Big questions about risk assessment of nanomaterials

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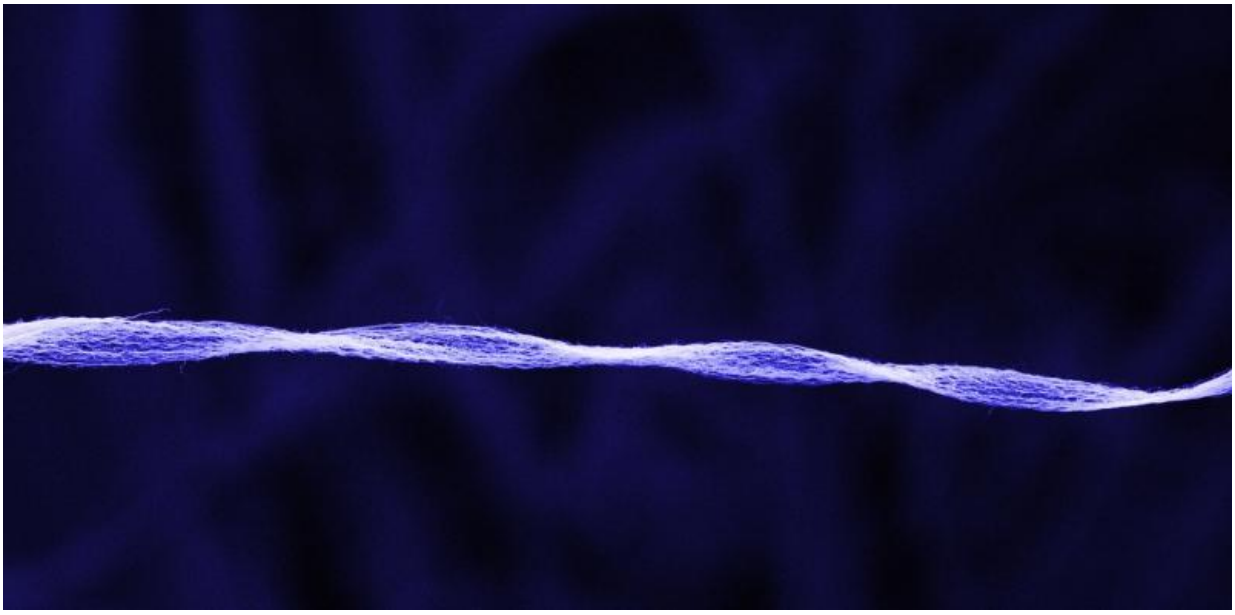

Substances, such as these carbon nanotubes, can behave differently at the nano-scale, and may post a health risk. Credit: ZEISS Microscopy/Flickr, CC BY-NC-ND

When it comes to nanotechnology, Australians have shown strong support for regulation and safety testing.

One common way of deciding whether and how nanomaterials should be regulated is to conduct a risk assessment. This involves calculating the

risk a substance or activity poses based on the associated hazards or dangers and the level of exposure to people or the environment.

However, our recent review found some serious shortcomings of the risk assessment process for determining the safety of nanomaterials.

We have argued that these shortcomings are so significant that risk assessment is effectively a naked emperor.

Size matters

Nanotechnology has been heralded as "the next big thing" for more than a decade. It is also increasingly found in a variety of products, including paints and surface coatings, sunscreens and cosmetics, clothing and textiles, specialty building products, kitchen appliances and sports equipment. This means they are also increasingly found in our homes, workplaces and environment.

In the nanoscale, familiar substances can behave differently to their macroscale counterparts. While some of these novel nano properties are potentially useful, the emerging science of nanotoxicology also suggests that this novelty can introduce risks to human health and the environment.

This does not mean that all nanomaterials are necessarily dangerous. What it does mean is that we can't rely on what we know of the same substances in bulk form to provide reliable information about their risks in nano form.

We also can't rely on the same test methods to investigate their safety. The novel properties of nanomaterials mean that they need dedicated safety testing and risk assessment.

Reaching for the trigger

Risk assessment has been the dominant decision-aiding tool used by regulators of new technologies for decades, despite it excluding key questions that the community cares about. For example: do we need this technology; what are the alternatives; how will it affect social relations, and; who should be involved in decision making?

Even on its own terms though, our review found that serious gaps and barriers compromise the risk assessment process when applied to nanomaterials.

A fundamental problem is a lack of nano-specific regulation. Most sector-based regulation does not include a "trigger" for nanomaterials to face specific risk assessment. Where a substance has been approved for use in its macro form, it requires no new assessment.

Even if such a trigger were present, there is also currently no cross-sectoral or international agreement on the definition of what constitutes a nanomaterial.

Another barrier is the lack of measurement capability and validated methods for safety testing. We still do not have the means to conduct routine identification of nanomaterials in the complex "matrix" of finished products or the environment.

This makes supply chain tracking and safety testing under real-world conditions very difficult. Despite ongoing investment in safety research, the lack of validated test methods and different methods yielding diverse results allows scientific uncertainty to persist.

The emperor's new clothes

Indeed, scientific uncertainty about nanomaterials' risk profiles is a key barrier to their reliable assessment. A review funded by the European Commission concluded that:

[…] there is still insufficient data available to conduct the in depth risk assessments required to inform the regulatory decision making process on the safety of NMs [nanomaterials].

Governments also lack information about the extent and location of nanomaterials' commercial use. In most countries, nano-reporting is not mandatory, and responses to voluntary calls for information have been low.

This leaves both the public and companies in the dark about where nanomaterials are being used. Kris de Meester, the chair of Business Europe's occupational health and safety committee, has given a personal estimate that 99% of European employers are unaware of the presence of nanomaterials in the supply chains for which they have responsibility.

There are also deficiencies in the capacity to manage workplace exposure. There are still relatively few nanomaterial-specific Safety Data Sheets, and those that exist generally provide insufficient information or struggle with insufficient instrumentation to manage workplace risks.

Taken together, these barriers mean that the risk assessment is effectively a naked emperor, predicated on capabilities that simply do not exist.

Exposing the naked emperor

We suggest that it is time to acknowledge the challenges facing risk assessment of nanomaterials and explore alternative decision-aiding tools that are more publicly accountable. They should incorporate non-risk

based questions of social value, and take seriously the need to act in the face of deep uncertainty without the pretension of control.

There are well-developed alternate decision-aiding tools available. One is multicriteria mapping, which seeks to evaluate various perspectives on an issue. Another is problem formulation and options assessment, which expands science-based risk assessment to engage a broader range of individuals and perspectives.

There is also pedigree assessment, which explores the framing and choices taking place at each step of an assessment process so as to better understand the ambiguity of scientific inputs into political processes.

Another, though less well developed, approach popular in Europe involves a shift from risk to innovation governance, with emphasis on developing "responsible research and innovation".

It is beyond the scope of this article to examine the potential of each of these approaches in depth. Nonetheless, in their explicit attempt to recognise and investigate the implications of scientific uncertainty, and to explore the trade-offs and value judgements implicit in different alternatives, we suggest that such decision-aiding tools would offer more robust bases for nanotechnology regulation than risk assessment.

Source: The Conversation