Do we need a legal definition for "nanomaterials" in occupational health and safety regulation?

BAuA position paper of 20. August 2019

Rolf Packroff[1]

baua: Focus

Based on an amendment to the European Chemicals Regulation REACH, additional testing and specific information requirements for the registration of nanoforms of substances will apply from 2020. This amendment is based on a proposal of the EU Commission for a definition of the term "nanomaterials", which aims at a uniform application in various areas of law. However, BAuA does not see any need to define nanomaterials as a uniform category in occupational health and safety regulation.

Content

1 Proposed EU definition of nanomaterials

Based on a technical definition of the International Organization for Standardization (ISO), the EU Commission has proposed a definition of the term "nanomaterials", which is to serve as a basis for regulations, especially in the areas of chemical safety, environmental and consumer protection.

INFOBOX BAUA : FOCUS

'Nanomaterial' means 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.(...). Where technically feasible and requested in specific legislation, compliance with the definition (...) may be determined on the basis of the specific surface area by volume. A material should be considered as falling under the definition (...) where the specific surface area by volume of the material is greater than 60 m^2/cm^3. (...) Fullerenes, graphene flakes and single-walled carbon nanotubes with one or more external dimensions below 1 nm should be considered nanomaterials [1].

[1] Federal Institute for Occupational Safety and Health (BAuA)

baua: Federal Institute for Occupational Safety and Health

The proposal is not yet binding. Nanomaterials are already defined, but not uniformly, in European Union regulations on biocides, cosmetics, food additives and food contact materials, among others. The recent amendment of the annexes to the European Chemicals Regulation REACH uses the definition of a "nanoform of substances" as the basis for specific testing, evaluation and information requirements for registration [2]. The EU directives on occupational health and safety, in particular the Chemical Agents Directive [3] and the Ordinance on Hazardous Substances as their transposition into German law [4], do not yet contain any direct references to nanomaterials.

2 Grouping approach for nanomaterials and occupational safety

The risk assumptions made 15 years ago of a "particular toxicity" of nanomaterials, based on their specific quantum chemical properties, and a high systemic mobility in the body due to the small size of the particles, could not be confirmed in extensive investigations. Instead, the adverse health hazards of nanomaterials in the workplace can be described using the classical approaches of substance and particle toxicology. The results of the extremely complex animal study "NanoInVivo", the final evaluation of which is to be published in 2020, have made a particular contribution here [5, 6]. For occupational safety, a regulatory grouping approach has been derived, which the World Health Organization (WHO) has also adopted in its evidence-based guideline on occupational safety and health for nanomaterials [7]. The grouping approach, which can also be applied to other materials (Figure 1), distinguishes between materials with different testing and evaluation strategies required for risk assessment in occupational safety:

1. materials that release respirable, granular, biopersistent dusts ("GBP")
2. materials that release respirable, biopersistent fibre dusts ("WHO fibres"), and
3. materials with a specific (chemical) toxicity, which is may due to the release of ions, among other things.

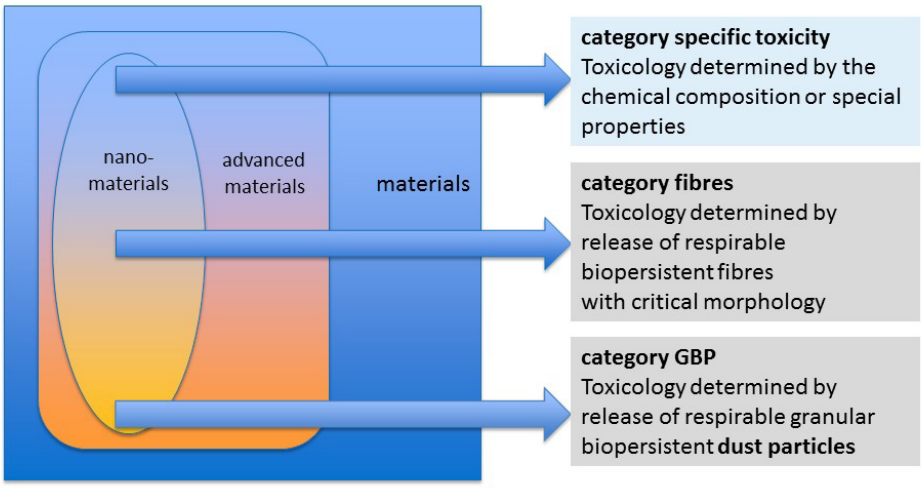

Fig. 1 Toxicological grouping approach for materials in occupational safety

A given (nano-)material may well exhibit combinations of two groups if particle and substance toxicology overlap. For example, nano cerium dioxide used as "GBP reference material" in the "NanoInVivo" study probably also shows a certain level of specific toxicity in additon to mere particle toxicity. The announcement on hazardous substances BekGS 527 "Manufactured nanomaterials" of the Committee on Hazardous Substances [8] additionally defines

a category "soluble nanomaterials", for which particle toxicity is of no importance for occupational safety. However, these can also be considered as a subcategory of materials with a specific toxicity, which may be very low (e.g. nanoforms of sodium chloride).

2.1 Category GBP

Extensive toxicological findings are now available on the health effects of respirable, granular and biopersistent particles (GBP), which for a long time were regarded as largely unproblematic due to their lacking specific toxicity. It is now assumed that health effects are determined by the total volume of dust in the deep respiratory tract, which accumulates there due to its biopersistence [9]. The effective threshold of toxicity (i.e. persistent inflammation) based on particle mass is therefore dependent on the material density. From the animal experimental data, a value of 500 µg/m³ can be derived for microscale GBP with a density of 1 g/cm³. For a typical workplace material density of 2.5 g/cm³ , this results in a value of 1.25 mg/m³ , which was defined in Germany as the a "general" limit value for the respirable dust fraction [10].
In the case of non-compact nanoscale GBP, the volume of their agglomerates, including the "void space" in these agglomerates, is decisive for the toxicological potency; this increases the total volume of the dust in comparison to microscale dust with identical mass. At a density of 1 g/cm³, this results in an effective threshold of 1.25 µg/m³, which is lower by a factor of 4 compared to microscale dusts. With the density of 1.5 g/m³ assumed typical for pure nanomaterials at the workplace, the calculated air limit value is 190 µg/m³ [10]. In practice, however, even activities involving nanomaterials always involve mixed dust with micro- and nanoscale particles. Therefore, the Committee on Hazardous Substances in the BekGS 527 recommends a value of 500 µg/m³ as a reference value (assessment criterion) for the effectiveness of occupational health and safety measures taken for activities with GBP nanomaterials. These values can be safely met with the protection requirements of the Ordinance on Hazardous Substances on handling of particulate hazardous substances.

2.2 Category fibres

Materials that release respirable, biopersistent fibrous dusts are a major challenge for occupational safety. The asbestos problem, which has not been solved even in Germany 25 years after the ban, makes this particularly clear. The toxic potency based on the inhaled fibre material mass is up to several orders of magnitude higher than that of GBP materials and has a wide range depending on the biopersistence. Obviously the stiffness (rigidity) of the inhaled fibres is also important. Extremely thin fibres therefore tend to have GBP properties because they get entangled[1]. In addition, there are very large differences in the dustiness behaviour of different materials, which can be up to 6 orders of magnitude for different types of carbon nanotubes, for example. When deriving risk reduction measures, therefore, a very wide range of risks must be taken into account, which in the worst case (as in the case of asbestos) can also lead to the result that conventional occupational health and safety measures cannot guarantee safe handling.

2.3 Category specific toxicity

The toxicology of these materials is dominated by the chemical composition and not by their morphology. As a rule, the classification for the "bulk form" under the CLP Regulation is here also valid for pure nanoforms. This also applies to occupational exposure limits and the cor responding risk reduction measures. One example is nanosilver, whose health effects ("agyrosis") can be attributed to soluble silver ions. However, nanomaterials coated with other substances or composed of several components require special assessment.

[1] A lower fibre diameter of 30 nm is currently assumed for multi-walled carbon nanotubes. However, animal experiments are currently being carried out to test whether the agglomeration of thin individual fibres, which can be observed particularly in single-walled carbon nanotubes, also leads to a relevant fibre-specific toxicological mode of action.

3 Conclusions for regulations in occupational health and safety

There are currently no uniform regulations for nanomaterials based on a definition in either German or European occupational health and safety law. In BAuA's view, these are not necessary either. In the case of GBP materials, this is due to the small differences in toxic potency between micro- and nanoscale materials of the same chemical composition. In the case of fibrous materials, uniform protective requirements for nanomaterials would even be counterproductive, since the toxicity of nanoscale fibres (below 30 nm for CNT) can decrease significantly at very small fibre diameters due to the loss of fibre stiffness. Moreover, relevant fibre diameters from 100 nm to approx. 3,000 nm are not covered by the definition at all. For risk assessment in the workplace, therefore, a characterisation based on the information in the safety data sheet is usually sufficient. The BekGS 527 provides guidance on how to deal with materials designated as "nanomaterials" in the context of risk assessment. For the further development of the EU occupational health and safety directives, the BAuA proposes that a "general limit value" for the respirable dust fraction and specific measures for "particulate chemical agents" be included in the Chemical Agents Directive 98/24/EC (based on Annex I of the German Hazardous Substances Ordinance). With the "Nano-to-go" information package, the BAuA has made an important contribution to the European and international dissemination of these occupational safety standards for nano and other advanced materials [11].

4 Conclusions for the further development of EU chemicals legislation

Only a sufficient, scientifically sound information along the supply chains can guarantee a proper risk assessment in the workplace and an adequate protection of employees, especially in SME. With the successful amendment of the testing and information requirements for nanoforms of substances under REACH, a first but incomplete step has been taken to adapt the regulations on European chemical safety to the current state of scientific knowledge on particle and fibre toxicology. We see a further important step, especially in an extension for fibrous forms of substances with specific testing and evaluation requirements for registration, which will allow a reliable identification of critical morphologies (i.e. fibres acting asbestos-like) and the derivation of exposure scenarios. Due to the focus in EU chemicals legislation on chemical substances and their "chemical" properties, there is a regulatory gap for materials that have a relevant potential for releasing respirable, biopersistent particles over their life cycle, regardless of whether they are nanoscale or microscale. In this context, there is an urgent need to identify fibres acting asbestos-like to avoid the return of a well-known disaster.

Literature / References

[1] Commission Recommendation 2011/696/EU of 18 October 2011 on the definition of nanomaterials, Official Journal of the European Union, No L 275, p. 38

[2] Commission Regulation (EU) 2018/1881 of 3 December 2018 amending Regulation (EC) No 1907/2006 of the European Parliament and of the Council on the Registration, Evaluation, Authorisation and Restriction of Chemicals (REACH) as regards Annexes I, III,VI, VII, VIII, IX, X, XI, and XII to address nanoforms of substances, Official Journal of the European Union No L 308, p. 1

[3] Council Directive 98/24/EC on the protection of the health and safety of workers from the risks related to chemical agents at work, Official Journal of the European Union No L 131, p. 11 of 7.4.1998, as last amended by Article 4 of Directive 2014/27/EU of 26 February 2014 (Official Journal of the European Union No L 65, p. 1

[4] Hazardous Substances Ordinance (Gefahrstoffverordnung - GefStoffV) of 26 November 2010 (BGBl. I S 1643), as last amended by Article 148 of the Act of 29 March 2017 (BGBl. I S 626)

[5] Gebel, T., Landsiedel, R (2013). Inhalte der Sicherheitsforschung: Langzeitwirkungen biobeständiger Nanostäube. Gefahrstoffe - Reinhaltung der Luft 10, 414, 2013

[6] Evaluation Bewertung der chronischen Toxizität / Kanzerogenität ausgewählter Nanomaterialien und Histopatologische Untersuchung von Proben aus einer Langzeitinhalationsstudie (in German), *www.bmu.de/themen/forschung-foerderung/forschung/forschungs-und-entwicklungsberichte/details/bewertung-der-chronischen-toxizitaetkanzerogenitaet-ausgewaehlter-nanomaterialien-und-histopatologisch/* (last accessed August 20, 2019)

[7] World Health Organization: WHO Guidelines on Protecting Workers from Potential Risks of Manufactured Nanomaterials, 2017

[8] Announcements on hazardous substances BekGS 527: Manufactured nanomaterials, GMBl 2016 p. 754 767 [No. 38] of 12.09.2016

[9] Committee on Hazardous Substances: Assessment criterion (reference value) for granular biopersistent particles without known significant specific toxicity (nanoscaled GBP) (respirable dust) generated from manufactured ultrafine particles, Edition: June 2015 (in German), *www.baua.de/DE/Aufgaben/Geschaeftsfuehrung-von-Ausschuessen/AGS/pdf/A-Staub.pdf*

[10] Technical Rules for Hazardous Substances TRGS 900: Occupational Exposure Limits, GMBl 2019 p. 117119 [No 7] v. 29.03.2019

[11] M. Baron: Safe handling of nano materials and other advanced materials at workplaces, 2015, *www.baua.de/nanotogo*

Imprint | Publisher: Federal Institute for Occupational Safety and Health (BAuA), Friedrich-Henkel-Weg 1-25, 44149 Dortmund | Telephone: +49 231 9071-2071, mail to: *info-zentrum@baua.bund.de*, internet: *www.baua.de*, Design: R. Grahl | DOI: 10.21934/baua:focus20191029 | January 2020

baua: Federal Institute for Occupational Safety and Health