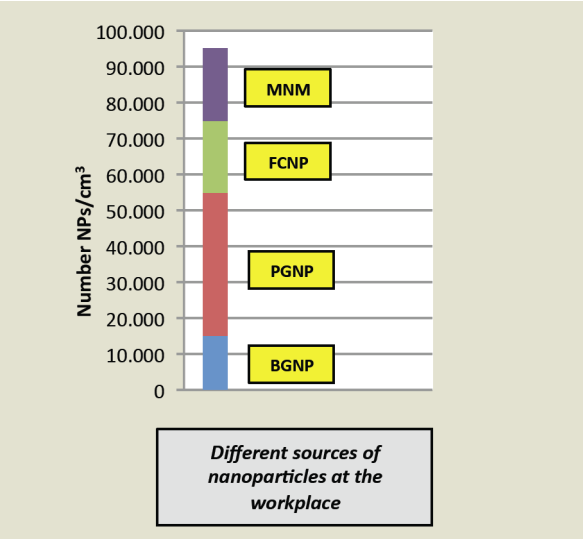
Project fact sheet 13

Regulatory research for effective risk assessment

Three regulatory research workshops were organized to discuss sensible ways forward for risk assessment and regulation of nanomaterials in Europe. Sessions took place at the NANOSAFE2014 conference in Grenoble, in Brussels 2015 with the German Institute for Occupational Safety and Health (IFA) and at Nanotech Italy 2015 in Bologna. Participants were researchers, industry, civil society organisations, risk assessors and policy makers.

At the first workshop, the issue of transparency and traceability of nanomaterials in products was thoroughly debated. The demands of regulators and civil society organisations for independent risk assessment contrasted with the commercial need for confidentiality within industry. The workshop participants noted that existing registries for nanomaterials so far do not generate sufficient transparency to independently assess the composition of products. They advocated a precautionary approach when insufficient hazard data is supplied, proactively making clear how potential – but as yet uncertain – risks will be managed. This includes the development of exposure values that trigger the concern, capacity building for societal stakeholders and assuring their concerns are addressed.



Different sources of nanoparticles at the workplace

The second workshop focused on the operationalisation of a precautionary approach, the need for benchmark levels in occupational hygiene and a thorough communication in the production chain. The concept of 'concern' was found to lead to confusion about the precise meaning and implications of a precautionary approach. The existing chemical legislation REACH (Registration, Evaluation, Authorisation and Restriction of Chemicals) uses 'concern' to identify substances with proven serious adverse effects, known as 'substances of very high concern', i.e. the hazards of these substances are well known. The precautionary approach however starts from a different interpretation of concern: the reasonable likelihood of adverse effects, given the chemical properties of the substance. A precautionary approach suggests that precaution should be applied if adverse effects are likely to occur, even in the absence of quantifiable indications of a hazard. In other words, precautionary measures may be required even though there is no conclusive scientific evidence of hazards on a quantitative level. While the 'traditional' notion of concern calls for quantified prevention, the qualitative interpretation of concern allows for developing provisional - and proportional - precautionary risk management measures based on a cost-benefit analysis. The widespread adoption of a precautionary approach, applying precaution in case of existing uncertainties

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rather than by established hazards, will depend on a better understanding of these different interpretations of the notion of 'concern'. To demonstrate the feasibility of the precautionary approach and the possibility of proportional risk management with insufficient hazard data, examples of existing precautionary levels for maximum workplace concentrations were presented (the Dutch nano-reference values (NRVs), and Germany's benchmark levels).

The third workshop discussed the precautionary approach more exclusively with research and industry representatives and confirmed that a better understanding of the precautionary approach is a prerequisite for its broad acceptance in risk management. The workshop discussed employers' duty-of-care for a safe workplace as defined in the Chemical Agents Directive (CAD). This duty of care implies the need for broader insight in nanomaterials at the workplace than simply using the data as available through REACH. REACH is predominantly hazard-based, but the CAD is exposure-based. This implies that the dominant focus of current risk research on establishing hazards as identified under REACH needs to be extended towards a downstream users oriented exposure-based approach. To put exposure to manufactured nanoparticles in a realistic perspective, workplace exposures during professional use of manufactured nanomaterials were compared to exposure to existing and generated concentrations of nanoparticles in the workplace and in the environment. Manufactured nanomaterials (MNMs) proved to be just one of several sources of nanomaterials exposure at the workplace. Other sources include fractions of nanomaterials in conventional compounds (FCNPs), process-generated nanoparticles (PGNPs) and those in the environmental background (BGNPs). It was also noted that nanomaterials to which workers may be exposed are not necessarily identical to the nanomaterials used in the product – during use and after release, nanomaterials may be transformed by chemical reactions, forming new materials.

Both the different possible sources and the possibility of transformation of nanoparticles have consequences for the employers' risk management initiatives. Given these scientific grounds for concern, a precautionary approach is warranted even in the absence of conclusive hazard data. Clear communication in the production chain on nanomaterials and their possible transformations during use should be included in the Safety Data Sheet.

MORE INFORMATION

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NanoDiode is a project for outreach and dialogue on nanotechnologies, funded by the European Commission.
From July 2013 to June 2016, NanoDiode has organised a range of engagement activities across Europe, involving stakeholders in a dialogue on the funding, performance and outcomes of nanotechnologies research.

The NanoDiode fact sheets present the different activities carried out as part of the project and discuss the main findings and recommendations. This is nr 13 of a series of 14 fact sheets, see: www.nanodiode.eu/factsheets.

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