Information note

What are next generation nanomaterials and why are regulators interested in them?

Several publications have discussed the problem of governance for "next generation", "second generation" or "future" nanomaterials. Van Teunbroek et al. state that "adapting and specifying the information requirements and test methods in REACH for nanomaterials that are now on the market, will not solve the regulatory hurdles **for next generation (nano) materials**".[1] Other publications have made similar points. For example in discussing risk assessment frameworks for nanomaterials, Oomen et al. state that "…the present assessment is based on knowledge that is gained from **'the first generation'** of nanomaterials, which comprise relatively simple inorganic and carbon-based nano-materials."[2]

What are these "generations" of nanomaterials, and are such predictions of regulatory hurdles correct based on the information on the market today? While several publications make similar references to the first generation of nanomaterials and next or future generation nanomaterials, these different generations are not well defined, or are not commonly agreed. To enable the challenges that may be associated with them to be identified, it is necessary to have precise and commonly agreed definitions, together with concrete examples.

The most frequently cited definition of different "generations" of nanomaterials can be found in publications by Mihail Roco[3,4,5]. In discussing the development of nanomaterials and nanotechnology, as well as their governance, Roco hypothesises that the development of nanomaterials would occur over different generations:

1) First generation products: passive nanostructures
2) Second generation products: active (evolving function) nanostructures
3) Third generation: systems of nanosystems
4) Fourth generation: heterogeneous molecular nanosystems

Roco has suggested that six different generations of nanoproducts can be expected by the year 2030[6]. The additional two generations are:

5) Nano Bio Info Cogno (NBIC) integrated technology platforms (expected between 2020-2025)
6) Nanosystem convergence networks (expected between 2025-2030)

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[1] Van Teunenbroek, T.; Baker, J. and Dijkzeul, A. (2017) Towards a more effective and efficient governance and regulation of nanomaterials. Particle and Fibre Toxicology 14:54

[2] Oomen A.G., K.G. Steinhäuser, E.A.J. Bleeker, F. van Broekhuizen, A. Sips, S. Dekkers, S.W.P. Wijnhoven, P.G. Sayre. Risk assessment frameworks for nanomaterials: scope, link to regulations, applicability, and outline for future directions in view of needed increase in efficiency. NanoImpact, 9, 1.

[3] Roco M.C. (2004) Nanoscale science and engineering: unifying and transforming tools. AIChE J 50:890

[4] Roco, M.C. and Renn, O. (2006) Nanotechnology and the need for risk governance. J. Nanopart Res, 8, 153.

[5] Roco, M.C. (2011): The long view of nanotechnology development: the National Nanotechnology Initiative at 10 years. J Nanopart Res 13: 427

[6] Roco, M.C. (2017) Overview: Affirmation of Nanotechnology between 2000 and 2030

Based on available information, nanomaterials on the market today have been there for long periods of time, sometimes for decades, or are "nanoforms" of previously existing materials. Substances such as silicon dioxide, titanium dioxide, and carbon black represent the largest portion of the market.

An examination of the French Registry for nanomaterials[7] shows that most, if not all of the notified materials represent passive/conventional materials, including a large number of pigments and fillers. These materials can together be considered as passive nanostructures[8].

Analysis of public literature indicates that there has been some shift in recent years towards research on, and production of, active, second generation nanostructures.[9,10] A key driver towards the emergence of such active nanostructures appears to be the development of active nanomaterials as drug delivery systems, although other applications such as the use of active nanostructures for the detection of spoiled foods, also exist.

Despite the presence of some examples of active second generation nanomaterials, overall the original predicted timelines for the emergence of higher generation nanomaterials have come and passed, and there appear to be limited examples available of third or fourth generation materials.

Regardless of the reasons for the lack of these materials on the market, the absence of precise and commonly agreed definitions of the terms involved, and in the absence of concrete examples, the ability to forecast future challenges can be difficult.

To address these issues, the European Union Observatory for Nanomaterials (EUON) commissioned a study to analyse whether the definitions, regulatory terminology and the ways in which we characterise and identify so called "next generation" nanomaterials are sufficient to regulate them. The study also examined whether these materials are already available on the EU market, or can be expected in the near future.

The study found that the current EU regulatory framework for characterising these materials is able to address the majority of them and that no significant changes are needed in the near future. It also found only a limited number of these materials currently on the market, mostly in medical and electronic applications. Taken together, these findings provide reassurance to regulators as well as the general public regarding the regulatory implications for these materials. Given the evolving nature of nanomateirals and nanotechnology, continued monitoring will be helpful to allow authorities to predict what materials will come to the market in the future, and how to adapt to new developments.

Further information

- A state of play study of the market for so called "next generation" nanomaterials [PDF] [EN]
- EUON: Study finds EU regulatory framework ready for the next generation of nanomaterials

[7] The European Union Observatory for Nanomaterials (EUON) includes a search for nanomaterials (https://euon.echa.europa.eu/search-for-nanomaterials) that retrieves results also from the French inventory.
[8] For the most recent list of substances notified to the French Registry on nanomaterials, see Annex I of the public report https://www.ecologique-solidaire.gouv.fr/sites/default/files/Rapport_R-nano_2017.pdf
[9] Subramanian, V.; Youtie, J.; Porter, A.L. ; Shapira, P. (2010) Is there a shift to "active nanostructures"? Journal of Nanoparticle Research, 12:1
[10] Suominen, A.; Li, Y.; Youtie, J.; SHapira, P.; (2016) A bibliometric analysis of the development of next generation active nanotechnologies. Journal of Nanoparticle Research, 18:270.