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How can risks from nanotechnology be managed? Researchers recommend global framework

Currently laws and regulations governing nanotechnology are fragmented and do not take account of the unique properties of nanomaterials, the effect of which on humans and the environment are not yet fully understood, argue researchers in a new study. In the study, a network of European researchers propose a new universal regulatory framework that deals specifically with nanomaterials. The framework should help policymakers, organisations and researchers evaluate the risks of any existing materials and new nanomaterials entering the market. It should also help SMEs and large companies use safer products and processes, limit the potential adverse effects of nanomaterials on workers and consumers, reduce the cost of insurance and reduce the risk of governments having to pay out money in the future due to unforeseen accidents or diseases.

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Contact:
marijn.poortvliet@wur.nl

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Nanotechnology is often referred to as the 'science of the very small'. Nanomaterials vary in size from 1–100 nanometres (nm), a width equivalent to 1/100,000th of a human hair. At this scale, chemicals behave in different ways to their conventional counterparts. Their increased surface area makes them more reactive and they move around in the environment in different ways to larger atoms and molecules, even though they are the same chemical. Nanochemicals have very special properties, such as high tensile strength, low weight, high electrical and thermal conductivity, and unique electronic properties.

Many products on the market already contain nanomaterials, such as paints, sunscreens, cosmetics and food. However, the rapid explosion in their use has prompted concerns over how safe they are to humans, other organisms and the environment.

Currently the laws and regulations governing nanotechnology are fragmented and spread over a wide range of bodies, as they are for the vast majority of materials and chemical substances. There are regulations that are designed to cover general chemical substances, such as those set out by the Registration Evaluation Authorisation and Restriction of Chemicals (REACH)[1]. There are also distinct laws governing the use of nanomaterials in goods such as foods (for example the EU regulation governing food additives[2]), chemicals, cosmetics and pharmaceuticals. There are also health and safety laws that aim to protect people exposed to nanomaterials.

These laws are not currently joined up, and sometimes do not take into account the unique nature of nanomaterials.

In this study, the researchers draw upon social, material, legal regulatory science and risk-related research to identify and describe essential elements of a risk governance framework for nanomaterials. They argue that there is a need for a **universal comprehensive, evidence-based risk governance framework** that deals specifically with nanomaterials, and goes beyond legislation. They argue that the framework should include **three pillars:**

i. *a model of human behaviour* that takes into account all the factors that influence decision-making and risk-taking, such as social context, culture within an organisation, and the perceived risks versus benefits of a technology.
ii. *an overview of the current legal and regulatory requirements governing nanomaterials*: these requirements will evolve with time, and so the framework would need to be able to adapt to changes in the broader regulatory environment.
iii. *an integrated set of tools* that can help organisations assess risk and make decisions about nanomaterials.

Continued on next page.

1. Regulation (EC) No 1907/2006 concerning the Registration, Evaluation, Authorisation and Restriction of Chemicals (REACH)

2. Regulation (EC) No 1333/2008 of the European Parliament and of the Council of 16 December 2008 on food additives

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3. SUN: Sustainable Nanotechnologies: addresses the entire lifecycle of nanotechnologies to ensure holistic nanosafety evaluation

4. SANOWORK: Safe Nano Worker Exposure Scenarios

5. NANOMICEX: Mitigation of risk and control of exposure in nanotechnology based inks and pigments

6. The EU FP7 large-scale integrating project NanoValid: Developing Reference Methods for Nanomaterials

7. GUIDENANO: Assessment and mitigation of nano-enabled product risks on human and environmental health: Development of new strategies and creation of a digital guidance tool for nanotech industries

8. caLIBRAte: Performance testing, calibration and implementation of a next generation system-of-systems Risk Governance Framework for nanomaterials

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How can risks from nanotechnology be managed? Researchers recommend global framework *(continued)*

These tools would include **risk banding** — a method of risk assessment that allows risks to be calculated even when the information you have is incomplete. This is necessary in the field of nanotechnology, where the pace of innovation is fast and there are so many gaps in our knowledge. The tool would look at everything we know about a particular nanomaterial, such as its chemical properties, and data on exposure and hazard levels. It would then use algorithms to fill in the missing data and gaps in the knowledge, giving governments and business an estimation of the risk posed by the material, whilst clearly communicating the uncertainties in the results.

This risk-assessment tool could be linked with **tools that can help organisations reduce risk**, for example, by recommending safer manufacturing processes, handling procedures and improved exposure controls. Management-support tools, including training materials designed to promote adherence to health and safety policies could also be included. Tools could also promote the 'safer by design' method, which limits the risk of people and the environment being exposed to nanomaterials by considering all stages of the chemical's life cycle, from manufacture to disposal, when designing the product. These methods and tools are already being developed by EU projects, including SUN[3], SANOWORK[4], NANOMICEX[5], NANOVALID[6] and GUIDEnano[7].

A third set of tools could **assess the experience, needs and values of the company, government or individual using the framework,** allowing it to be tailored to them, whilst a fourth tool could be used to **transfer risk**. Risk transfer is a risk control strategy that involves the shifting of a risk from one party to another, for example, through the purchase of an insurance policy. This tool would enable legal, contractual and insurance arrangements to be made.

These four sets of tools would need to be fully integrated together, an endeavour which is already being attempted by the European Commission project caLIBRAte[8].

The final product will be a framework that will help people and organisations involved in the nanomaterials industry to evaluate the risks of any existing materials and new nanomaterials entering the market. The researchers say their governance framework will have a significant impact on nanotechnology industries and investors in nanotechnology. They argue it will help SMEs and large companies select safer products and processes, limit the potential adverse effects of nanomaterials on workers and consumers, reduce the cost of insurance and reduce the risk of governments having to pay out money in the future due to unforeseen accidents or diseases. They also argue that the framework would be a cornerstone for optimising the social and economic benefits of nanotechnology.

While the study does not give concrete examples of the deficiencies of the existing regulatory frameworks that deal with nanomaterials under a wider chemicals framework, it highlights how an integrated perspective is needed when dealing with novel technologies such as next generation nanomaterials.