

NIA written evidence for

Royal Commission on Environmental Pollution

***Study on the Environmental Effects of Novel
Materials and Applications***

July 2007

Introduction to the NIA

Formed in 2005, the Nanotechnology Industries Association (NIA) creates a clear single voice to represent the diverse industries' views in the multi-stakeholder debate on nanotechnology, by providing an interface with government, acting as a source for consultation on regulation and standards, communicating the benefits of nanotechnologies and interacting with the media to ensure an ongoing advancement and commercialisation of nanotechnologies.

The unique feature of the NIA is that it provides a purely industry-led perspective derived from the views of the collective membership, which is made up of many varied companies all at different stages of their life cycle and with a variety of interests in the huge range of technologies that derive their benefit from the nanoscale. This enables those seeking comment from industry to have a single point of entry to the industry and avoids the need to approach individual companies for statements on specific issues. In addition the breadth of the membership enables the NIA to put forward strong proposals to government and regulatory authorities to promote an environment that supports the application and utilisation of nanotechnologies. Initial aims of the association are:

- promoting the responsible use of nanotechnology and raising awareness of its many applications in an unbiased way among key audiences within the UK,
- generating position statements and papers in areas relevant to its members and providing responses to consultations exercises,
- technology foresight exercises examining current products, developments and future applications of nanotechnologies with an industry-based perspective on the risk-based classification of emerging technologies including nanotechnology, which is linked to a new hazard assessment methodology as the current project,
- working closely with regulators to represent the interests of the NIA to ensure the future of nanotechnology is secured and to realise its full potential,
- encouraging and stimulating industry participation and support for nanotechnology, and
- providing a forum for discussing topics of relevance to its members.

For further information visit <http://www.nanotechia.co.uk>.

Theme 1:

Scene-setting: what are novel materials and what developments are likely over the next 5-10 years? Which ones should be investigated for the purposes of the study?

1. What do you understand by the term novel material? How might novel materials best be classified? What novel materials should be included in the study?

The collective term 'novel materials' includes a large variety of materials at different stages of their life-cycle, including any combination of the following categories: hard matter and soft matter, inorganic and organic materials, newly discovered naturally occurring materials, incidental / anthropogenic materials, and manufactured / engineered materials. Strictly speaking, 'novel materials' are materials that are either new combinations of existing elements or molecules that are chemically or physically bound together, or existing materials that are produced in a new form that gives appreciably different properties. Examples of the former would include chemicals or polymers with new formulas or new alloys and of the latter new composite materials and some nanomaterials for example QDs or CNTs.

A new use for an existing material would not qualify as a novel material.

It is best to classify new materials according to their state i.e. metallic, inorganic or organic (essential molecules with a chain like structure). It should not be done based on application or hazard as this is highly variable and complex.

*The remit of the Nanotechnology Industries Association covers nanoscale materials only; the following answers are focussed on novel **nanomaterials only**.*

The use of manufactured nanomaterials is central to the property-enhancement of many nanotechnology-enabled products; these novel materials, which consist of building-blocks smaller than one hundred nanometres in at least one spatial dimension, often exhibit properties that are very different from those of their macroscale form, such as new mechanical, optical, chemical, magnetic or electronic properties. The use of only small quantities of nanomaterials as additives in traditional materials enables an optimisation of the required established properties, while the application of nanomaterials in new areas provides entirely new technologies and processes.

Nanomaterials are not new; for millions of years, nature has used and produced large quantities of nanomaterials (e.g. to create optical effects in the wings of butterflies, for self-cleaning mechanisms on the leaves of plants, and for the storage and transport of minerals in living tissue), and mankind has both incidentally created nanomaterials (mostly in combustion processes) and deliberately exploited the properties of nanomaterials (mostly for the manipulation of materials' optics and colours); it is important to distinguish these natural and incidental nanomaterials from the deliberately manufactured nanomaterials, which are developed to enhance the properties of novel products.

The NIA distinguishes two different types of manufactured nanomaterials:

(a) nanostructured materials, which consist of traditional materials with nanometre-sized cavities and holes (e.g. foams, sponges, etc.), and

(b) materials containing discrete nanoparticulate matter (often referred to as 'nano-objects'), with at least two dimensions smaller than one hundred nanometers (e.g. nanotubes, nanorods, nanowires, nanoparticles, etc.).

2. At what point does a novel material cease to be novel?

There is no defining point at which a material ceases to be 'novel', as the 'novelty' of a material is often subject to complex factors and perceptions; it is, however, appropriate to use the following characterisation of 'novel' materials:

A material ceases to be novel, when it has been incorporated firmly within an economical, ecological and societal context; two aspects contribute to the perception that a material is no longer 'novel': (a) once the volume use exceeds a certain level which is in proportion to the industry norm. For example in bulk polymers volumes in excess of (one) thousand(s of) tonne(s) might be considered no longer novel, whereas for pharmaceuticals, the threshold might lie at volumes exceeding (one) hundred kilo grams; (b) the quantity of information available on the properties of the material (at different stages of its life-cycle) available in the public domain (i.e. the understanding of its incorporation within an economical, ecological and societal context, as indicated above). This understanding can be supported through academic papers or through industry published specifications.

Just because a material ceases to be 'novel' does not mean that it is fully understood; knowledge of a material's behaviour will continue to grow over time. It is not possible to fully ascertain that a material is totally safe, and most risk assessment will evaluate relative levels of hazard and risk. Even materials that are essential to living organisms (i.e. those that oxygen, water, etc.) are also lethal in excessive doses, but these risks are mitigated against.

3. What sort of materials and technologies are being developed – over the next 2, 5 and 10 years?

New materials and technologies are being developed across the whole range of materials science, from new metallic alloys to new polymers to new ceramic materials. A big aspect of this is the growth in nanotechnology. In every discipline where materials have an impact, there are investigators active in developing novel materials. In particular it is materials that have new functionality or multi-functionality that are of particular interest. However, a differentiation must be made between new materials and new structures built from a number of different materials.

The development of (manufactured) nanomaterials will play an important role to technological advancement in the next 10-20 years.

4. What are the drivers for the development of novel materials? What are the potential benefits of novel materials and the drivers for these?

The drivers for the development of novel nanomaterials can be manifold, including the development of entirely new functionalities (e.g. smart materials with sensor and actuator properties, theranostics, novel photovoltaics, printable electronics), the substitution of 'old' materials with novel materials of improved functionalities (e.g. carbon nanotubes with high mechanical stability replace 'conventional' carbon fibres), the substitution of less efficient 'old' materials with novel materials of enhanced efficiency (e.g. high-efficiency barrier material for packaging that significantly can reduce waste production), the substitution of 'old' toxic materials with 'novel' materials that do not pose risks to human and environmental health (e.g. new high-performance composites to replace nickel alloys, targeted 'point-of-care' pharmaceuticals). The specific materials performances that are sought to be improved are manifold; they include physical, chemical, optical, magnetic and electronic properties. Without new materials or combinations of materials there will be no new applications and revolutionary products.

Business competitive forces are increasing all the time and companies have to innovate and advance materials technologies to obtain a commercial advantage over competitors.

5. Can the development of novel materials have an impact on resource depletion?
Today's R&D and manufacturing processes enable the synthetic production of many naturally occurring materials, so that resource depletion can be greatly reduced. The enhanced activity of nanomaterials furthermore enable the use of significantly less material in order to achieve the same effect as would be achieved with larger quantities of the equivalent macro-scale material. The development of composite materials based on natural fibres and the use of nanomaterials to replace existing micron sized materials has the potential to reduce the quantities required by orders of magnitude are two examples.

6. Are issues of re-use and recycling considered when developing novel materials – e.g. could the phasing out of metals for composites make recycling difficult?
Issues of re-use and recycling are always considered when developing novel nanomaterials, since there are requirements in many industrial sectors to implement recycling schemes, e.g. automotive and packaging. However, may novel materials pose new challenges to re-use and recycling particularly where different materials are in intimate combinations.

7. Are novel materials likely to alter the amount of waste generated and the ways in which it has to be handled?
*Novel materials could have a significant impact with the potential to reduce waste through more efficient use of materials with improved properties. As the functionality of materials increases the value in them will also increase making recycling more commercially attractive. For some new materials new methods of handling will probably be required, but the drive is for direct replacements that will not require changes in handling and processes.
(see also answers to questions 4 - 6 above)*

Theme 2:

Environmental and health impacts of novel materials

8. What are the most important impacts that novel materials could potentially have on the environment and human health? What are the main mechanisms and pathways for those impacts? How do we begin to conceptualise environmental impacts when we are in such unknown territory?

Manufactured nanomaterials are developed for their improved or new properties; they are likely to share many of the characteristics of natural and incidental nanomaterials, but their specifically engineered novel properties might also introduce entirely new physical and chemical properties, which might also be accompanied by new biological behaviour (i.e. different mobility or inflammatory response in the lung). The properties of nanoparticulate matter can be very different from the well-characterised properties of the macroscale material with the same internal structure and chemical composition. Currently the scientific community is involved in a controversial discussion about different ecotoxicological and toxicological profiles of manufactured nanomaterials compared to the macroscale equivalents of the same material. Industry contributes to this discussion with its own research and participation in national and international research projects to this debate.

However, not all nanomaterials exhibit properties that are entirely different from those of larger particles; unless proven otherwise by state-of-the-art risk assessment methods, it is therefore recommended to assume that the nanoparticulate form of a material has the same properties as the macroscale material with the same internal structure and chemical composition, whilst the greater 'surface-area to mass'-ratio of nanomaterials compared to larger particles could lead to an enhanced reactivity.

It is important to note that all NIA members ensure the safety of their commercially available nanotechnology-enabled products through the application of appropriate hazard assessment methods.

The most important detrimental impact that any human activity can have is on the biosphere, if certain materials harmfully interfere with natural processes. This issue that surrounds all developments of novel materials and give rise to stringent regulations to mitigate the risks around the introduction of new materials. However we should be cognisant of the fact that it is these very characteristics that provide many benefits. It is the controlled introduction of new materials that provides the safe use and minimises the risks. It should also be considered that the number of materials that have had a major hazardous impact is small compared to the total number of new materials introduced in the same timeframe. The mechanisms and pathways for environmental and health impacts are well known and directly linked to exposures routes. A major challenge, however, is the assessment of long term cumulative effects, for which accelerated testing is not always a reliable measure.

9. Do novel materials have the potential to help 'solve' environmental problems, e.g. land contamination, energy generation? If so, how and are there potential risks?

Nanomaterials promise solutions to many of mankind's challenges, including the following:

- *giving rise to advanced renewable energy technologies (e.g. improved photovoltaic materials, improved hydrogen storage materials, improved energy storage materials, etc.),*
- *water purification and desalination through improved membrane materials and novel forward osmosis materials,*
- *remedial materials for decontamination of polluted land/water*
- *more efficient catalysts, and*
- *reduced waste, biodegradable products.*

The risks associated with the new nanomaterials associated with the above innovations are no greater than for other materials in other applications.

10. Do we have sufficient research and monitoring in terms of understanding toxicology and exposure in place in order to understand the effects of novel materials on the environment and human health?

Dedicated (eco)toxicological assessment of nanomaterials is still in its infancy, but manufactured nanomaterials are likely to share many of the characteristics of natural and incidental nanomaterials, and many toxicological and epidemiological studies already document the respective properties of natural, incidental and commercially established nanoparticulate materials.

The nanotechnology industries conduct research and development as well as commercialisation of nanotechnology-enabled products in a responsible manner, so that the work force, the consumer and the environment are all protected from any unreasonable harm at any time of a product's life-cycle.

The industries are furthermore involved in the pursuit of technological innovations with relevance to the economy, and delivery of benefits to the quality of life and the environment. In this context, the industries play an important role within the debate on nanotechnology held between the public, the governing bodies, industries and scientific experts from both the (eco)toxicology/epidemiology and the nanotechnology innovation camp; in their own interest, that of the wider economy, and the citizens' quality of life, the nanotechnology industries support governments in identifying and promoting innovations that are relevant for the nation's/region's future.

Wherever possible, the nanotechnology industries show transparency of operations and governance, to assist the government's development of policies that supports the advancement of nanotechnologies, and to collaborate with toxicology- and nanotechnology-oriented public research institutions, in order to establish new methods of investigation, tailored to the specific effects of nanotechnology.

Proposed toxicology studies should be related to realistic exposure, dose and bioavailability of nanomaterials. The predominant exposure routes to nanomaterials

are likely to be through exposure to airborne particles. Nanoparticles are described by distributions, e.g. number distributions, mass distributions, surface area distributions. The nature of these distributions can have a critical effect in determining exposure and dose. This distinguishes nanomaterials from other materials such as industrial chemicals. The nature of these distributions and their impact on human and environmental health needs to be studied. Hazards can be underestimated or overestimated if the impact of size and distributions are not taken into account. This will help focus future research and monitoring on those features of nanomaterials which present the greatest hazard.

We are not aware of any universally approved monitoring of exposure to nanomaterials and effects on human health and the environment.

There are early investigations by groups such as HSE Laboratories and NIOSH in the USA into how this might be done in the workplace, but nothing covering the general environment.

11. Are current testing protocols 'fit for purpose' to test the potential environmental and health impacts of novel materials? If not, what needs to be developed or are there other strategies needed to address this issue?

Current regulatory frameworks were not designed specifically with nanotechnologies in mind, but existing safety-legislation encompasses an extensive list of directives and guidelines that cover a large range of applications and products, and is widely regarded as appropriate to govern the R&D, manufacture and commercialisation of manufactured nanomaterials. If, however, future scientific assessments identify the need for additional control, existing frameworks should be adapted to cover the recognised gaps in current governance. The NIA will constructively contribute to this process.

National and international standard setting bodies are also conducting invaluable work to advance the harmonisation of nanotechnology definitions and taxonomies.

There are a few major issues that are not addressed by current protocols:

- 1. How to distinguish target new materials from background and measure exposure to engineered nanoparticles*
- 2. How to monitor and control long-term low level exposure*
- 3. How to relate distributions to exposure/dose and environmental and health effects*

12. Do we have adequate methodologies and instrumentation to detect and monitor engineered free nanoparticles in the environment?

There are techniques available but they are not always the most practical and tend to be lab based or require lab evaluation. There is a need for a truly portable monitoring device akin to the radiation monitors currently used. Current methodologies and instrumentation to monitor exposure to anthropogenic particles in environmental pollution are often geared to detect much larger particle sizes (e.g. PM10, respirable sampling and PM2.5), and the detection of smaller particles is often severely limited.

Instrumentation which is capable of distinguishing engineered from natural and equilibrium size distributions will be necessary to adequately monitor these effects. Such instruments will have to be easier to use, more robust and affordable than those currently available.

13. Are the full life cycle impacts of novel materials being considered in terms of their potential effects on the environment and human health?

Full life-cycle impacts are essential, when assessing hazard. Past experience has shown that materials incorporated in mass products can be released and accumulate over time to hazardous levels (e.g. PCBs and lead in paints and gasoline, Pt in auto catalysts and many others). If materials are included in products that are subjected (legally or illegally) to processes such as abrasion, incineration and wear they could very well be released and accumulate in the environment.

There are already some possible examples:

- 1. inclusion of nanotubes in advanced composite materials (i.e. these could be subjected to further processing, such as grinding, cutting, welding, and disposal, which could release particles into the atmosphere),*
- 2. incorporation of nano-materials in tyres or other materials subject to abrasion, and*
- 3. incorporation of nanomaterials in consumer products where disposal is uncontrolled.*

Full life-cycle assessments are increasingly being undertaken for nanomaterials, but the limited ability to properly estimate realistic exposure scenarios and to measure true exposure levels severely hampers their progress.

The effects of dilution need to be considered when materials are released, legally and intentionally or unintentionally into the environment. Toxicology and epidemiology studies will go towards understanding the issues.

The Nanotechnology Industries Association and its members are proactively addressing the issues outlined above through initiation with (eco)toxicology laboratories and participation in dedicated research programmes.

14. How can you look at the effects of novel materials as a coherent whole, if they are even more difficult to categorise than nanomaterials?

The NIA considers it not feasible or productive to look at effects of novel materials as a coherent whole; each material has to be considered on its own merits. It is impossible to generalise about novel materials in this way.

15. Are there lessons to be learned from 'green chemistry' – and ways that manufacturing could be made more benign?

Nanotechnology promises to support the advancement of green/sustainable manufacturing, by enhancing the efficiency of current manufacturing processes, as well introducing entire new techniques. Furthermore, more benign manufacturing

has multiple benefits both from an environmental view point but also from a commercial aspect.

Theme 3:

How to manage novel materials in society: governance and regulation

16. Is REACH the right framework for regulating novel materials and nanotechnologies?
Yes

17. Are the regulations which affect novel materials fit for purpose? Is existing legislation sufficient to deal with potential problems that could arise during the different stages of the novel material's life cycle, i.e. manufacture, use and disposal?

Existing safety-legislation encompasses an extensive list of directives and guidelines that cover a large range of applications and products, and is widely regarded appropriate to govern the R&D, manufacture and commercialisation of manufactured nanomaterials. If, however, future scientific assessments identify the need for additional control, existing frameworks should be adapted to cover the recognised gaps in current governance. The NIA will constructively contribute to this process.

National and international standard setting bodies are also conducting invaluable work to advance the harmonisation of nanotechnology definitions and taxonomies.

18. Is the UK, EU and global science and knowledge base sufficient to support current legislation frameworks and any future regulation? Where are the gaps and what are the research priorities?

The UK nanotechnology industries and research community are very proactive in (eco)nano-toxicology and -epidemiology studies, as well as the life-cycle assessment of products.

If further regulation is considered necessary, any future regulation on nanotechnology should be developed on an international level and in consultation with industry, in order to ensure harmonisation across the nations and regions engaged in nanotechnology research, development and commercialisation.

19. Is the UK's and EU's research funding sufficient in this area? Is it being delivered in the right way?

No, it is not. There is very little funds directed towards size-resolved toxicological research. Governing bodies should establish research funding mechanisms that enable the conduct of general nanotechnology innovation, and ring-fence an adequate percentage of that money for developing the fundamental test protocols, life-cycle analyses and risk assessments of novel manufactured nanomaterials.

Governmental initiatives in nanotechnology test protocols, life-cycle and risk assessment should be conducted in collaboration with and in support of the nanotechnology industries.

(See comments from RS/RAEng and CST responses to this; the NIA supports the RS/RAEng's response and has actively contributed to the CST's response.)

20. Can novel materials and technologies be effectively governed and regulated if it is not possible to obtain exposure data before products containing novel materials are produced and made available to consumers?

Some form of effective monitoring is important in this respect. This will identify accumulation in the environment, possible long-term low level exposures and give a basis for action if unexpected environmental or health effects are observed.

In this respect, nanomaterials pose no real difference to existing chemical or pharmaceutical materials, where thousands of different compounds can be generated very rapidly. The central question of effective monitoring processes is not concerned with the diversity of possible materials but with their large-scale application and commercialisation (i.e. how many novel materials actually make into products and hence into the wider world, and how much of a novel material goes into such products). This is the difference between researching novel materials and commercially producing the novel material. The existing regulations are sufficient for the numbers of materials that actually come to market.

21. What is the role for engaging the range of different interests and perspectives, commercial, political, public and societal, on the development of novel materials in the context of global markets?

The industries are proactive in the pursuit of technological innovations with relevance to the economy, and delivery of benefits to the quality of life and the environment. In this context, the industries play an important role within the debate on nanotechnology held between the public, the governing bodies, industries and scientific experts from both the (eco)toxicology/epidemiology and the nanotechnology innovation camp; it is in their own interests and those of the wider economy, and the citizens' quality of life, the nanotechnology industries support governments in identifying and promoting innovations that are relevant for the nation's/region's future.

22. Are there general lessons to be learned from the development and use of other novel technologies, e.g. the development of genetically modified organisms?

Nanotechnologies are often compared to GMO, but there are as many differences as there are similarities between the two technologies: similar to GMOs, nanotechnologies require a good stakeholder dialogue, in order to avoid the public's rejection of the technology. In this context, the nanotechnologies have already learnt valuable lessons from the failure of GMOs: continual engagement with industry and other interested parties is essential.

In contrast to GMOs, however, nanotechnologies provide a much larger range of diverse benefits to the quality of life in general, as well as solutions to some of

mankind's more urgent challenges, such as renewable energies and clean drinking water.

23. How can an appropriate balance be achieved in the design of regulatory systems to effectively manage uncertainty?

An appropriate balance can be achieved by a providing balanced information (i.e. without hype, both positive and negative), and thereby enabling objective decisions based on 'risk-benefit'-judgements. An appropriate balance is furthermore supported by an understanding of the hazards and risks and a continual dialogue between regulators and the regulated.

24. What are the implications for liability when problems arise even if procedures are properly followed in good faith: who should bear responsibility and what issues arise for insurance and redress?

This question is still debated within the circles of insurance companies, governments and the nanotech industries; at the moment, there is no unique answer to this question. The question is beyond the scope of environmental aspects of novel materials and gets into legal and insurance issues more appropriate to those industries.

25. How would you apply the precautionary principle to the management and regulation of novel materials?

There is currently much doubt if the precautionary principle is a valid model. The precautionary principle is something that needs to be well defined and understood, before deciding how to apply it, as different interpretations are given to this. There needs to be an element of reasonableness applied here. It is quite right that there should be caution around the introduction of new materials but this should not mean that every conceivable test needs to be done before the allowing a new material onto the market. There should be a link between the materials and the specific application. The application, usage, disposal, potential exposure routes, etc. need to be taken into careful consideration on a case-by-case basis. It is up to the introducer of the material to justify the introduction.

26. In debate about new technologies, questions of need and control, as well as questions about consequences, have emerged as being important. To what extent should our study engage with questions about the need for novel and novel uses of materials; about who exercises control over such technologies; and about public trust in the institutions involved?

There is no doubt that there is a need for novel materials; economic growth and benefit are intimately linked to this, so it should not be a question for this study. Similarly the exercise of control of new materials technologies is not an issue for the study. This aspect is essentially covered through the patent regime since it is possible to re-engineer or at least understand the composition of materials relatively easily these days. Production processes to make the material is often

where the commercial advantage lies but this does not tend to last for long. Public trust is an issue for another group as it covers a much broader range of issues around science and technology than just new materials and the environment. The RCEP's report on this study is likely to have a large impact within the stakeholder community. It is therefore of utmost importance to address questions about the need for novel materials and novel uses of materials, as well as who exercises control over such technologies and about trust in the institutions involved. In this context, the RCEP plays an important role to deliver an objective and well-balanced report that outlines the responsibilities of all stakeholders and make appropriate recommendations.

And finally:

27. Are there any other major questions or issues that the Commission should examine?

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