding tools. Efforts in the direction of the grouping of nanomaterials and read-across missing properties of nanoforms are encouraged by stakeholders, such as the nanotechnology industry, national regulators and international bodies, like the OECD.
There is a recent international standard dealing with nanosafety in occupational settings: ISO Technical Standard ISO/TS 12901-2:2014 ‘Nanotechnologies – Occupational risk management applied to engineered nanomaterials’. The standard defines five nano-hazard groups which combine with four exposure bands. This is constrained by five control bands, which identify measures to be implemented in order to reduce the risk for the personnel.

The main assumption of the standard is that the risk is measured in a relative way. This assures the genericity of the approach, as the hazard can be compared to reference materials and interactions, for example considering the inhalational exposure route.

**Why the semiconductor industry?**

Identifying methodologies for risk assessment and governance of such situations is part of the work undergoing the H2020 project NanoStreeM,\(^1\) which targets the semiconductor industry.

The semiconductor industry can be presented as a use case on how potential occupational and environmental risks brought about by such products are governed. Specifics of this industry, which make it interesting, include:

- The nanoelectronics industry plays a key role to solving Europe’s societal challenges; its products and innovations are essential in all market segments where Europe is a recognised global leader; and the intensity of its industrial research and innovation is among the highest in the world. Industrial production accounts for 16% of Europe’s GDP and remains a key driver for innovation, productivity, growth and job creation; and

  - Nanoelectronics enjoys a very fast innovation cycle governed by Moore’s law. This brings about a variety of new materials and combinations into production, while some of them are in nanoform.

Nanoelectronics relies on multiple semiconductor processes resulting in patterning of macroscopic objects (silicon wafers) on the nanoscale. Semiconductor mass manufacturing employs top-down high precision approaches offering nanometre resolution of detail. Engineered nanomaterials are used in several processing steps. On the other hand, nanomaterials can be developed as by-products of several generic processes.

At present, the efforts of the NanoStreeM project are focused on evaluation of several risk governance paradigms, starting from the ISO standard. We have prioritised several common scenarios for the semiconductor industry. The consortium industrial partners evaluate state-of-the-art risk assessment tools and compare them to available emission measurements.

**Reference**

1. EC definition: at least 50% primary particle threshold, except in specific cases.

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**What are nanomaterials?**

Nanomaterials are broadly defined as those materials that have a certain percentage of particles at the nanoscale, between 1 and 100 nanometres.\(^1\) While the size cut-off used in the definitions is somewhat arbitrary it nevertheless conveys the important fact that properties of materials with nanoscale features (e.g. nanoforms) can substantially differ from the properties of ‘macro’ materials in bulk.

Nanoforms can have desirable characteristics, such as increased strength of the material, modified chemical reactivity or electrical properties. These features offer possibilities for new applications in a broad range of sectors; for example in medicine (e.g. detection of genetic sequences using DNA-tagged gold nanoparticles); environment (e.g. waste-water treatment with carbon nanotube filters); or energy production (e.g. solar cells using silicon nanocrystals).

At the same time, the use of manufactured nanomaterials in a number of commercial applications raises questions about potential unintended risks to humans and the environment: for it is known that particles of nanometre size can get deposited in the lungs, pass easily through alveoli or even get dispersed in the body.

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**To address challenges in nanomaterial risk assessments**

the H2020 projects NanoStreeM (www.nanostreem.eu) and calIBRAtE (www.nanocalibrate.eu) organise a joint workshop entitled ‘Governance of emerging nano-risk in semiconductor industry’. The event will take place in Brussels on 26 April 2018. More information is available on www.nanostreem.eu/events/governance-event

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