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November 2008



ROYAL COMMISSION ON ENVIRONMENTAL POLLUTION

## Novel Materials in the Environment: The case of nanotechnology

Summary of the  
Royal Commission  
on Environmental  
Pollution's Report



**Novel Materials in the Environment:  
The case of nanotechnology**

SUMMARY REPORT

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# **About the Royal Commission's study of Novel Materials in the Environment: The case of nanotechnology**

This study examines issues related to innovation in the materials sector and the challenges and benefits arising from the introduction of novel materials. This was prompted by concerns about potential releases to the environment from industrial applications of metals and minerals that have not been widely used previously and from the use of manufactured nanomaterials in a wide variety of products and applications. In the event, the evidence we received was almost entirely focused on manufactured nanomaterials. We therefore decided to use nanomaterials as an exemplar to investigate the current governance frameworks surrounding innovation and protection of human health and the environment in this sector.

During the course of the study over 100 organisations and individuals submitted evidence or provided information on request. The Commission hosted a seminar in London to discuss how we manage the emergence of new technologies in democratic society. A consultancy study on nanomaterial innovation systems and a literature review of the ecotoxicology of manufactured nanoparticles were carried out.

Members of the Commission and its Secretariat made visits to Belfast, Oxford, Edinburgh, Japan, the United States, Brussels and industries based in Derby and Hampshire.

A full text of the Commission's report is published by The Stationery Office (Cm 7468, £26.60) and is available on the Commission's website at: [www.rcep.org.uk](http://www.rcep.org.uk)

# Overview

We looked at the properties of nanomaterials currently being used or developed and the functionalities derived from those properties which provide the basis for the introduction of new products or improved products and performance. We also looked at the potential pathways by which these materials throughout their life cycle could enter and present potential hazard to the environment and to people.

Our extensive enquiries produced no evidence of actual harm. However, having analysed the potential health and environmental impacts which flow from the properties of nanomaterials, we concluded that there is a plausible case for concern about some (but not all) classes of nanomaterials. Examples of potentially harmful nanomaterials include nanosilver, carbon nanotubes and Buckminsterfullerenes ( $C_{60}$ ). However, we are very conscious of the extent to which knowledge about the potential health and environmental impacts of nanomaterials lags significantly behind the pace of innovation, although this could change as new scientific information arises.

A major conclusion of the report is that nanomaterials are hugely variable in their nature. They are not a uniform class of materials, and attempts to regulate or legislate solely on the basis of their size (1-100 nm in one or more dimensions) or how they are made are misguided. It is the functionality of materials including nanomaterials, i.e. what they do and how they behave, that matters and this should form the basis of governance and regulation.

We identified three areas of particular concern regarding governance and regulation of nanomaterials. The first is profound ignorance and uncertainty about the behaviour of some types of nanomaterial in the environment or the risks that they pose for human health. Second, the nanoform of an element or material may have significantly different properties to its bulk form. And third, in the longer term, we are also concerned that more sophisticated third and fourth generation nanoproducts may represent a further step change in functionalities and properties, which would be even more difficult to capture in a regulatory system primarily focused on the bulk chemical properties of a material. Approaching the topic from this perspective, we found that many aspects of nanomaterials are already covered by existing regulatory arrangements, notably those of REACH (see the section entitled 'The reach of existing regulations'). Other dimensions could be covered by logical extensions of the existing framework (see 'Extending our reach'). Finally, we address issues that go well beyond the existing regulatory arrangements (see 'Beyond our reach'). For this last set of issues, we concluded that new governance arrangements are necessary to

## *Overview*

deal with ignorance and uncertainty. We note that the general principles underlying these arrangements could also apply in areas of technological development other than nanomaterials, where similar issues might arise.

# Novel materials

## USES AND APPLICATIONS

Novel materials and new applications for existing materials are continually being developed. They are intended either to improve the performance of existing technologies, such as fuel additives to improve the energy performance of vehicles, or to make new technologies possible, such as MP3 players and mobile telephones which use trace quantities of exotic minerals.

Other drivers include the need to find substitutes for raw materials that are in short supply or have been found to have adverse effects on the environment or human health. In some cases, the discovery of novel functionality actually drives a search for profitable applications.

Novel materials include a wide range of industrial products such as polymers, ceramics, glasses, liquid crystals, composite materials, nanoparticles, nanotubes and colloidal materials. In turn, these kinds of materials may be used in a wide range of applications including energy generation and storage, transport, engineering and construction, electronics and display technologies, food packaging, and environmental and biomedical applications. The novel materials sector, and the nanomaterials sector in particular, are not monolithic 'research-innovation-manufacturing' sectors. They are highly complex webs of interaction involving many key players. The nanomaterials market in particular is growing rapidly. The Woodrow Wilson Center's database lists over 600 products self-identified as containing nanomaterials currently available in the global marketplace.<sup>1</sup>

The improved efficiency and functionality of novel materials can bring tangible environmental benefits, such as those offered by the development of photovoltaics, fuel cells and lightweight composites for cars and aircraft.

The properties of a novel material can arise from two key factors: first, the chemical composition of the material and second, its physical size and shape. As scientists exert ever more sophisticated control over molecular level organisation, the morphology of materials is becoming increasingly important. For instance, in its natural bulk form, gold is famously inert. However, at a particle size of 2-5 nm, gold becomes highly reactive. The chemical composition of these two materials is identical: it is the different physical size of bulk materials and nanoparticles that accounts for their very different chemical properties.

No single classification of novel materials has yet been devised. We believe it is unlikely that one is possible or even necessarily desirable. Each approach to classification emphasises different attributes of the materials in question and their applications. *However, the functionality of the material and what it is capable of doing appears to be the most robust focus for evaluating its potential environmental and human health implications.*

This emphasis on functionality, not on how a material is produced, or on physical size alone, pervades our thinking throughout this report.

## **NANOMATERIALS**

The small size of nanomaterials gives them specific or enhanced physico-chemical properties, compared with the same materials at the macroscale. This results in great interest in their potential for development for different uses and products.<sup>2</sup> A good working definition of a nanomaterial is one that is between 1 and 100 nm in at least one dimension.

Nanomaterials can have one, two or three dimensions in the nanoscale. One-dimensional nanomaterials include layers, multi-layers, thin films, platelets and surface coatings. They have been developed and used for decades, particularly in the electronics industry. Materials that are nanoscale in two dimensions include nanowires, nanofibres made from a variety of elements other than carbon, nanotubes and, a subset of this group, carbon nanotubes.

Materials that are nanoscale in three dimensions are known as nanoparticles. They exist naturally (for example, natural ammonium sulphate particles), but they can also be manufactured, as for example in the case of metal oxides such as titanium dioxide and zinc oxide. Metal oxide nanoparticles already have applications in cosmetics, textiles and paints and, in the longer term, could potentially be used for targeted drug delivery. Buckminsterfullerenes (also known as fullerenes and Buckyballs) are a class of nanomaterial of which carbon-60 ( $C_{60}$ ) is perhaps the best known. Potential applications include use as lubricants and electrical conductors.

## **PROPERTIES AND FUNCTIONALITY**

As already emphasised, the properties and functionalities of nanomaterials can be very different from those of the bulk form. Furthermore, some properties being discovered have not previously been observed in traditional chemistry or materials science.<sup>3</sup> While the resulting difference in behaviour from the bulk form makes it

possible to use nanomaterials in novel ways, it may also give rise to different mobility and toxicity in organisms and the environment.

The features of nanoparticles which underlie these properties and behaviour include: greatly increased surface area per unit mass; changes in surface reactivity and charge; and modified electronic characteristics. The electronic features can become quantized, leading to so-called 'quantum effects' which can influence optical, electrical, magnetic and catalytic behaviour.<sup>4</sup> The strong surface forces which may be exhibited at this size range are also important as they may play a significant role in self-assembly of nanostructures.

It follows that some novel properties of nanoparticles are predictable, but others will be unexpected. These effects are often well characterised in relation to the functionalities for which the new properties are being exploited. However, they are usually much less well characterised in terms of fate and behaviour in organisms and the environment, or not characterised at all.

While the basic principles employed in characterising substances for health and environmental effects are the same whether or not they are in the nanoform, certain properties are particularly or uniquely important in the case of nanomaterials. These include particle size, particle shape, surface properties, solubility, agglomeration and aggregation. Furthermore, the way these properties determine behaviour can be profoundly influenced by extrinsic variables, such as temperature, pH, ionic strength of containing medium and presence or absence of light.

## **SHOULD WE BE CONCERNED?**

It is a matter of concern that we were repeatedly told by competent organisations and individuals that there is currently insufficient information to form a definitive judgement about the safety of many types of nanomaterials. In some cases, the methods and data needed to understand the toxicology and exposure routes of nanomaterials are insufficiently standardised or even absent. There appears to be no clear consensus among scientists about how to address this deficit.

Current toxicological protocols for general chemical substances are fairly coarse screening mechanisms which tend to pick up acute effects. Almost by definition, with novel materials and particularly nanomaterials, there are virtually no data on chronic, long-term effects on people, other organisms or the wider environment.

So, new toxicological and ecotoxicological testing protocols are required. However, and crucially, under current procedures, it can take up to 15 years for a new testing protocol to achieve regulatory acceptance. Given the rapid pace of market penetration of nanomaterials and the products that contain them, existing regulatory approaches cannot be relied upon to even detect, let alone manage, problems before a material has become ubiquitous.

Difficulties also arise because the form in which materials make their way into the environment might not be the same as that encountered during manufacture. Many free nanoparticles agglomerate and aggregate in the natural environment, forming larger structures that may have different toxicological properties to those exhibited by the original nanoform.

Most nanomaterials are incorporated into products whose specific behaviour and properties are often well understood, but our inquiries suggested that very little thought has been given to their environmental impact as they become detached from products in use or at the point of final disposal. Moreover, techniques for their routine monitoring in the environment are not widely available, nor is it currently possible to determine their persistence in the environment or their transformation into other forms. Laboratory assessments of toxicity suggest that some nanomaterials could give rise to biological damage. But to date, adverse effects on populations or communities of organisms *in situ* have not been investigated and potential effects on ecosystem structure and processes have not been addressed. Ignorance of these matters brings into question the level of confidence that can be placed in current regulatory arrangements.

## **PATHWAYS INTO THE ENVIRONMENT**

As nanomaterials become incorporated into more and more consumer and industrial products, the routes by which they might enter organisms and the environment rapidly increases.<sup>5</sup> They may be discharged directly into rivers or the atmosphere by industry, or inadvertently escape when products are used or disposed of in the environment, for example paints, cosmetics, sunscreens and pharmaceuticals.

In view of the apparent absence of evidence of harmful impacts of manufactured nanomaterials in 'real world' situations, we can only examine the plausibility of damage based on the extrapolation of evidence from laboratory investigations and occupational exposure studies on dust and other related substances. As is often the case in toxicology, the approach which remains is to identify the characteristics of the manufactured nanomaterial in question, determine its bioavailability and persistence

in natural settings, then use data derived from measured or estimated concentrations in the environment as well as toxicological research in the laboratory to assess potential hazards and risks. However, although there is a widespread consensus that comprehensive characterisation of nanomaterials, during manufacture, use and disposal, is required to understand fully their potential fate and effects on human health and the environment<sup>6</sup>, such characterisation is lacking in the vast majority of studies.

## Environmental and health impacts

Free manufactured nanoparticles and nanotubes (e.g. powders) are likely to present the most immediate toxicological hazard to living organisms as they are at liberty to interact with organisms in the wider environment.<sup>7</sup> There is not the same level of concern regarding fixed nanomaterials (i.e. those incorporated into solid matrices or attached to surfaces), although there is clearly potential for them to become detached and enter natural ecosystems, especially when products containing them abrade or weather during use or when they are disposed of as waste or are recycled.<sup>8</sup>

Evidence presented to us on the environmental and human health risks posed by nanomaterials has often been contradictory. On the one hand some environmental scientists and policy-makers feel strongly that the threat posed by most nanomaterials is small, whereas others are clearly worried about the possible toxicity of some nanomaterials, both to the wider environment and to human health. For example, concern was expressed about an increased risk of lung and cardiovascular damage from carbon nanotubes and C<sub>60</sub> in humans, and the effects of nanosilver particles on microbial communities and sediment-feeding organisms. There is a consensus that mechanisms of toxicity are poorly understood and that, with minor exceptions,<sup>9</sup> appropriate ecological studies have not been undertaken, including studies that address food chain transfer and multi-generational effects.<sup>10</sup> Currently it is extremely difficult to evaluate how safe or how dangerous some nanomaterials are because of our complete ignorance about so many aspects of their fate and toxicology.

From an extensive review of the original published literature, several important conclusions can be drawn:

- There appears to be little consensus over the critical or even most important characteristics of manufactured nanomaterials that determine their toxicity profiles.
- Little information is available on how the various physical and chemical properties interact to generate an overall toxicity profile for a particular nanomaterial.
- There has been little attempt to use standard particles to study individual characteristics and their interactions, nor concerted attempts to develop approaches similar to quantitative structure-activity relationships (QSARs) that are currently being used for traditional chemicals.

- Knowledge on the medical applications of nanomaterials with respect to organ, cell and sub-cellular localisation should be harnessed to aid understanding of predictive toxicology.

The number of experimental centres involved in nanotoxicology is small and they seem to use different materials and experimental protocols. There is an urgent need for standardisation and co-ordination of research effort and focus in this field, although we are aware of, and welcome, the efforts being made to address these problems through the Organisation for Economic Co-operation and Development (OECD). There is also remarkably little link between knowledge gained from ecotoxicology and that from the study of toxicity in higher organisms including humans. Greater co-ordination and application of basic principles is needed between the two fields of research.

Toxicology as a discipline has declined over the last 20 years in the UK, Europe and the US with reduced training and career development dedicated to this subject. The requirement for high quality science, the integration needed between the biological and physical sciences and the urgent need for scientists to integrate findings from animal toxicology and ecotoxicology demands that more attention is given to toxicology training in our higher education institutions to take on the challenges of nanotoxicology.

In principle, all these issues can be addressed by more research. But the Commission is very concerned by the long lead times required for research to provide results that will be useful for legislation and regulation. We received expert opinion that lead times of 'several decades' could easily be involved.<sup>11</sup> As a consequence, and however good the research effort, significant uncertainties and areas of ignorance will remain.

## Trans-science, world views and the control dilemma

The policy challenge posed by novel materials is a specific instance of the more general dilemma of how to govern the emergence of new technologies where knowledge and understanding of potential risks is not only uncertain but where ignorance of even the key questions to ask will remain. This is characterised as a ‘trans-scientific’ problem.<sup>12</sup>

Ethical values, ideas about the nature of things and different belief systems come together to define an individual’s ‘world view’. Scientists and regulators, as well as the wider public, invariably use world views to interpret data or other kinds of evidence. But where information is missing or evidence is ambiguous, people draw even more heavily on world views to inform their decision making. For example, those who believe that nature is maintained in a delicate balance are more likely to regard any discharge into the environment as a dangerous insult than those who see nature as robust and forgiving.

In gathering our evidence for this report, it was clear to us that different organisations and individuals interpreted the same information, or lack of it, in very different ways, reflecting their broader interests and outlooks. We heard at least three distinctive approaches to the problem of the governance of novel materials under conditions that we consider to range from high uncertainty to profound ignorance.

One optimistic view was that no regulatory attention to novel materials could be justified unless and until there were clear indications that harm is being caused. Those expressing such a position were generally more concerned to forestall any unjustified regulatory intervention that might stifle innovation. A less optimistic version was the argument that any attempts to devise governance arrangements for novel materials should be ‘risk based’. This usually means that the technology should be controlled only to the extent that there are clearly articulated scientific reasons for concern, and only then where the cost of risk reduction is deemed proportionate to the probability and extent of danger. At the other extreme was the view that novel materials should not be permitted until they had been given a clean bill of health, meaning that they had been demonstrated beyond any reasonable doubt to be safe.

We were not persuaded by any of these positions. The first assumes that nature is always benign until proven otherwise. History is replete with instances where such assumptions were shown to be flawed too late to avoid serious consequences. The

second approach assumes that the state of the science is up to the job of detecting problems unambiguously and at an early enough stage to prevent widespread damage, which we have not found to be the case here and which could take decades to rectify. The third view would deny citizens and consumers the real lifestyle and health benefits that technologies based on novel materials might provide. In any case, we know that science can never definitively prove that something is completely safe.

Contemporary society is characterised by the accelerating pace of the proliferation of new technologies. Increasingly, it will be impossible to settle questions about the environmental and human health impacts of nano- and many other new materials consistently and in a timely fashion using traditional risk-based regulatory frameworks. The problem is exacerbated by the fact that in a technologically interdependent world, individual states cannot realistically exert the power to monitor and enforce rules governing the incorporation of materials in a wide range of products or their disposal.

We are therefore faced with an instance of what David Collingridge described as the ‘technology control dilemma’.<sup>13</sup> In the early stages of a technology we do not know enough to establish the most appropriate controls for managing it. But by the time problems emerge, the technology is too entrenched to be changed without major disruptions.

The solution to this dilemma is not simply to impose a moratorium that stops development, but to be vigilant with regard to inflexible technologies that are harder to abandon or modify than more flexible ones. Thus, key questions are how reversible is society’s commitment to the technology and how difficult would it be to remediate if problems arose? These considerations of trans-science, world views and the control dilemma suggest that nanomaterials, like other emerging areas of technology, require an adaptive governance regime capable of monitoring technologies and materials as they are developed and incorporated into processes and products. An effective, adaptive governance regime will have to be capable of applying the indicators of technological inflexibility identified in the technology control dilemma to decide when to intervene *selectively* in areas where it deems that a material represents a danger to the environment or human health. While any kind of blanket moratorium does not seem appropriate, there may well be specific cases where it is necessary to slow or even hold up the development while concerns are investigated.

## The reach of existing regulations

An important question is whether existing regulatory frameworks provide sufficient safeguards. The uncertainty and ignorance that characterise our understanding of the impacts of nanomaterials mean that traditional top-down regulatory mechanisms on their own may not provide protection without adversely affecting innovation. We are likely to have to adopt a wide suite of measures and involve many actors.

There are no specific regulations for nanotechnologies or nanomaterials in Europe or the UK. Instead, the manufacture, use and disposal of nanomaterials are covered, at least in principle, by a complex set of existing regulatory regimes. These include REACH, which is concerned with the **R**egistration, **E**valuation, **A**uthorisation and **R**estriction of **C**hemical substances,<sup>14</sup> and product- or sector-specific regulations for pharmaceuticals, veterinary medicines, pesticides and biocides. There are also specific regimes dealing with toys, cosmetics and end-of-life practices, such as the Waste Electrical and Electronic Equipment (WEEE) Directive.<sup>15</sup>

The effect of this legislation is to impose a responsibility on those who manufacture and sell the products to identify and understand potential threats to human health and the environment, and to minimise or eliminate the risk of adverse effects.

REACH operates on the premise of ‘no data, no market’. Chemical substances manufactured or imported at or above a threshold of one tonne per annum per manufacturer or importer are subject to a registration requirement. This registration obligation imposes a duty on industry to provide data on the substances concerned, including physico-chemical, toxicological and ecotoxicological data. The type and amount of data required depends upon the volume of production and to a lesser extent upon the level of risk posed by the substance concerned. For example, the second, higher, ten tonne threshold is a key one, triggering as it does the obligation to undertake a Chemical Safety Assessment and submit a documented Chemical Safety Report to the competent authorities in each EU Member State.

At least in principle, it would appear that REACH is capable of meeting the criteria for effective governance of nanomaterials. It provides a framework for the continuing review of authorisations, and even for the revision of key elements of the regulation itself. But a potentially major weakness is that regulatory instruments like REACH have not been specifically designed with nanomaterial products and their applications in mind. We therefore welcome the request by the European Commission for the Scientific Committee on Emerging and Newly Identified Health Risks (SCENIHR)

to undertake a review of REACH and to recommend how it may be modified to deal with nanomaterials.

## **EXTENDING OUR REACH**

One problem is that some nanomaterials may simply escape attention. Under REACH, nanoscale versions of existing substances (e.g. titanium dioxide) are treated in the same way as the equivalent bulk material, even if they have very different properties.

The most significant potential limitation of REACH in relation to nanomaterials is the one tonne threshold for registration. Because of the very large number of particles present even in tiny quantities of a nanomaterial, one tonne may be too high a threshold to capture potentially problematic effects.

We agree with the findings of a number of ‘regulatory gap’ analyses which have concluded that the existing framework is capable of adaptation to make it fit for purpose in dealing with nanomaterials, provided that the adaptation is underpinned by research to assess impacts and inform the setting of standards.<sup>16</sup>

We have seen no convincing evidence of the need for a special regulatory regime for nanomaterials. Not only is the legislative field already crowded, but nanomaterials do not constitute a unified class of substances. Most importantly, we have argued that the issue with all materials is their functionality. It is not the fact that they are created by any particular technology that is important, or even, in the case of nanomaterials, that they are of a particular size. What matters is what they *do*, and the implications of their properties and functionalities for environmental protection and human health. There is no logical reason why size of particle should in itself provide the basis for new regulatory controls.

## Beyond our reach

All this said, the Commission remains deeply concerned about the scale of the challenge involved and the timescales required to modify the existing regulatory framework and to gather the necessary data.

These challenges raise two important questions: what might be done while we wait for a better informed and adapted regulatory framework, and how do we encourage greater public involvement in decisions about nanotechnology in the face of the control dilemma?

We considered a number of other possible measures, in addition to the regulatory adjustments we advocate, aimed primarily at anticipating and avoiding potential harm from nanomaterials. Some of these measures could be applied within a modified form of REACH while others might be additional to these requirements. None of them is without difficulty.

We acknowledge that there is considerable potential, within a wider system of governance, for self-policing and the development of *codes of conduct*. However, in our view voluntary codes of conduct are likely to be most effective when they are backed up at appropriate points by 'harder' legal and regulatory measures.

We also discussed extending *product take-back* requirements to products containing nanomaterials. Take-back is intended to prevent or limit the entry of harmful substances into the environment, and enables the consumer to return a product to a retailer for recycling. If they can be effectively implemented, we support such regulations for novel materials where their functionality suggests that there may be grounds for concern.

We concluded, however, that in the current global marketplace there is no prospect that a take-back requirement could effectively provide for the return of nanomaterials to their original producers. We do not see how any such scheme covering a wide variety of consumer products containing nanomaterials would be workable, not least because nanomaterials are already incorporated into many products (including clothing, sunscreens and food packaging) for which take-back seems impracticable, if not impossible.

*Labelling* is another possible tool for the management of nanomaterials. There are powerful arguments in principle that consumers should be informed, and some may

legitimately wish to know whether products contain nanomaterials. But labelling might also convey the false impression that nanomaterials have uniform properties, and is unlikely to be able to provide useful information about impacts on health or the environment. At present, we see no reason to recommend product labelling for nanomaterials.

We also considered, briefly, whether an *international convention*, in the style of the United Nations (UN) Persistent Organic Pollutants (POPs) Convention, might usefully be set up to regulate nanomaterials. Initially this idea had some attraction because of the global nature of nanotechnologies, but evidence presented to us did not support such a step, on the grounds that it was too complex and would in practice be unmanageable.<sup>17</sup>

Of the additional measures that we considered, we were most attracted by the development of some kind of *early warning system*, one that might be managed by the competent authorities for REACH or a body or bodies authorised by them to do so. Indeed, as we confront the control dilemma, it seems to us that an early warning system incorporating reporting requirements is a vital component of governance of nanomaterials.<sup>i</sup>

We recommend that such reporting should be kept as simple as possible. We are attracted by the idea of a straightforward checklist aimed primarily at nanomaterials that are not currently captured by REACH. All importers or manufacturers of such materials, or of products containing them (above some still-to-be-decided threshold for the quantities involved) that are not captured by REACH, would be required to complete the checklist in as much detail as they are able with current knowledge. It should be designed so as not to be onerous, should elaborate the special properties (i.e. functionalities) of the nanomaterials including the reason that they have been produced or incorporated in the product, and should also consider the pathways of environmental and human exposure throughout the entire life cycle of the product – not just at the point of use. Experience suggests that checklist reporting will have to be compulsory if it is to be effective.

Manufacturers or importers who complete the checklist to the best of their abilities with current knowledge would gain protection against legal action if the material subsequently proved to be harmful in some way.

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i The Commission recognises that by advocating the development of an early warning system for nanomaterials, we appear to be contradicting our principle that it is the functionality that matters, not how they are made or their size. But until we have greater knowledge of the behaviour of nanomaterials in organisms and the environment, we see no other effective way of gathering data on potential hazards.

Whatever additional measures are employed, there is a requirement for a robust programme of *environmental monitoring*, using new techniques to detect manufactured nanoparticles in living organisms and the environment. Monitoring is an essential component of any early warning system. While blanket monitoring of the environment is not practicable, targeted monitoring for particular nanomaterials such as nanoscale silver is highly desirable. Obvious points for surveillance might include sewage outfalls, river water and sediments downstream from major conurbations, coastal marine sediments and sediment-feeding organisms. Detection of significant quantities of a nanomaterial in a top predator (e.g. pike or otter) could also be a cause for concern.

We envisage that knowledge about nanomaterials, their behaviour in organisms and the environment, and their potential risks, will accumulate, and that over time REACH and the sector-specific regulations will be adjusted. In the meantime, there is clearly a need for vigilance. That is why we propose that attention should be given to the development of an early warning system as a supplementary measure to ensure as far as possible that significant and irreversible harm will not occur.

## Governance of emergent technologies

Nanomaterials exemplify the kind of challenge for which attention to closing gaps in knowledge and regulation is necessary but insufficient. Effective governance will mean looking beyond traditional regulation for other, more imaginative solutions, often involving a wider range of actors and institutions than has been customary in the past. The aim must be to create *adaptive management systems* that can respond quickly and effectively as new information becomes available.

The more substantive challenge, therefore, is to find the means through which civil society can engage with the social, political and ethical dimensions of science-based technologies, and democratise their ‘licence to operate’. It has been characterised as a challenge of moving beyond the governance of risk to the governance of innovation.<sup>18</sup>

This is not an easy task. It will demand the engagement of a wide range of different perspectives and, quite possibly, the establishment of new institutions (an aspect to which we return below). There is growing recognition of these requirements, and we are aware of energetic activity particularly in the areas of opinion gathering and public and stakeholder engagement with nanotechnologies.

There is a growing, formal literature on how to achieve these ends, for example through techniques such as ‘Real-time Technology Assessment’ (RTTA)<sup>19</sup> and ‘Constructive Technology Assessment’ (CTA).<sup>20</sup> CTA has three elements: socio-technical mapping combining stakeholder analysis and the systematic plotting of recent technical dynamics; early experimentation to identify and mitigate unanticipated impacts; and dialogue between innovators and the public. RTTA has a similar objective, but it is usually less focused on experimentation and more on the knowledge generation process itself.

However in our view, it is not feasible (or even desirable) to achieve public engagement that effectively interrogates scientific and technological developments on a case-by-case basis. The more specific the focus, the more numerous the cases will be. Informed and inclusive deliberation on a huge range of potential developments seems as distant, and indeed unmanageable, a prospect as the resolution of many of the technical uncertainties identified elsewhere in this report.

A different approach to the governance of innovation – given the problems of deliberating emergent developments on a case-by-case basis – might be to begin

with questions of principle, instead of working from technologies through to implications. A key task would be to consider which kinds of interventions in the human and non-human worlds, controlled by whom, might be deemed acceptable or problematic. Such principles could then act as a filter, directing attention to aspects of particular science-based innovations that seemed worthy of special scrutiny. Deliberation on these issues might be a role for a commission on emerging technologies and society.<sup>21</sup>

Whatever institutional arrangements are adopted in pursuit of social intelligence, we are convinced that more rigorous attention needs to be paid to the treatment of the outputs. It seems to us that enthusiasm to be seen to engage has sometimes run ahead of any real commitment or institutional capacity not only to support the activities adequately but most importantly to make intelligent and transparent use of the findings, especially if the latter raise fundamental questions about the direction and development of innovation. Genuine 'upstream engagement', the outputs of which influence science and technology policy at an early stage,<sup>22</sup> has proved elusive, and is particularly challenging under conditions of ubiquity when world views vary widely across countries and cultures.<sup>23</sup>

We return, finally, to the control dilemma. We have argued that this dilemma clearly confronts us in the case of nanomaterials, on which we have focused in this report, and that our response should be to strive towards an open and adaptive system of governance grounded in reflective and informed technical and social intelligence. Such a regime, while encouraging appropriate innovation, would seek to avoid technological inflexibility, would be vigilant, and would be capable of intervening selectively but decisively when developments threatened humans or the non-human environment.

We have argued that a system of adaptive governance for novel materials would in part be served by modifying and extending the existing regulatory framework as a matter of urgency, and by developing an early warning system, which must include robust arrangements for environmental monitoring. But, as in other fields characterised by ignorance, uncertainty and ubiquity, regulation must be complemented and informed by the full range of perspectives on innovation. It is to these ends that we have made our recommendations, some of which we consider applicable beyond nanomaterials to novel materials in general, and indeed to the governance of wider categories of emergent technologies.

# Recommendations

Our recommendations reflect three main priorities, namely:

**Functionality:** focus on the properties and functionalities of specific nanomaterials as the key driver rather than treat all materials in the size range as one single class.

**Information:** establish a directed research programme on the properties and functionalities of nanomaterials in order to inform risk assessment and risk management strategies.

**Adaptive management:** recognise the degree of ignorance and uncertainty and the time it will take to address these (insofar as they can be addressed). We also need to develop flexible and resilient forms of adaptive management to allow us to handle such difficult situations and emergent technologies.

## ENVIRONMENTAL AND HEALTH IMPACTS

The research requirements that we highlight in the report need to be undertaken on a more systematic and strategic basis, which is difficult to deliver under response mode funding as currently used as the main driver in the UK. We appreciate that the Government did not wish to take up the recommendations of the Royal Society and Royal Academy of Engineering report for a new research centre, but we strongly recommend a more directed, more co-ordinated and larger response led by the Research Councils to address the critical research needs raised by this report, with emphasis on regulatory and policy programmes.

These include:

- The validation of *in vitro* tests against *in vivo* models.
- Evaluation of methodologies for predicting the likely fate and effects of nanomaterials based on their physical and chemical properties as well as their novel properties, and where possible, the development of exposure scenarios.
- Based on the significant gap in our knowledge, the programme of directed research should ensure a concerted and co-ordinated effort to understand better the principles that determine toxicity of manufactured nanomaterials and how individual properties interact to enhance or diminish toxicity profiles both *in vitro* and *in vivo* with a long-term objective of developing predictive toxicology.

- The enhancement of *in situ* monitoring and surveillance methods to provide early warnings of unexpected effects of nanomaterials and to permit timely remedial action.
- The research programme should pave the way for much greater interdisciplinary co-operation, including co-operation between those engaged in medical toxicology and those in ecotoxicology, so as to enhance the development of robust test systems and also to act as a catalyst for early warnings from observations on lower organisms to be extrapolated to humans.

We recommend that urgent attention is given to undergraduate and postgraduate training in toxicology across all of its domains and that the Department for Innovation, Universities and Skills (DIUS), the higher education sector and the professional societies that represent medical toxicologists and ecotoxicologists establish new initiatives to build multidisciplinary capacity in this field.

## **GOVERNANCE**

We make the following recommendations:

- In any revisions to existing regulations, the relevant authorities should focus specifically on the properties and functionalities of nanomaterials, rather than size. Since these properties and functionalities will often differ substantially from those of the bulk material, strict chemical equivalence does not preclude the need for a separate risk assessment.
- The UK Government should press the European Commission to proceed with urgency, in consultation with Member States, the European Chemicals Agency and the Scientific Committee on Emerging and Newly Identified Health Risks (SCENIHR), to review REACH and the product- or sector-specific regulations. The object of this review should be to amend the regulations to facilitate their effective application to nanomaterials and the provision of adequate testing arrangements.
- Clear priorities for testing, beginning with those nanoparticles with functionality which suggests that they might pose the greatest risk of harm to the environment or human health should be established.
- As REACH is adapted to meet the challenges presented by nanomaterials, particular attention should be given to the issue of weight thresholds. In view of the persistent uncertainties involved, a precautionary approach should be adopted when determining new, lower thresholds for nanomaterials.

- Responsible organisations should set up structured systems to keep a watching brief on the development of novel materials and to enhance the sharing of information and the opportunities to work together to identify and manage emerging problems.
- The idea of a simple checklist as part of an early warning system should be developed and defined further by the Government to investigate the potential for development amongst the wider materials community.
- Experience suggests that checklist reporting will need to be compulsory if it is to be effective. The Department for Environment, Food and Rural Affairs (Defra) should make nanomaterials reporting mandatory.
- The Government should impose an additional legal duty on companies to report at the earliest opportunity to the competent authorities any reasonable suspicion that a material presents a risk to people or the environment. Compliance with this requirement should offer duty holders a degree of immunity from criminal liability, should problems associated with the nanomaterials arise in future.
- Environmental monitoring to detect manufactured nanoparticles should be the responsibility of the Environment Agency in England and Wales, the Scottish Environment Protection Agency (SEPA) and the Northern Ireland Environment Agency to ensure that robust processes are used.
- Government should move beyond one-off public engagement ‘projects’ to recognise the importance of continual ‘social intelligence’ gathering and the provision of ongoing opportunities for public and expert reflection and debate. We see these functions as crucial if, as a society, we are to proceed to develop new technologies in the face of many unknowns.

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