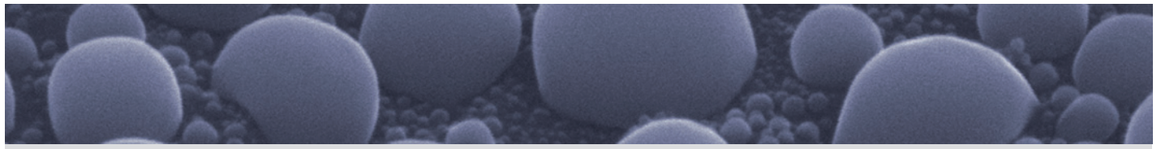

KEY CONCLUSIONS & CHALLENGES

The authors conclude that even if many areas of nanotechnology do not create new hazards, it is important to evaluate whether new forms of engineered nanomaterials may require modification of existing regulations. Given the magnitude of the task, there is also the need for screening approaches that inform decision makers how to set priorities for testing in more depth and tailored to different nanomaterials.

Key recommendations include greater cooperation between regulators and researchers to identify priorities for gaining new knowledge; the use of scientifically sound approaches for managing potential nanomaterial related risks in the absence of sufficient specific data; and the identification of opportunities to minimise risk by "safety-by-design" before nanomaterials enter into use.

Nanotechnology science could look to build on the increasingly well understood principles and standards that are now part of the broader field of toxicology, for example in the safety assessment of chemicals and pharmaceuticals. This strategy must be based on the precautionary principle, similar to the European Chemicals Legislation (REACH) process. However, it must benefit from further refining once sufficient knowledge is available to understand hazards, exposure potential and the means to protect workers, consumers and the environment from unwanted levels of contact.

The European Commission together with the European scientific community should also strengthen efforts to identify common needs for data collection for safety endpoints. This would enable comparison of results from disparate groups and nanomaterials. Researchers and regulators may need to develop a more differentiated approach to assessment and regulation while also recognising that the status of the nanomaterial may vary during its lifecycle. Nanospecific training, for example, in EU research programmes and both at Master's and PhD-level is seen as a priority. There is also broader need for training toxicologists, material scientists and production engineers in the risk assessment procedures for developing new materials. The authors underscore the need to develop a new generation of interdisciplinary scientists in tandem with new generations of nanomaterials. New training initiatives are also essential to confer this interdisciplinarity and secure the future of nanotechnology.

The report identifies the need for greater public engagement as a tipping point for the future success of nanotechnology. The authors argue that only by means of an accessible and accurate information campaign about the benefits versus risks of engineered nanomaterials will the science advance. Researchers and regulators must learn from past mistakes when not speaking up early enough in layman's language on topics of public concern. They must act in unison as spokespersons for innovative science, while stressing the societal protection afforded by proportionate, sector-specific regulation.

The overriding message and conclusion reached by the expert panel is that the EU needs a well-orchestrated, coherent strategy that has the flexibility to respond to future developments. This strategy must be multidisciplinary and multi-sectoral, requiring new effort in data collection, new infrastructure and new training initiatives, involving academia, industry, policy-makers and others in society.

The overriding challenge identified by the report's authors is how to accomplish this assessment when the number and extent of industrial applications is growing so rapidly, and how to ensure that benefit–risk is judged rather than risk alone. For nanotechnology to realise its potential, it is vital to empower the research and regulatory community to apply the precautionary principle in a case-specific and cost-effective manner. In so doing, the authors firmly believe that new knowledge will help to engineer safer nanomaterials, societal engagement, EU competitiveness and worldwide harmonisation.

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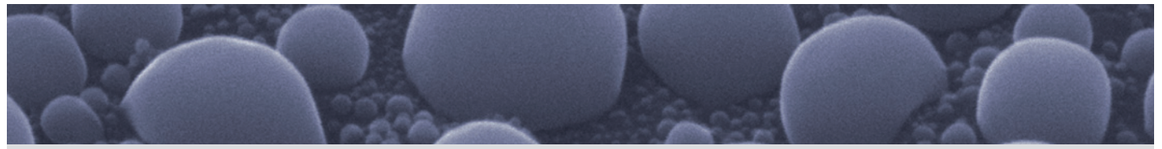
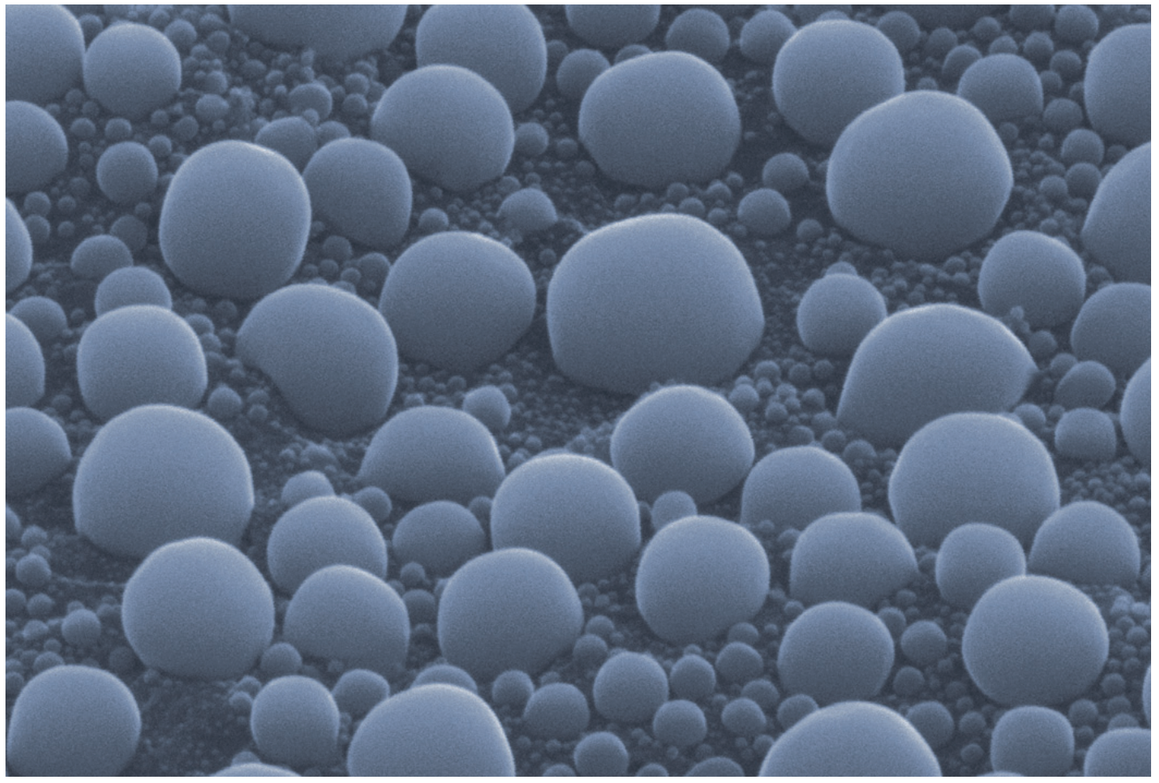


Report Synopsis

Impact of Engineered Nanomaterials on Health:

Considerations for Benefit-Risk Assessment



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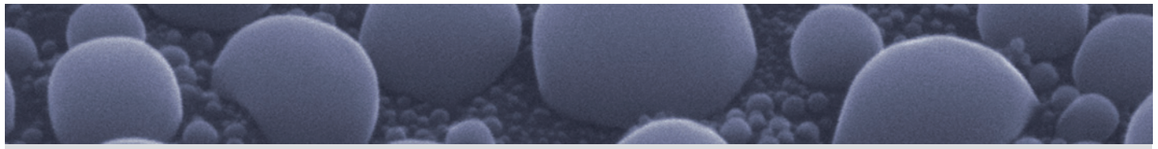


FOREWORD

From the JRC Director General and the EASAC President

This policy report is the result of the first strategic liaison between the European Commission's Joint Research Centre (JRC) and the European Academies Science Advisory Council (EASAC) and provides independent, cross-referenced, science-based analysis of the impact of nanomaterials on human health. Our report is directed at European and national policy-makers and citizens. Nanomaterials have the potential to play a major role in European innovation, economic growth and industrial competitiveness. However, a co-ordinated approach for the assessment of their safety must be the foundation of harmonised European and national policies. A strengthened dialogue between policy-makers and scientists is essential for addressing the issues associated with nanomaterials' safety assessment, as well as for accomplishing the EU 2020 targets.

This joint initiative of EASAC and the JRC contributes to the collective EU 2020 targets and supports integrated efforts for nanotechnology innovation, as well as public debate on the future of nanomaterials. Based on the experience of the initiative, and with existing synergies between the activities of the two organisations, a more structured co-operation will be developed to address other scientific topics relevant to the key priorities of the EU and to create closer links between EU national science academies and the policy-making processes in the EU.

Dominique Ristori
JRC Director General

Sir Brian Heap
EASAC President

CONTEXT

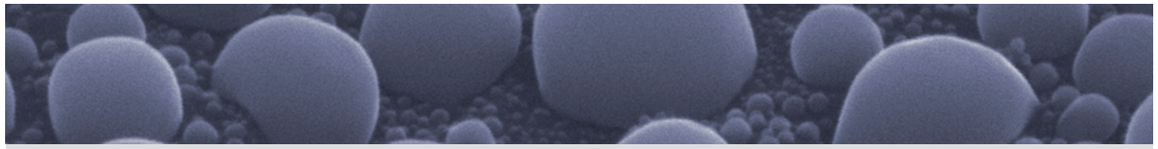
This timely expert panel report on the *impact of engineered nanomaterials on health* is the first in a series of strategic collaborations between the European Commission's in-house science service, the Joint Research Centre (JRC) and the European Academies Science Advisory Council (EASAC).

This contribution follows the first widely read report on nanotechnology published by the Royal Society and the Royal Academy of Engineers in 2004, a Code of Conduct issued by the European Commission in 2008, and a recent publication emphasising the continuing requirement for high-quality toxicology data issued by policy-makers in the European Commission, OECD and US Environment Protection Agency.

Both the JRC and EASAC are responsible for providing evidence-based, independent scientific advice to policy-makers such as Members of the European Parliament who, in turn, establish binding European norms that are closely followed by industry. The JRC practices specific nanotechnology research in its own laboratories, while EASAC openly accesses first class research through Academy members and their academic networks.

The international expert panel of 13 established in 2009 to compile this report draws on this pool of knowledge. It includes members from national medical research institutes, Academies and European Institutes, plus leading minds in environmental health and materials sciences.

In general, researchers, policy-makers and their advisory bodies widely acknowledge that there is no generally applicable paradigm for safety assessment of consumer and other products containing nanomaterials.



Given this shortage of comprehensive, joined-up research to-date and in order to obtain the strongest possible impact of its findings, the panel decided to focus the report on the impact of engineered nanomaterials on human health, although environmental effects are also discussed when directly relevant. The authors argue that the improved assessment of the potential risks of engineered nanomaterials requires significant effort to promote, extend and co-ordinate basic and applied research, and to translate research outputs into products and into informed policy decisions.

The authors do not seek to speak on behalf of the scientific community to establish formal guidelines, for example, on how to define nanomaterials. It is important to note in this respect that a new European Commission recommendation on a harmonised definition for nanomaterials was just issued (18 October, 2011). They do, however, draw on key principles and issues, cross-referencing sources for detailed information, rather than attempting a comprehensive account of the science.

This JRC/EASAC joint initiative supports ongoing efforts for nanotechnology innovation and will be widely disseminated. It identifies key recommendations towards a new joined-up approach. This is underpinned by better debate, engagement and action between science, industry, and government. The collective goal is safe nanotechnology-based products in our homes, workplaces and on our shelves.

The report equally underlines the scientific community's collective responsibility to better advise the European Commission and European Parliament about the opportunities now coming within range. While difficult to estimate the timeframe for the development of specific engineered nanomaterials and their launch as novel products, the report highlights that care must be given to create an appropriate supportive environment for innovation and flexibility in risk management.

The report's authors take a longer term, upbeat perspective encompassing the current and next generation of products. To this end, it is essential to invest in the science of safety assessment while, at the same time, seeking to expedite the regulatory review of the products emerging from that science so as to maximise their true potential.

An important consideration throughout the report is that there is only a limited amount of scientific evidence to suggest that nanomaterials present a risk for human health. The authors advise that the principles of risk assessment procedures applied to nanomaterials should conform to the same procedures as any other new material.

The report is structured in four sections:

1. An introduction charting the development and uses of nanotechnology, its safety considerations and the response of public and private organisations;
2. An overview of the legal and societal implications of nanosafety, the background to existing policy, regulation and governance and insights into standardisation and the harmonisation of testing methods;
3. An appraisal of future opportunities for nanotechnology balanced against ever-changing safety considerations and the risk assessment methodologies being used; and
4. Concrete recommendations on how to stimulate research leading to more effective product and policy stewardship, while filling the knowledge gaps on basic science, exposure, knowledge transfer, and education and training.

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