FOR IMMEDIATE RELEASE

NIA Comment

on the 27th Report of the Royal Commission on Environmental Pollution, entitled ***Novel Materials in the Environment: The case of nanotechnology***

Background

The NIA, Nanotechnology Industries Association (NIA), is the market-independent, responsible voice for the industrial nanotechnologies supply chains; it supports the ongoing innovation and commercialisation of the next generation of technologies and promotes their safe and reliable advancement.

The NIA stands for science- and technology-based expertise in nanotechnologies, encompassing members companies that have successfully developed and commercialised nanotechnologies for over 25 years.

Through proactive collaborations with regulators on the national, European and international level, as well as engagement with other nanotechnology stakeholders, the NIA promotes a framework of shared principles for the safe, sustainable and socially supportive development and use of nanotechnologies, by securing a publically and regulatory supportive environment for the continuing advancement and establishment of nanotechnology innovation.

On the 12th November 2008, the Royal Society on Environmental Pollution (RCEP) published its 27th Report, entitled *'Novel Materials in the Environment: The case of nanotechnology'*. The RCEP had launched the study that led to the report on the 11th January 2007; since this launch, the Nanotechnology Industries Association (NIA) and its member companies contributed to the evidence gathering process in a number of ways, including a presentation delivered by NIA Board Member Dr Paul Reip during the launch event,[1] written response to a questionnaire circulated by the RCEP,[2] initiation of a meeting between the RCEP review panel assigned to the study and industry representatives, as well as invited visits of the RCEP panel representatives to NIA member companies.

The NIA welcomes the RCEP report, and supports many of its findings and recommendations; the following section gives detailed comments on some of the issues raised in the RCEP report, as well as the press.

[1] see ANNEX A1
[2] see ANNEX A2

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Comments

- The NIA welcomes the RCEP's conclusion that *'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.'* Furthermore the NIA agrees with the European Commission conclusion that *'current legislation covers to a large extent risks in relation to nanomaterials and that risks can be dealt with under the current legislative framework.*[3]

- The NIA applauds RCEP's objectivity in reporting that '*the Commission found no evidence of harm to health or the environment from nanomaterials [...]'*.

- While noting *'that it is not the size of nanomaterials per se that is important, but their functionality, what they do and how they behave, that needs to be evaluated'* the RCEP recommends focussing 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.'* The NIA welcomes this recommendation, a key-element in the current debate of nano-specific policies. It is 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 make sweeping generalisations about a broad range of novel materials.

- In its written evidence to the RCEP, the NIA noted that *'there are 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.'* The NIA has since been working closely with the UK Government, in order to set up an extensive research programme in this direction.[4]

- The RCEP report highlights that *'there is an urgent need for more research and testing of nanomaterials.'* While the NIA agrees with this comment in

[3] Communication from the European Commission to the European Parliament, the Council and the European Economic and Social Committee, entitled 'Regulatory Aspects of Nanomaterials', 17th June 2008.

[4] This programme is currently being finalised; full public announcements will be made as soon as it ha been agreed.

principle, it needs to be pointed out that proposed toxicology studies should be related to realistic exposure routes, doses and bioavailability of nanomaterials. The predominant exposure routes to nanomaterials are likely to be through exposure to airborne particles and their impact on human and environmental health needs to be studied. The focus of future research and monitoring should be nanomaterials that present the greatest hazard.

- The NIA believes that it is unnecessary *'to extend the coverage within the European Union of the existing regulatory regime for chemicals (REACH),'* as proposed by the RCEP because, as explained by the European Commission, nanomaterials are already fully covered by REACH as it is currently implemented.

- The NIA congratulates the RCEP for its clear position that the best next steps with regard to nanomaterials are *'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.'*

- In its report, the RCEP speaks of '*profound ignorance and uncertainty about the behaviour of some types of nanomaterial in the environment or the risks that they pose for human health.'* Given that the term nanomaterial covers a broad range of materials, used in a wide variety of applications, some of which have been commercialised for over 25 years, others that are relatively new to the market, there are going to be case where the behaviour of some materials are better characterised than others. The NIA and its members actively promote the setting up of a framework of shared best practices for the safe, sustainable and socially supportive development and use of nanotechnologies. In particular, the NIA, in collaboration with Insight Investment, the Royal Society and the UK Nanotechnology Knowledge Transfer Network has developed the 'Responsible Nano Code'.[5] Furthermore, the NIA is working closely together with regulators, in order to develop appropriate guidelines and implementation documents to support the existing regulatory framework, which is adequate for the regulation of nanomaterials.

- It needs to be clarified that the '*deliberate discharge of nanomaterials into the environment*', as mentioned by the RCEP, eludes to a scenario in which nanoparticles are used for environmentally remedial purpose. None of our member companies currently commercialise materials used in this manner, or in ways that involve discharge into the environment.

[5] For more information, see www.responsiblenanocode.org.

- Further clarification is necessary with regard to the RCEP's finding that *'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.'* Unfortunately there are currently no agreed or recommended standard particles for this purpose. Attempts to develop QSARs have been made, but it is widely accepted that the currently available test results are not sufficient to support QSARs, in particular, since these test results are often contradictory. The underlying problem is the lack of agreed measurement and test protocols, which, in the absence of 'standard particles' could indeed recommend the comparative testing of specific agree particles in order to compare test methodologies used by different laboratories.[6]

- The NIA particularly welcomes the RCEP's assertion that labelling, despite fulfilling the legitimate wish of consumer information, *'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.'*

- The RCEP recommends *'an early warning system incorporating reporting requirements is a vital component of governance of nanomaterials'* and adds *'that such reporting should be kept as simple as possible. [...] It should be designed so as not to be onerous, [...].'* The latter recommendation reflects elements of the NIA's feedback to the UK's Voluntary Reporting Scheme (VRS), in which it was pointed out that the time and human resource required to complete the current VRS for just one particle, represents a huge burden on some companies, in particular small and medium sized companies.

- The RCEP goes on to highlight that *'Experience suggests that checklist reporting will have to be compulsory if it is to be effective,'* and adds that *'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.'* . While the NIA does not support a mandatory reporting scheme, the Association

[6] The nanotechnology industries are proactively engaged in national and international standardisation for a (such as BSI NTI/1, CEN/TC 352, and ISO/TC 229, to name only those standardisation bodies that are dedicated to nanotechnology, whilst many other standardisation bodies are also working on aspects of nanotechnologies). The nanotechnology industries furthermore are involved in many projects, which drive the development of test protocols. The NIA is are particularly active on the OECD level, where, in close collaboration between regulators and industries, a extended research programme is being be conducted on 14 globally agreed nanomaterials.

welcomes the RCEP's suggestion to introduce incentives to the participating industries.

- The NIA and its member companies are involved in the research and development of novel detection equipment and measurement protocols, thereby proactively answering to the RCEP's recommendation of *'a directed and substantial research programme on the properties and functionalities of nanomaterials must be established as a matter of urgency, in order to inform risk assessment and risk management strategies. One essential part of such a directed programme will be the development of techniques that allow the presence of particular nanomaterials to be detected in the environment.'*

In summary, the Royal Commission on Environmental Pollution has written an objective and balanced report on '*Novel Materials in the Environment: The case of nanotechnology*'. The Nanotechnology Industries Association and its members companies support the call for further research into the properties of nanomaterials and are in the process of finalising a detailed research programme in this direction.

* * * *

The NIA and its member companies thank you for the opportunity to provide these comments.

The Nanotechnology Industries Association

Formed in 2005 by a group of companies from a variety of industry sectors including healthcare, chemicals, automotive and consumer products, the Nanotechnology Industries Association (NIA) creates a clear single voice to represent the diverse industries in the multi-stakeholder debate on nanotechnologies.

The NIA provides a purely industry-led perspective, derived from the views of the collective membership and forms 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 commercialization of nanotechnologies.

For further information visit http://www.nanotechia.org or contact us on enquiries@nanotechia.org.

London, 12th November 2008

APPENDED Documents

A1 Presentation delivered by Dr Paul Reip at the RCEP Seminar, entitled *'Nanomaterials & Industry'* (11th January 2007)

A2 NIA written evidence for Royal Commission on Environmental Pollution 'Study on the Environmental Effects of Novel Materials and Applications' (July 2007)

RCEP Seminar

Nanomaterials & Industry

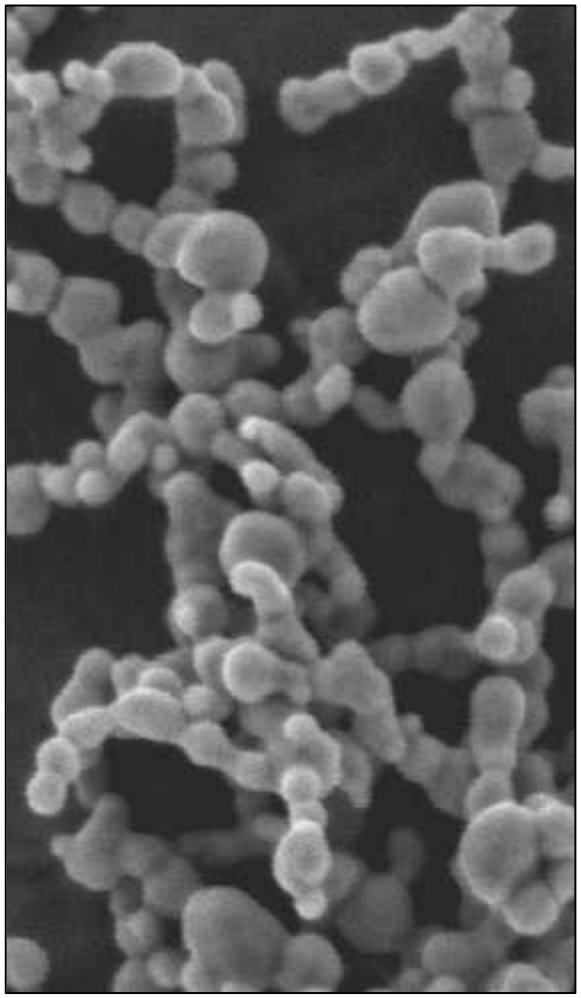
11th January 2006

… making a material difference to your business

Dr Paul Reip
Founder and CTO

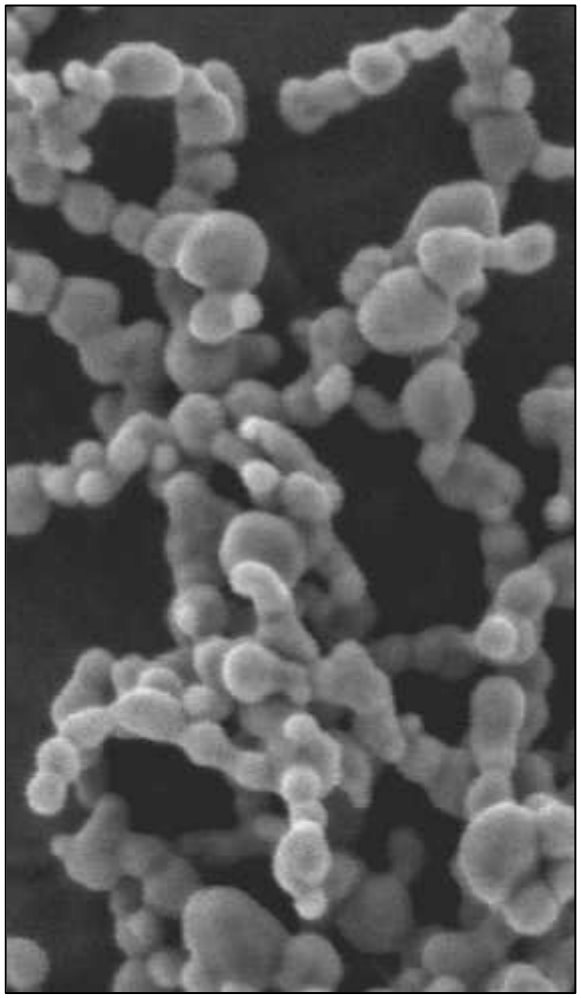
QinetiQ Nanomaterials

What are the Industrial benefits?



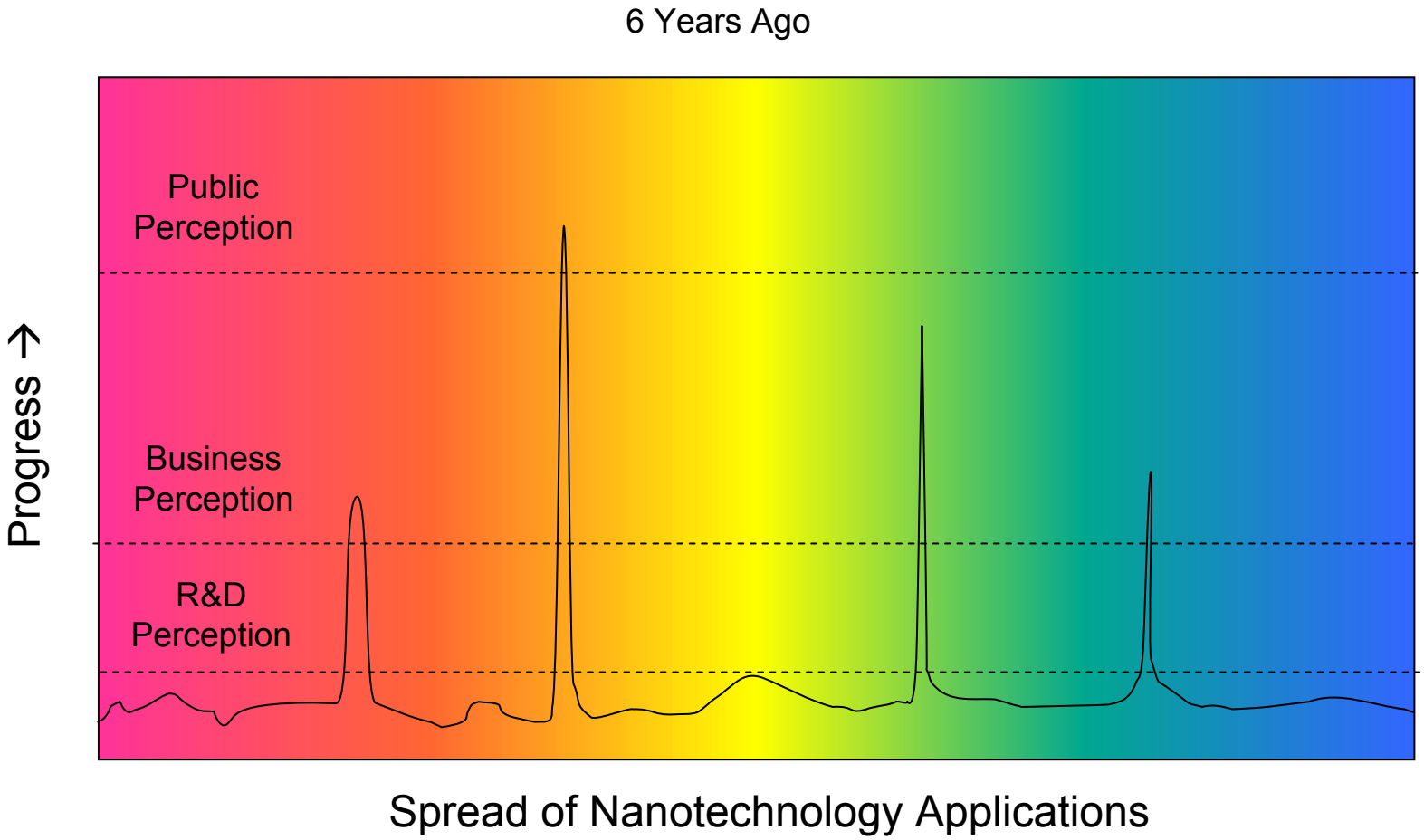
- There is demand for nanomaterials because
  - They provide increased functionality and a key market driver is for more functional products
- More effective materials
  - Physical properties
  - Magnetic properties
  - Electrical and electronic properties
  - Optical properties
  - Biological properties
- Next generation capabilities
- New technologies to solve current application problems
  - Low Power Electronics
  - Hydrogen Storage
  - Fuel Cells
  - Solar Cells

What are the Industrial markets?

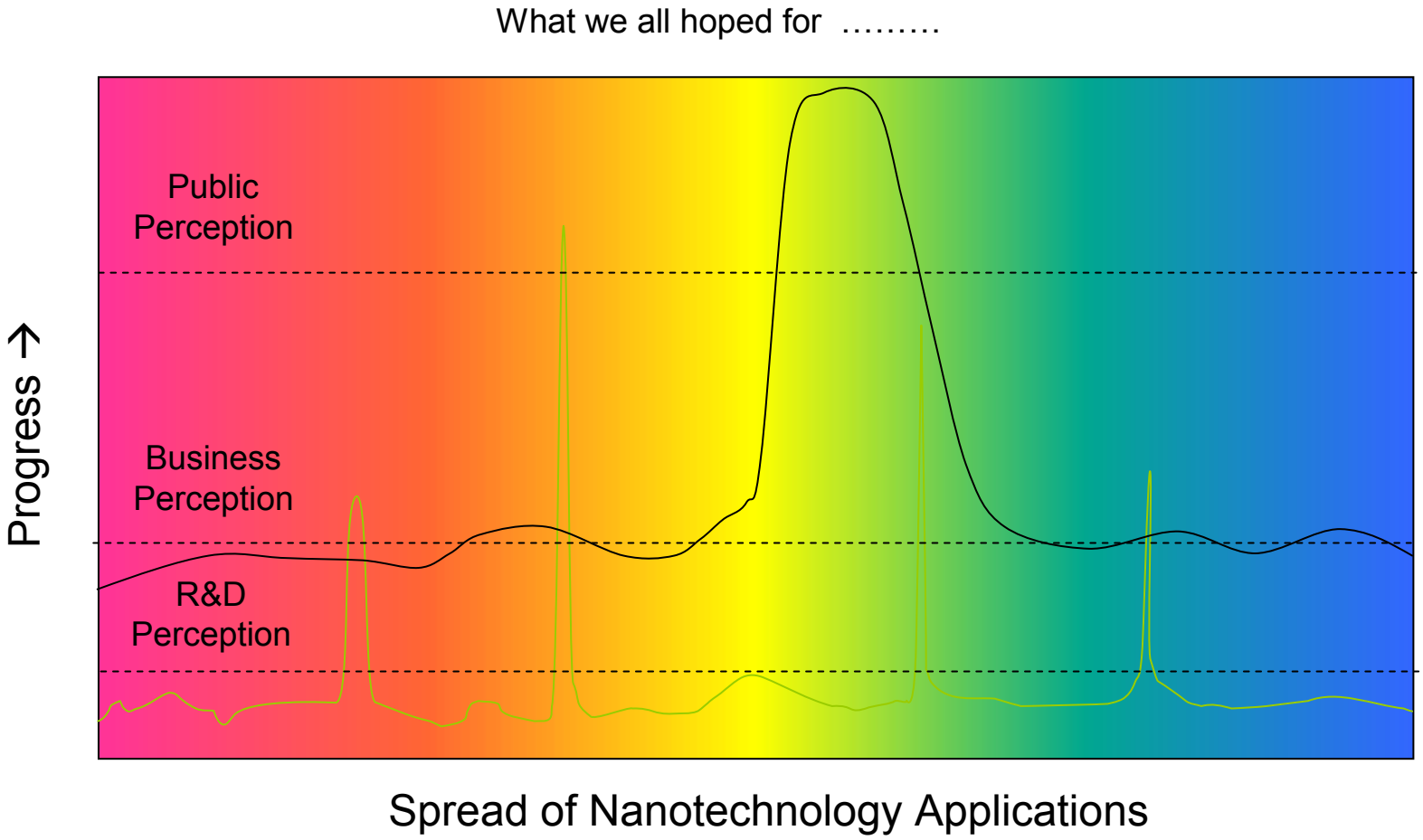


- Replacement Markets
  - *nano Tungsten & nano Cobalt for cutting tools (Cermets)*
- Enhancement
  - *nanoclay for barrier coatings*
- Carrier / Platform Material
  - *nano Silicon in drug delivery systems*
- New innovations
  - AVNP

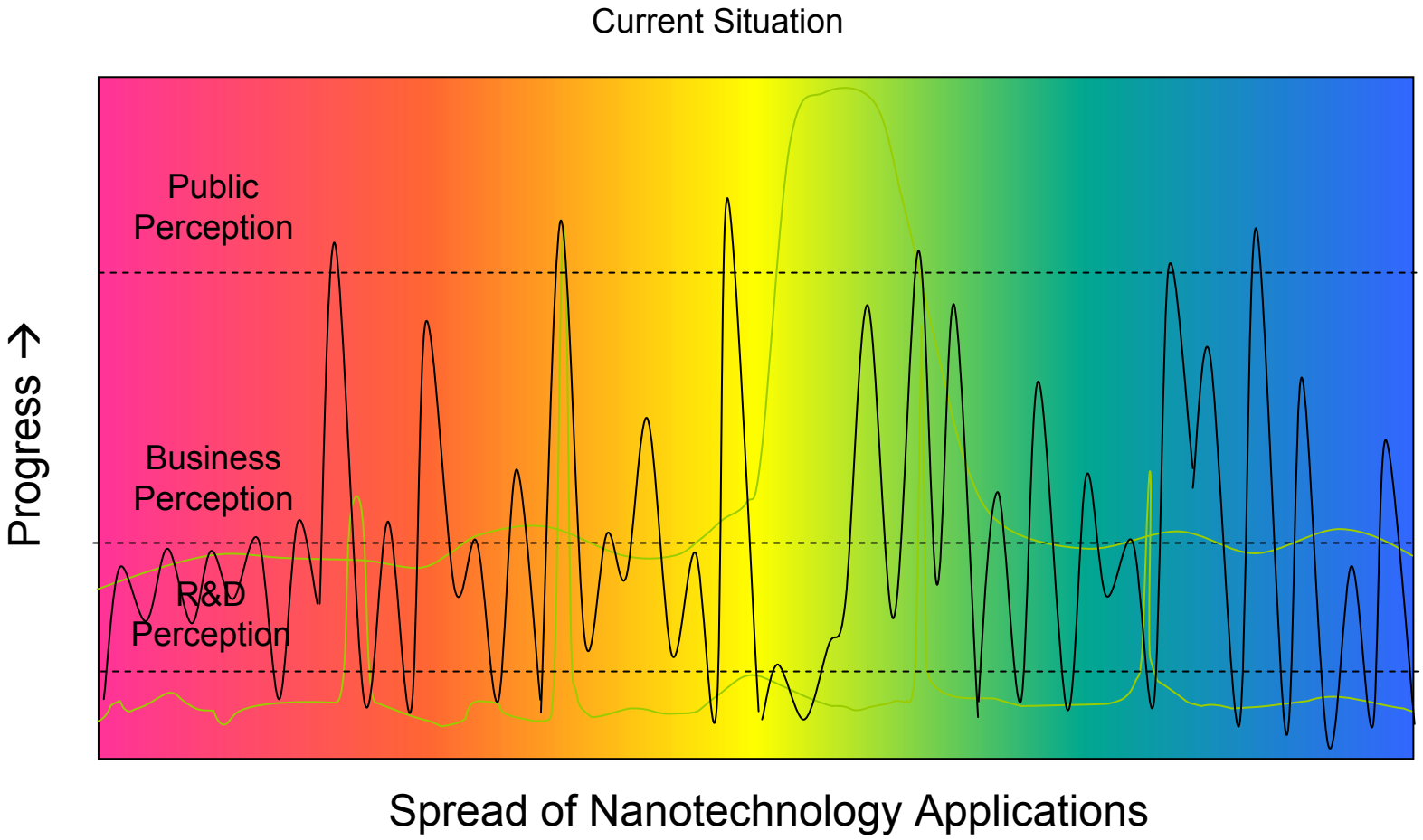
Progress


6 Years Ago
Public Perception
Business Perception
R&D Perception
Progress →
Spread of Nanotechnology Applications

Progress

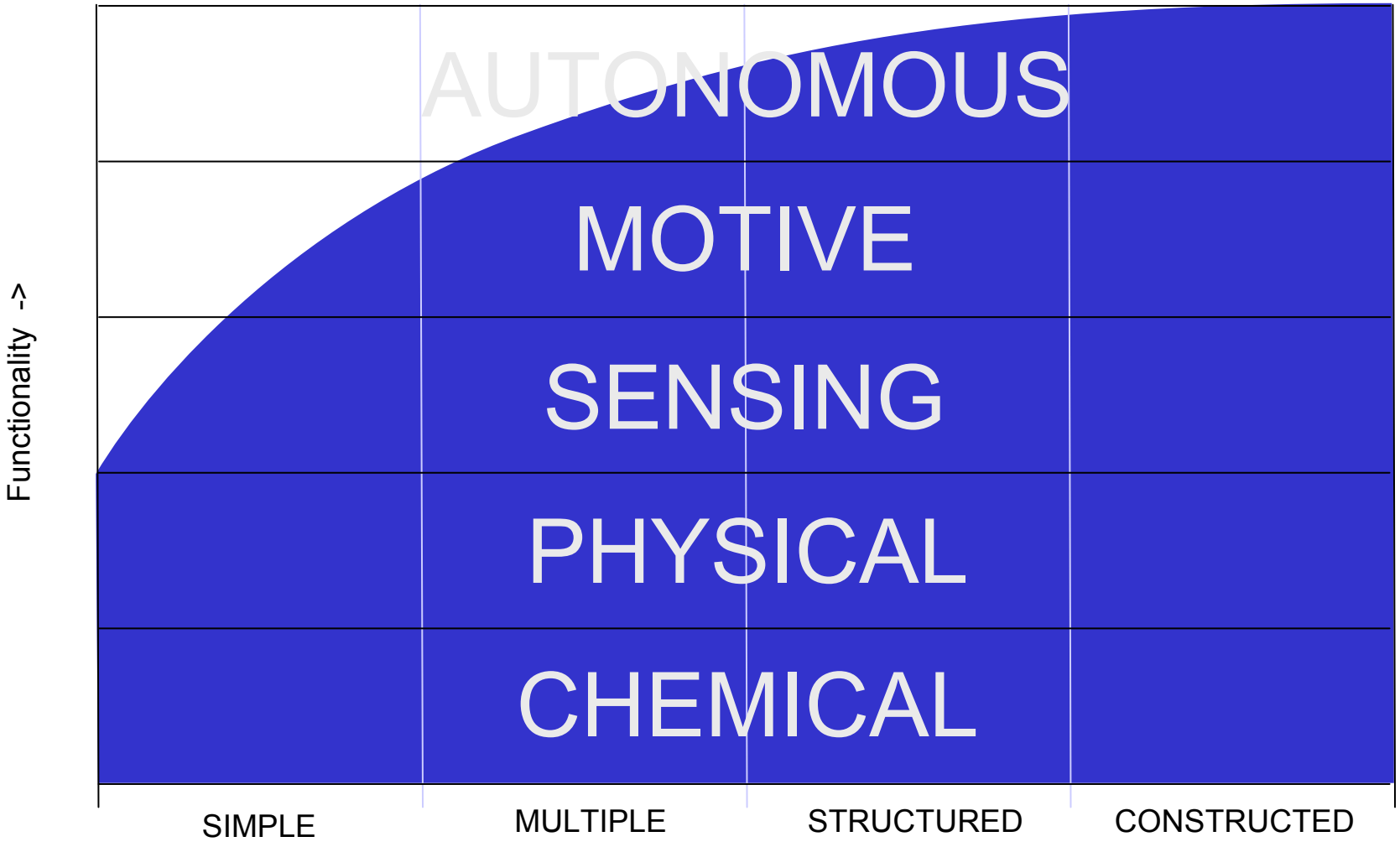

What we all hoped for ……
Public Perception
Business Perception
R&D Perception
Progress →
Spread of Nanotechnology Applications

Progress



- Increase in customers levels of sophistication !!

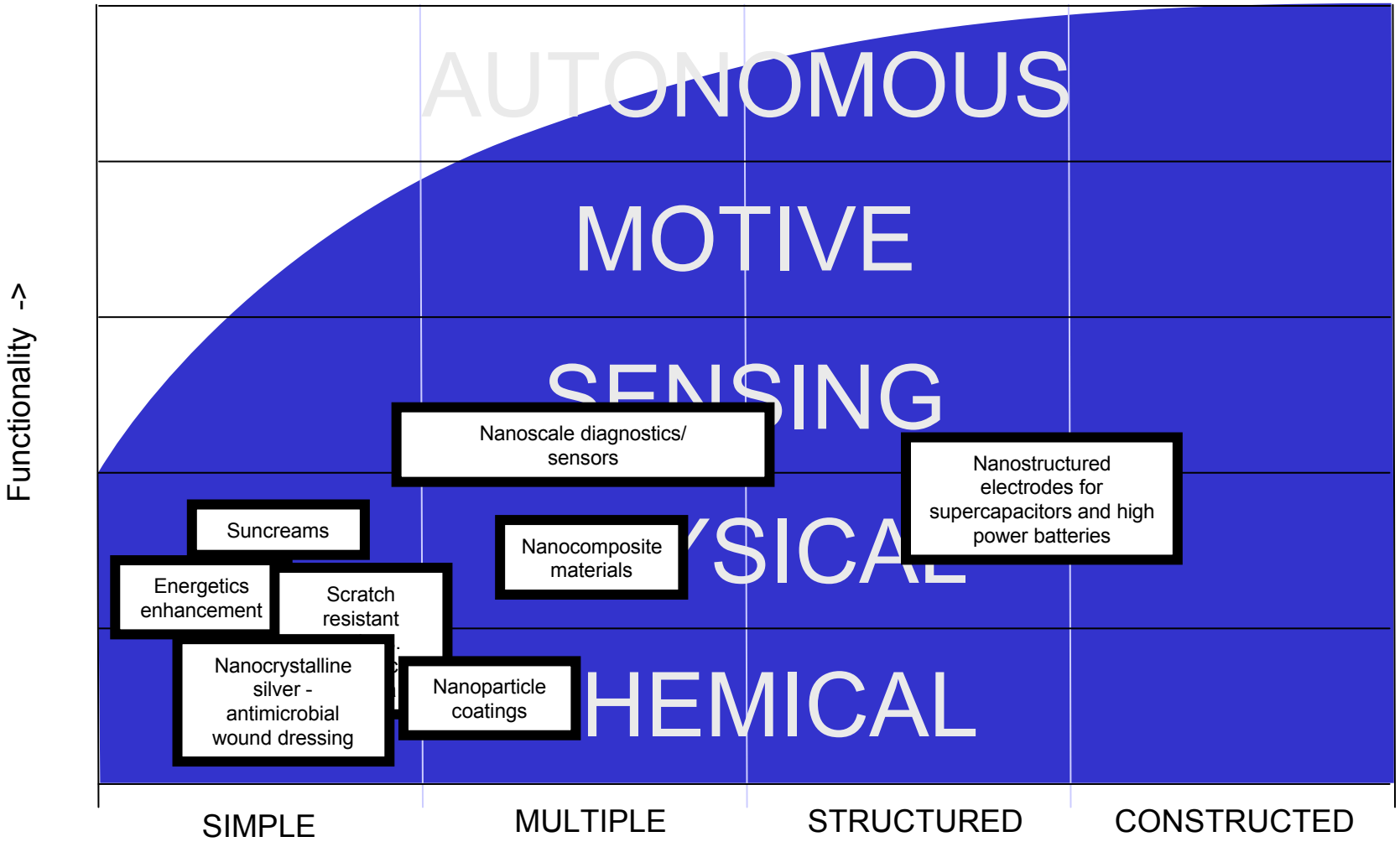
Technology Spread



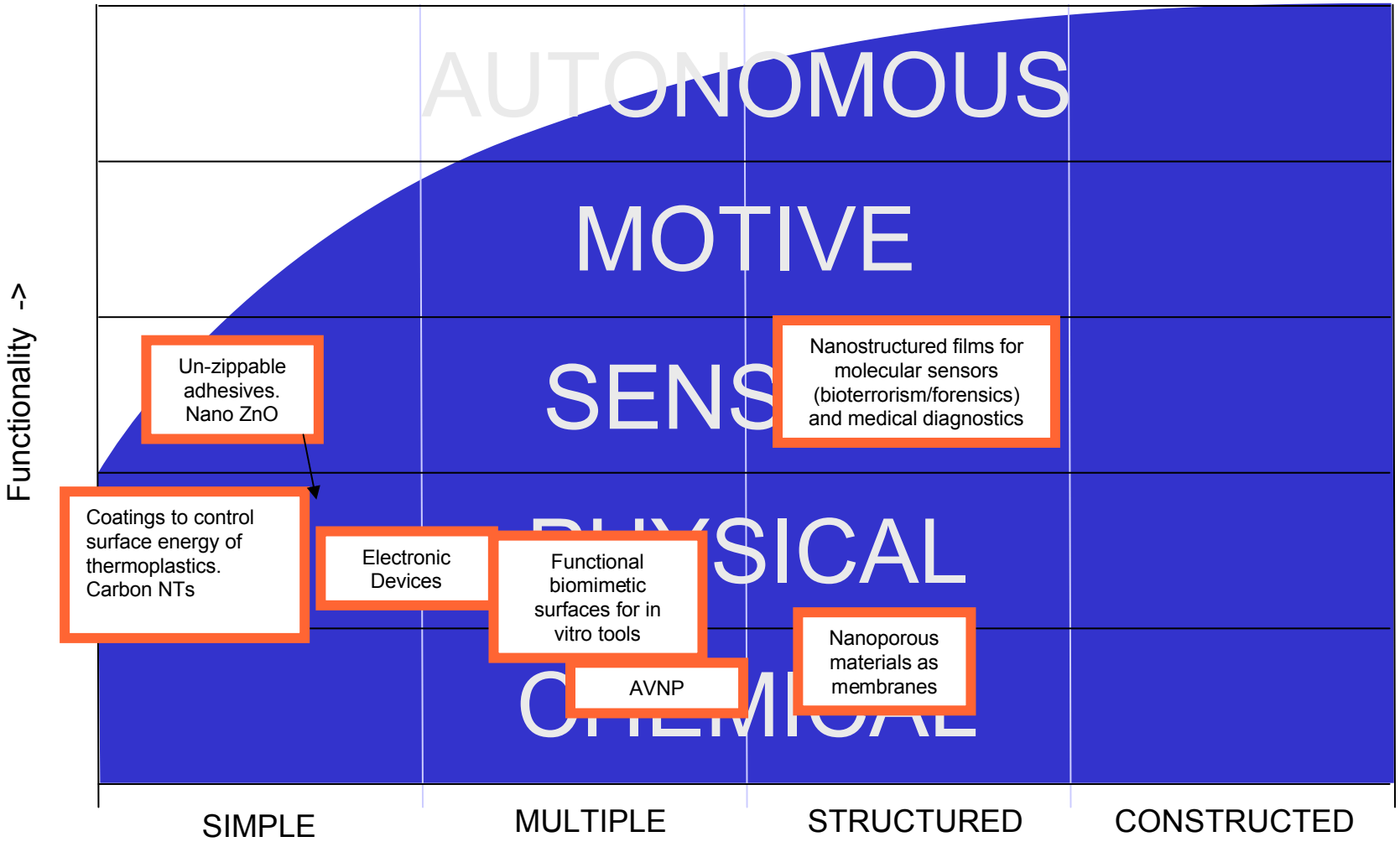
Nanotechnology Industries Association

QinetiQ Nanomaterials

Technology Spread – Existing App



Technology Spread – In Development



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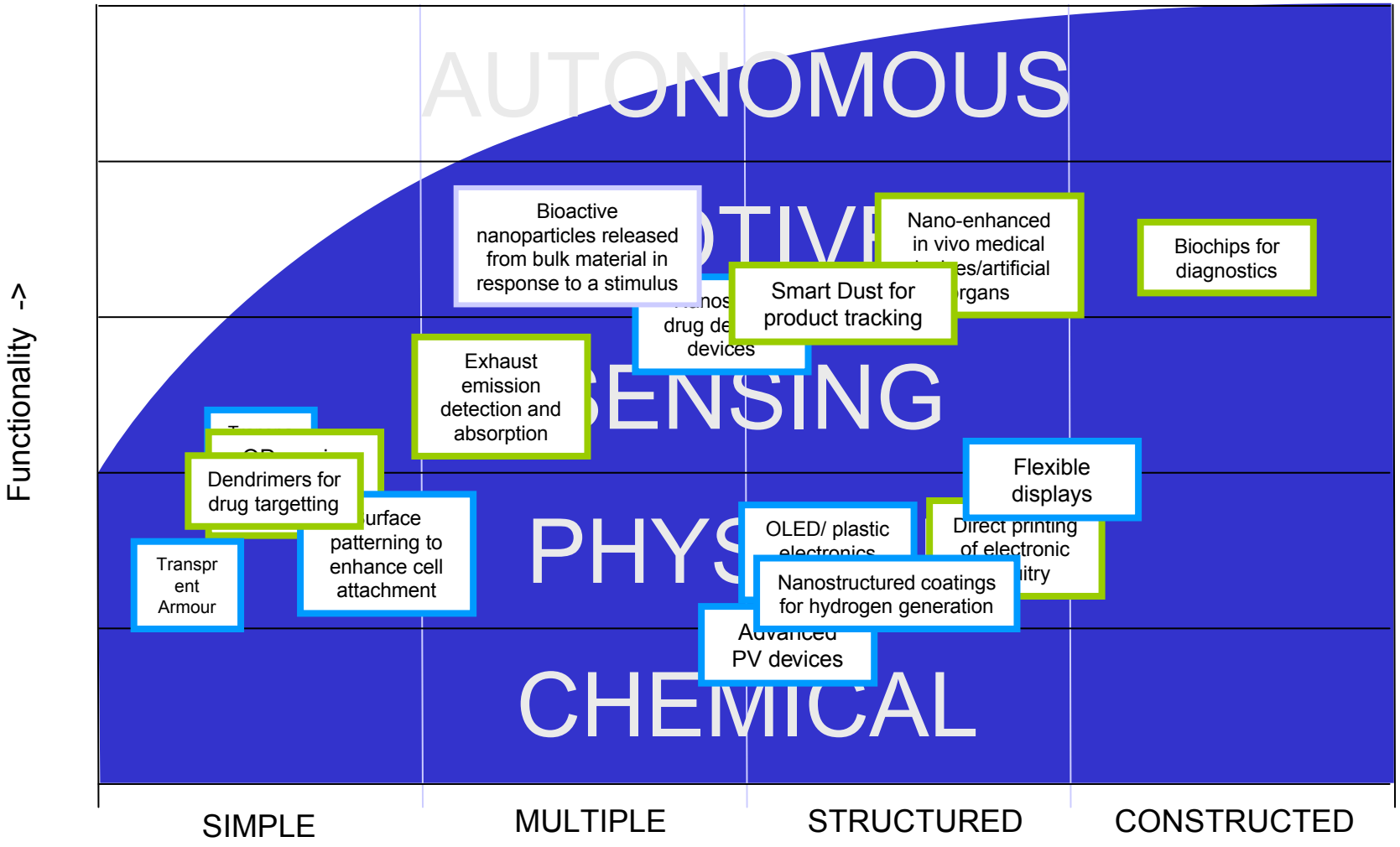
Technology Spread – Targeting 3 to 10 years



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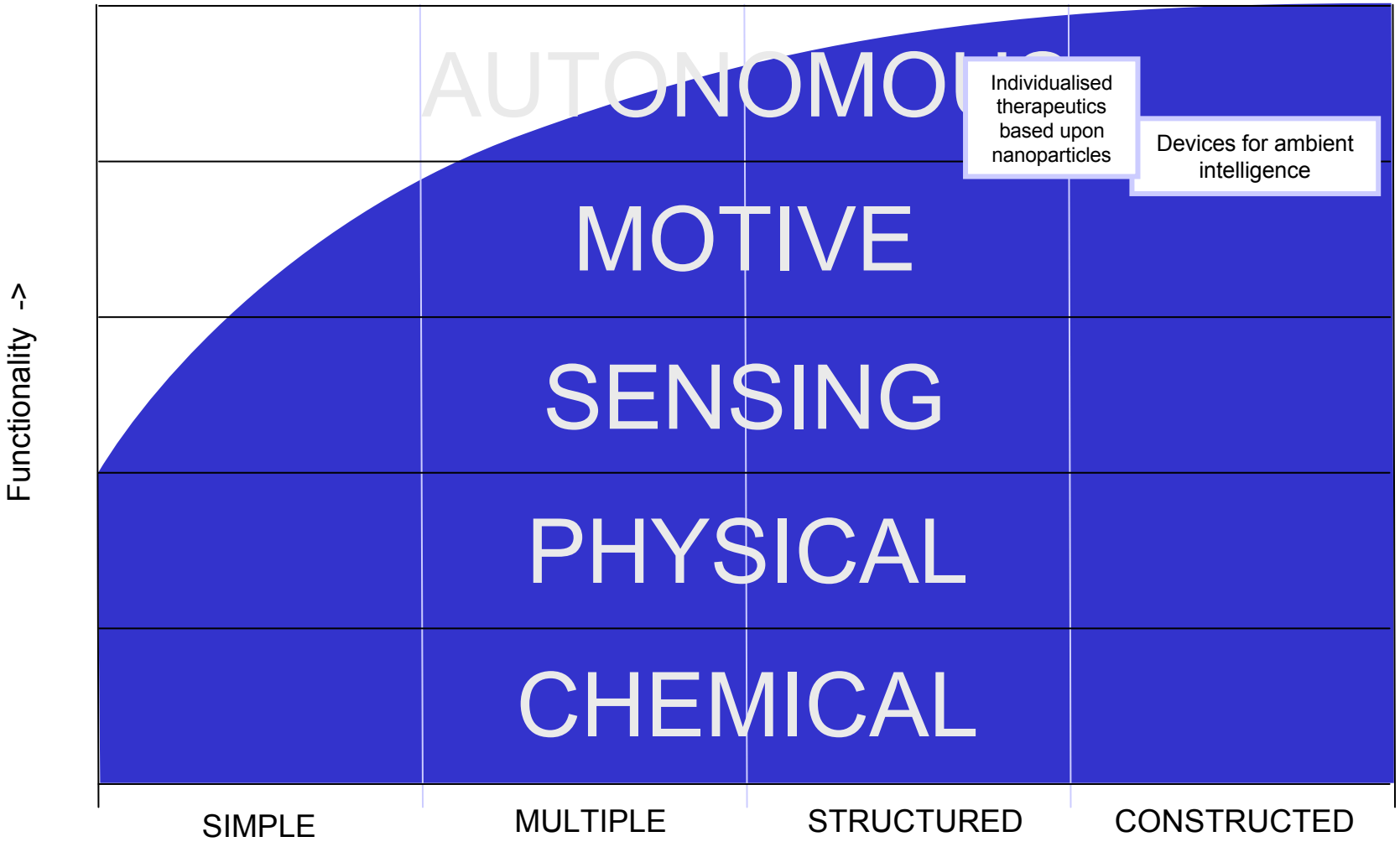
QinetiQ Nanomaterials

Technology Spread – Long Term Aspirations



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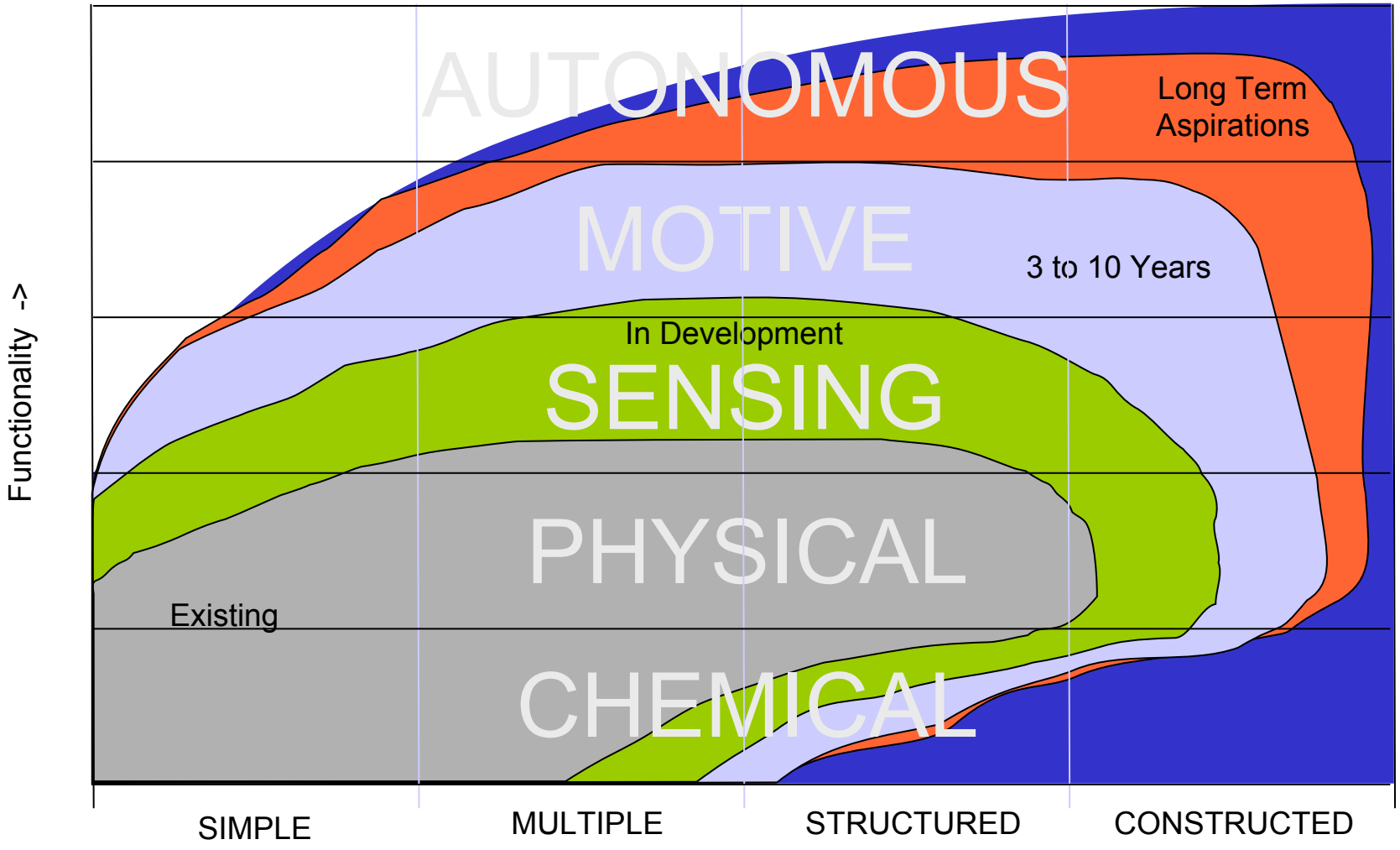
QinetiQ Nanomaterials

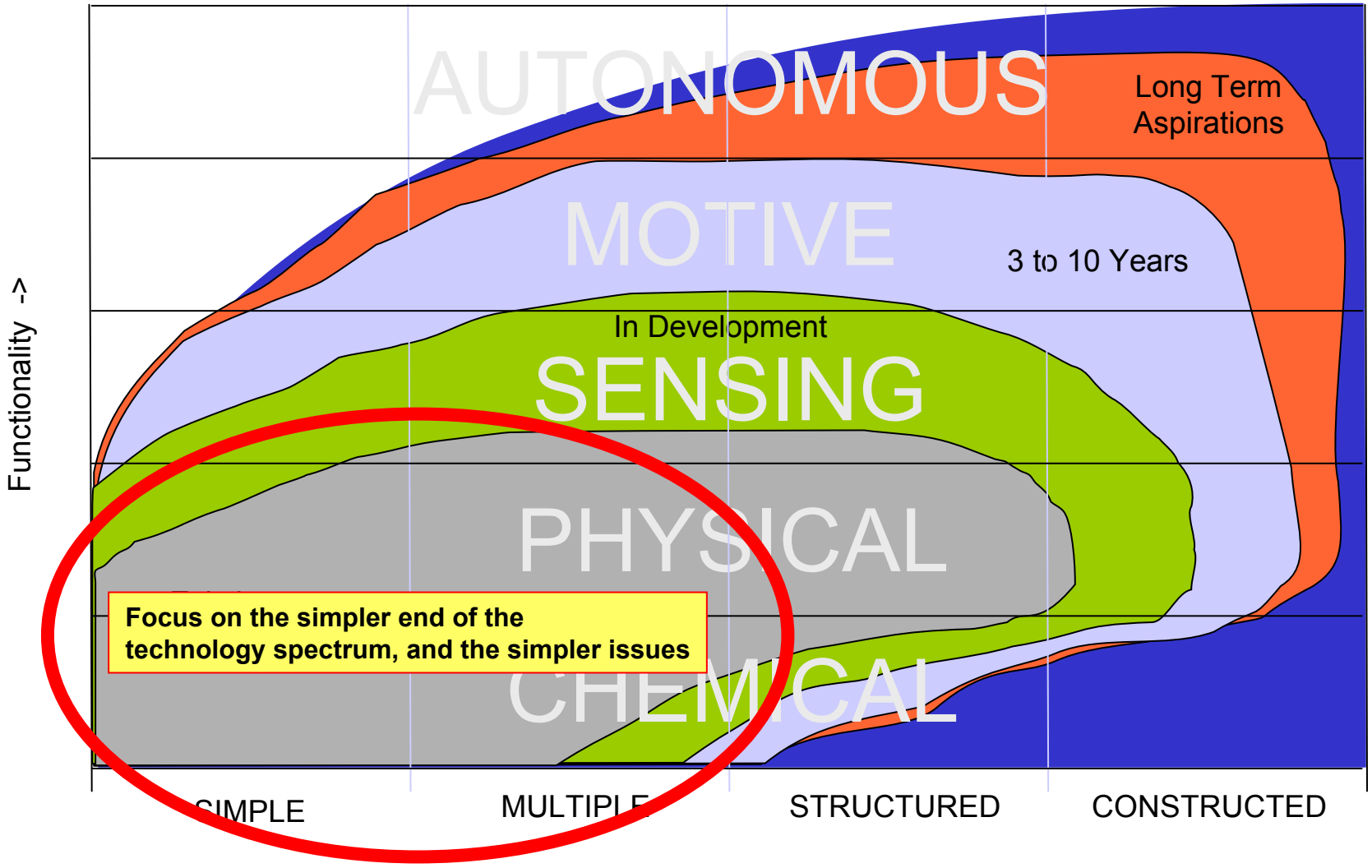
Technology Spread Over Time



Nanotechnology Industries Association

QinetiQ Nanomaterials

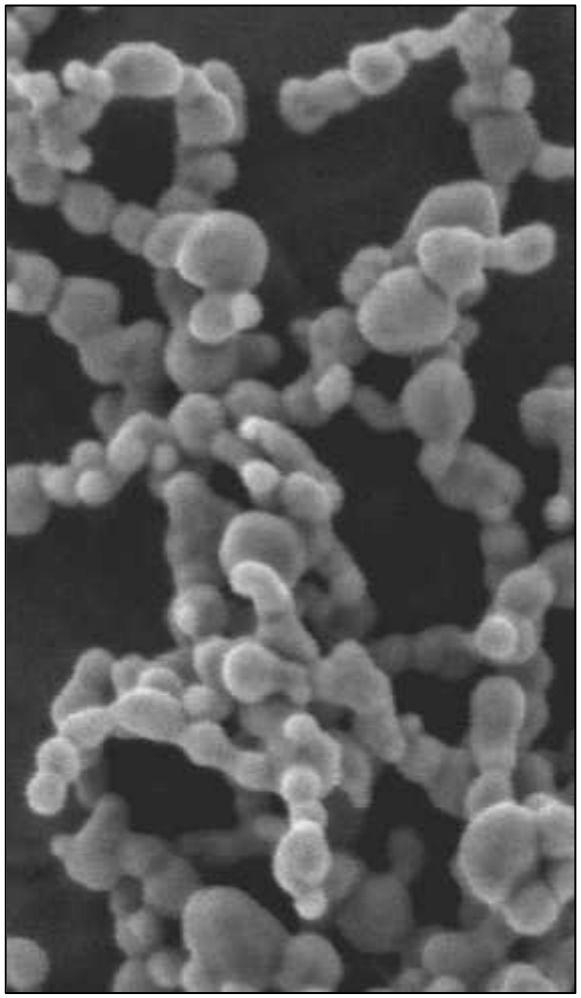
Technology Spread Over Time



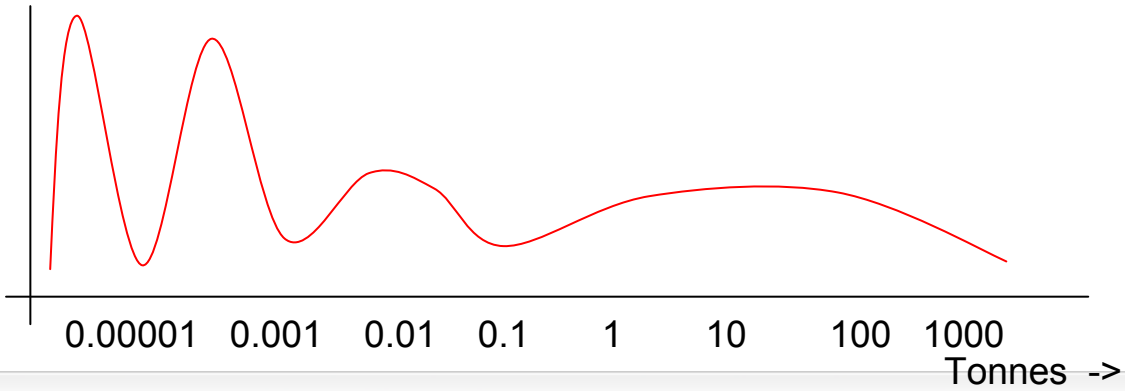
Nanotechnology Industries Association

QinetiQ Nanomaterials

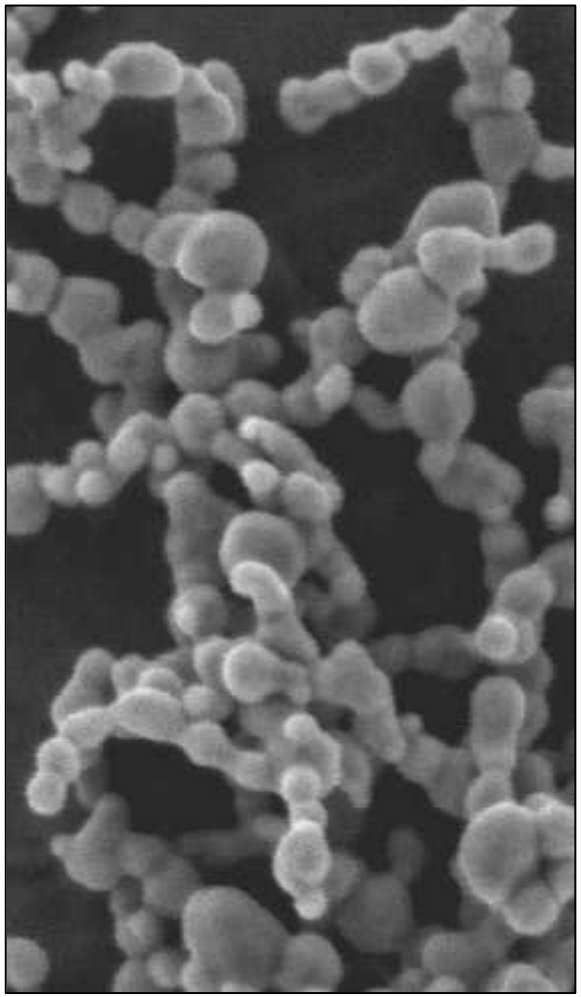
What are the Industrial technology issues?



- Bulk production
  - Process scaling is the key
- Technical Support
  - understanding material interactions
- Functionality
  - Morphology, activity, composition
- Systems
  - Overall impact of nano
- Analysis
  - Instrumentation, quality, standards



What are the General Issues?



- Timescales
- Funding
- Backwards Compatibility
- Survivability
- Logistics and packaging
- Industrialisation
- Multidisciplinary approach
- Environmental
- Social
- Government & Legislation

Anti Viral Nano Particles

AVNP

- Nano scale inorganics are capable of defeating viral activity/deactivating viruses
- *This is are only apparent at the nano scale*
- Potential to use combinational elements to
  - target various specific viruses
  - multi-viral contaminants
- Can be used to develop anti viral systems for
  - Coatings
  - Filters
  - Medical devices
- Team AVNP created to develop and market

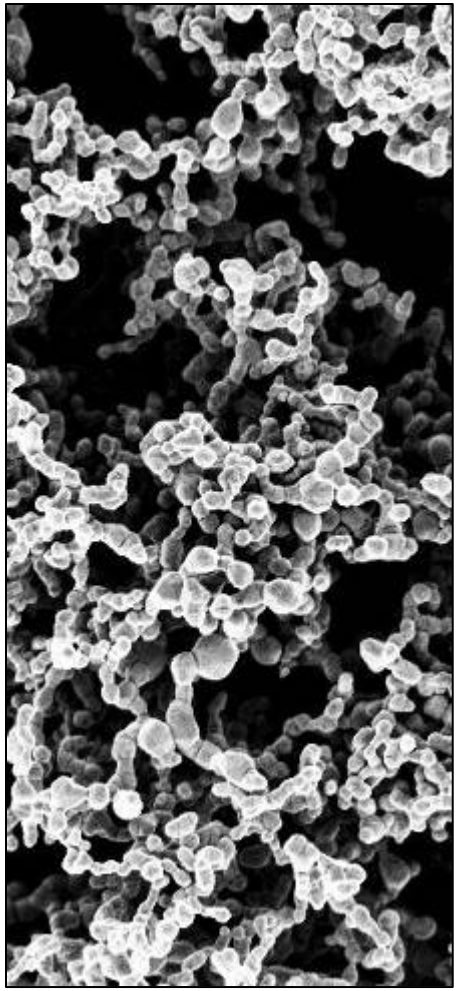
Brunel UNIVERSITY WEST LONDON | PALL Pall Corporation | QinetiQ Nanomaterials | Queen Mary University of London | RETROSCREEN VIROLOGY | SunChemical

Nanotechnology Industries Association

UK Nanotechnology Industries Association

- Created this year to represent the voice of the industry
- Not intended to replace or supplant any of the existing organisations, but to complement
- Provide information and education in the nanotechnology areas, and to provide a single point for all industry related issues

Summary



- Existing environment has always contained them
- The applications of Nanotechnology is pervasive – and broadening by the day
- The issues are not “if” they will be used but “when”
- We have to also be aware of the scale of the issue, and the focus and rate of its development
- We have to manage the risks, but must look at them in a contextual way
- UK Industry is not blind to the issues and is actively working with other stakeholders to responsibly gain the benefits of the technology

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Nanotechnology
Industries Association

Seminar Report:

Novel Materials and Applications: How do we manage the emergence of new technologies in democratic society and a global economy?

Summary & Author's Comments

The Seminar entitled '*Novel Materials and Applications: How do we manage the emergence of new technologies in democratic society and a global economy?*', was held on the 11th January 2007, at the IoM^3 as part of a new study launched by the **Royal Commission on Environmental Pollution** (RCEP). The meeting was exclusively focused on (engineered) nanomaterials. Both the invited speakers and the audience consisted of a number of high-profile players in the nanotechnology and -toxicology community, and most of the talks were of excellent quality and gave the required evidence by covering exactly those topics they were asked to comment on.

The meeting started with an introduction to the RCEP, followed by a set of invited lectures on the *Development of Novel Materials*. In this session, the industries' viewpoint was given a lot of weight; an excellent account of the environmental and the economic impact of nanomaterials from manufacture to final application was presented by Dr Reip (QinetiQ Nanomaterials), and Neil Glover (Rolls Royce).

The second session focused on the *Health & Environmental Effects of Novel Materials*; unfortunately, industry was not represented in this session, and the overall viewpoint that was delivered in this session excluded industry contribution, with the exception of Professor Colvin's remark that the International Council of Nanotechnology (ICON, Rice University, USA) included 10 industrial companies, who were contributing to a multi-stakeholder debate. The demonstrated exclusion of industry contributions from this topic was later criticized by members of the commission, who assured the author that the RCEP would during the future study ensure a more balanced view through the active involvement of industry representatives and through inviting evidence from industry-facing toxicology labs, such as the SnIRC (SafeNano) initiatives.

The meeting concluded with a session on *Governance and Regulation Issues*, during which a number of social science experts gave evidence, followed by an overview of relevant initiatives in the European Commission. The session concluded with an excellent presentation by Dr Richard Owen (Environmental Agency), who eluded to a risk assessment scheme, which is anticipated to be adopted by the OECD Working Party on Manufacture Nanomaterials Steering Group 6 (*i.e.* OECD WPMN SG6 is lead by DEFRA; it's remit is to establish a risk assessment methodology).

Overall, the industry representatives received a warm welcome from the commission, and were invited to participate in the following evidence-gathering processes, as well as collaborate on related issues. In the Chairman's closing speech, the NIA was referred to as 'the good guys', and was praised for participating in the event and the study.

Next Steps:

The NIA will liaise with the RCEP, in order to formalize its future contribution to the study.

Nanotechnology Industries Association

Background

In April 2006, The Royal Commission on Environmental Pollution announced the topic for the 27th report: *the environmental effects of novel materials and applications*. The Seminar held on the 11th January 2007 at the IoM[3] formed the start of the two-year study, during which the RCEP is planning to gather the necessary information and evidence for their report.

Welcome & Introduction:

Professor Sir John Lawton, Chair of the RCEP, welcomed the delegates and gave a brief description of the RCEP: The RCEP is the only standing RC; established in 1970, it is independent from Government, and it provides advice on environmental issues to the Queen, Government, Parliament, the devoted administrations and the public. For more information on the RCEP and its members, see here: http://www.rcep.org.uk/.

Key-Note Speech:

Professor Andrew Stirling, Science and Policy Research Unit, University of Sussex.

Professor Stirling introduced the concept of 'New Technology & the Democratic Process: reconciling innovation & precaution on societal appraisal'.

He continued to elaborate on 'The nature of Innovation': he quoted speakers of the UK Government, who call to 'promote pro-innovation culture', and explains that the questions in this context is not 'which technology' to innovate, but 'how much' / 'how fast' to innovate any technology. He concluded the argument by pointing out that innovation can take many pathways, and that no innovation is absolutely correct (e.g. Betamax *vs* VHS). In his opinion, new materials face the same basic choice, and the markets for these new materials will not provide the solutions to this choice; in the case of nanotechnology, there is no given pathway for any application, and a conversation about 'pro' / 'anti' innovation is wholly inappropriate in this context.

He continued to explore the concept of 'Sound Science', as promoted by the Government; the concept had certain limitations. Prof. Stirling showed a chart that rated the 'soundness' of energy generating technologies, and that displayed enormous error bars, corresponding to the wide spread risks associated with any of the investigated technologies (see Figure 1.). He concluded this example by remarking that all analysis required framing, and all framing required judgement.

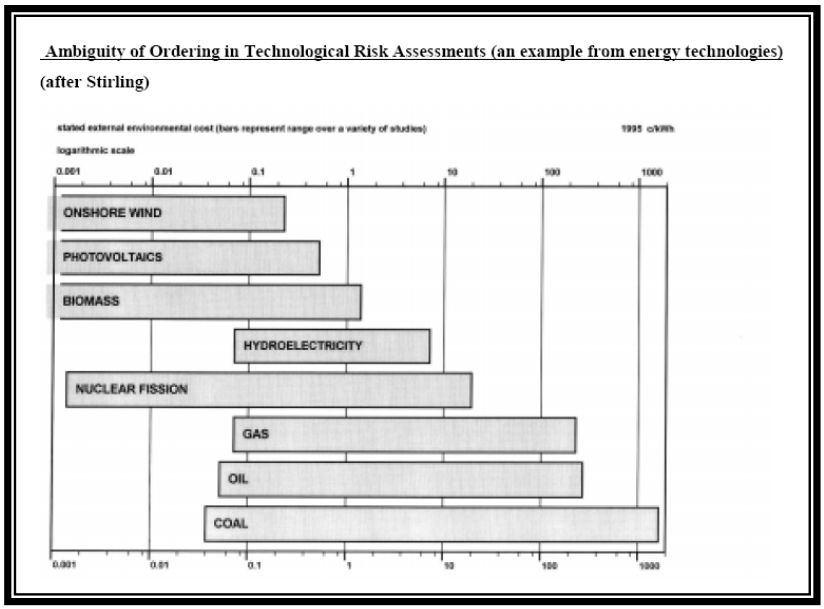

Figure 1: Reconstruction of the plot shown by Professor Stirling during his presentation at the RCEP Seminar.[1]

Professor Stirling went on to explain the context of 'Precaution', using a plot of 'Known Probability' *vs* 'Known Outcomes' (see Figure 2).

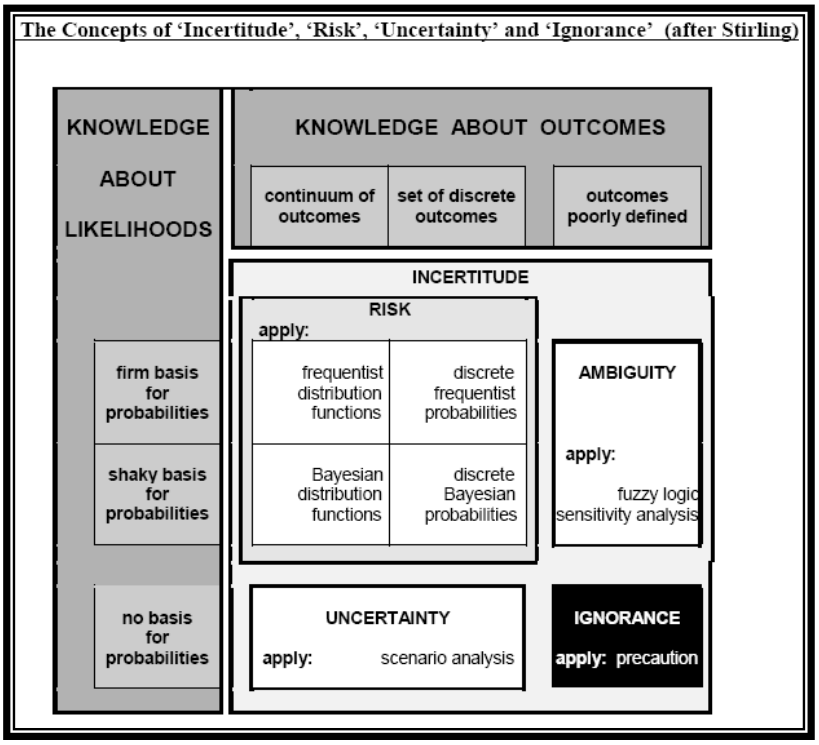

Figure 2: Reconstruction of the plot shown by Professor Stirling during his presentation at the RCEP Seminar.[1]

Session1: Development of Novel Materials: Chair: Professor Janet Sprent

1. Professor Mark Welland, NanoScience Centre, Cambridge

Professor Welland gave an introduction to nanotechnology, by explaining both the top-down and the bottom-up approach to fabricating on the nanometre scale. He continued to show many examples of implemented nanoscience and –technology, achieved by the researchers in the NanoScience Centre in Cambridge (and the IRC in Nanotechnology), including nanoelectronic devices, nanooptical devices, and nanotoxicological research. Professor Welland emphasised the increasing proportion of surface area with decreasing particle size, and alerted the audience to the recent news about the potential EPA-regulation of silver-nanoparticles (Samsung washing machine) in the US.

2. Dr Paul Reip, QinetiQ Nanomaterials Ltd

Paul explained the manifold reasons for industry to work with nanoparticles, and alerted the audience to the fact that some nanotechnology had been invented a long time ago (e.g. nano-sunscreen had been invented by Shisheido in the 70s).

Paul pointed out that the nanotechnology industry wasn't really an industry but a collection of capabilities. He illustrated the manufacture of nanomaterials, as conducted by QinetiQ, and their wide-spread applications, ranging from the replacement of other materials to applications that utilise the unique nanoscale properties of the material.

He presented the NIA roadmap and explained the anticipated benefits on nanotechnologies in a number of existing and emerging markets.

Neil Glover, Rolls Royce plc

Neil Glover explained Rolls Royce's interest in nanotechnology: in the case of aero-engine technologies, the main drive is to make the engines more efficient (incl. thermodynamic efficiency, thrust efficiency). Novel materials are necessary to increase the efficiency of existing engines, but any changes in the technology or the material used for aircraft engines is subject to lengthy safety testing procedures.

Neil went on to describe one of the main drivers for innovation in aviation technology: environmental issues (*i.e.* climate change, local air quality, noise levels). He explained that the aviation industry achieved a 70% reduction in fuel consumption since the 1960. Nanotechnology is anticipated to have an impact on the required high-performance materials used in the hollow Ti-fanblade (this might be replaced by a nanocomposite material), and the high-temperature turbine blade, as the industry is experiencing an increasing move towards ceramic matrix composite technology, but applications in this area are limited by the brittleness of ceramics; additional hurdles to the currently adopted technology are posed by the fact that the Ni-alloy composite, used in this blade, is manufacture using Ni-powder, which is expected to be regulated under REACH). Other areas, in which the use of nanomaterials could advance the technology: shape-memory alloys (i.e. smart materials) that enable a better control of the fuel-air – mixing process, reducing the noise level; structural nanomaterials (extra light/strong/etc.), nanocomposite coatings (e.g. erosion protection).

3. Professor John Kilner, Imperial College

Professor Kilner explained the advantages that nanomaterials are anticipated to bring to the fuel cell technology (incl. electrode materials, electrochemical conversion, energy storage, etc.). Professor Kilner concluded by remarking that challenges were not only a matter of risks, but that benefits, as well, needed to be considered for the discussion of innovation.

Session 2: Health & Environmental Effects of Novel Materials: Chair: Professor Stephen Holgate

1. Professor Anthony Seaton, University of Aberdeen

Professor Seaton commenced by explaining the relationship between Hazard, Exposure, Dose and Risk, and pointed out that the media often wrongly used 'Hazard' and 'Risk' interchangeably. He continue to explain the similarities between asbestos fibres and carbon nanofibres (and carbon nanotubes), and illustrated that the hazardous properties of fibres were attributed to their persistence in the lung alveoli, typically caused by their morphology (*i.e.* diameter < 3μm, length > 15 μm), combined with the inability of the body to dissolve the fibres (*cf.* glass fibre are soluble), and the surface activity of the fibres (the latter aspect is not well understood, but experiments suggest a link to the creation of free radicals).

With regard to spherical particles, Professor Seaton eluded to the Mexico-City study that had found evidence of a link between air-pollution caused by the combustion of fossil fuels and some serious diseases in inhabitants of Mexico-City (incl. Alzheimers and Parkinsons). Thanks to these and similar epidemiological studies, a lot of data is available that shows the link between airborne ultrafine particles and serious diseases, or fatalities, of which the latter are largely due to heart attacks of the subject.

Professor Seaton went on by pointing out that a mass metric was no longer appropriate when describing the toxicity of nanoparticulate matter, but that a particle-count metric should be adopted in its stead.

He concluded by calling for a collaboration between academics, regulators and occupational health researchers (no industry was mentioned in this contexts), to work together on the development of toxicology testing procedures that must go beyond traditional toxicity tests; he described the necessary change in procedure as a paradigm shift.

2. Professor Vicky Colvin, Rice University, USA

Professor Colvin explained that structure-activity relationships are going to be critical in the assessment of nanomaterial toxicology; as an example, she illustrated the necessary effort to test all kinds of synthesised single-walled carbon nanotube (SWNT) samples individually, without the help of structure-activity relationships: 50000 SWNT samples would need to be tested, if no assumption between the structure and the activity of the material was allowed.

Professor Colvin went on to describe some of her work on C_{60}, which has a high reactivity and had previously been shown to generate free radicals; in biological experiments, C_{60} has been shown to be a strong biologically active cytotoxine. Professor Colvin's lab achieved a hydroxylisation of C_{60}, which appeared to significantly decrease the cytotoxicity of C_{60}. Highly purified SWNTs show a similar behaviour (*i.e.* their cytotoxicity decreased with increasing derivatisation); this observation is attributed to the interaction with the cell wall.

She concluded by challenging the audience with the suggestion that the question 'Are engineered nanoparticles dangerous?' ought to be changed to 'How can we engineer safe nanoparticles?'

3. Professor Gunter Oberdoerster, University of Rochester

Professor Oberdoerster explained the fractional deposition of inhaled particles in the human respiratory tract, using an (ICRP) model (nose-breathing), he had referred to in a number of review articles (see Figures 3 and 4).

He went on to explain how a number of studies gave evidence that very small particles were able to travel from the nasal region along the olfactory nerves into the brain (*i.e.* through the 'blood-brain barrier').

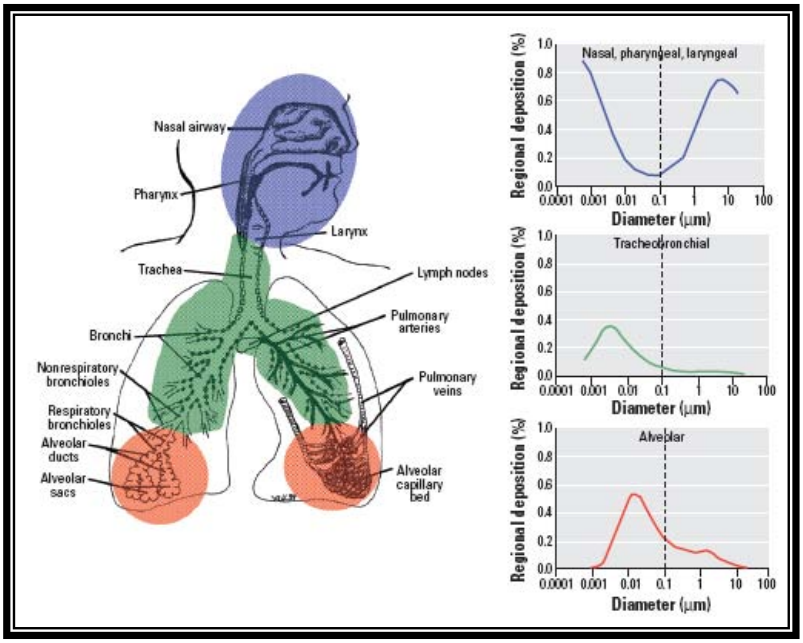

Figure 3: Predicted fractional deposition of inhaled particles in the nasopharyngeal, tracheobronchial, andalveolar region of the human respiratory tract during nose breathing. Based on data from the International Commission on Radiological Protection (1994). Drawing courtesy of J. Harkema.[2]

Professor Oberdoerster continued by discussing a number of other published studies, such as the inhalation toxicology studies of polystyrene particles in small rodents, and Mn particles in rats, as well as TiO_2 (P25) particles in the brain cells of mice. He pointed out that one of the most dangerous (toxic) particles were PTFE particles, created when a PTFE-coated pan was overheated.

He concluded by referring the audience to the studies by Donaldson and Tran, which investigated the interaction between particles and living cells, in order to understand the reaction mechanism that underlies the toxic effect of nanometre-sized particles; so far, substantial evidence pointed towards an 'oxidative stress'-mechanism.

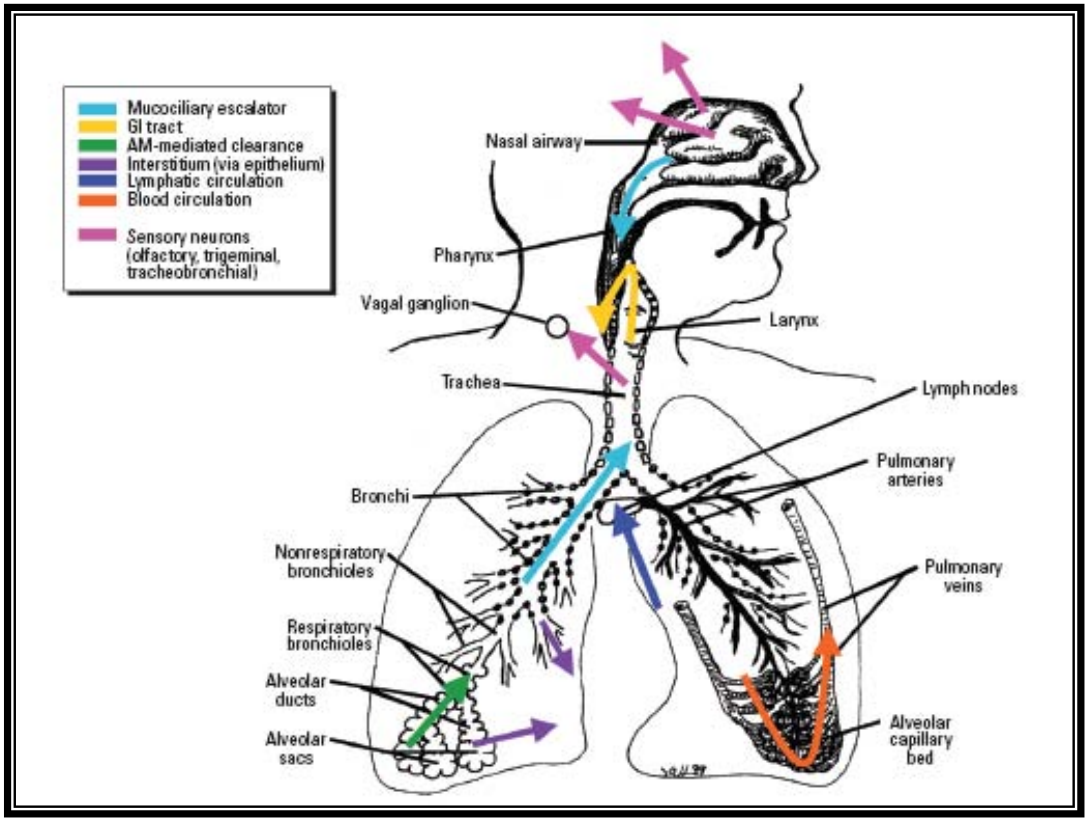

Figure 4: Pathways of particle clearance (disposition) in and out of the respiratory tract. There are significant differences between NSPs and larger particles for some of these pathways (see "Disposition of NSPs in the respiratory tract"). Drawing courtesy of J. Harkema.[2]

Session 3: Governance and Regulation Issues: Chair: Professor Susan Owen

1. Professor Sheila Jasanoff, Harvard University, USA

Professor Jasanoff commenced by explaining the general understanding of pollution, as 'Matter out of Place'. Her following talk gave an overview of the history of risk assessment and regulation (incl. 1983 (under Reagan): the separation of science from judgement; 1996: the Analytic-Deliberative Model).

Professor Jasanoff concluded by discussing if the problem of nanotechnology regulation was 'A NEW Regulation Problem'; the question was answered with a 'no', as there were plenty of examples where new technologies required new regulations (*cf.* GMO).

2. Professor Daniel Sarewitz, Arizona State University, USA

3. Cornelius Brekelmans, European Commission

Cornelius Brekelmans gave an overview of the EC's position and initiatives on nanotechnology and the regulation of nanotechnology; there are a number of committees looking into the potential health risks of engineered nanomaterials. The EC is currently following an evidence-gathering strategy, which is aimed at bridging the existing knowledge gap, and is not looking at passing any regulation on nanomaterials, as it considers the current legal structure adequate.

4. Dr Richard Owen, Environmental Agency

Dr Owen explored ways of 'Managing the emergence of new technologies in a democratic Society'; he pointed out that it was essential to realise the (environmental) benefits of novel technologies, in order to lead an open, inclusive dialogue of innovation (*i.e.* 'Risks versus Benefits'). He introduced a report, called 'Small World', which is due to be published by the EA, and went on to describe a proposed procedure for 'Co-Operation on Risk Assessment Approaches' (*i.e.* the proposal was presented to the OECD WPMN Steering Group 6, which focuses on Risk Assessment, under DEFRA's leadership). The process encompasses (a) a control banding exercise, (b) the development of an emission scenario document for nanomaterials, and (c) a protocol for the qualitative risk assessment of nanomaterials: guidance for problem formulation and prioritisation.

Dr Owen concluded by saying that risk assessment should be an interactive process of shared responsibility.

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References

[1] *ON SCIENCE AND PRECAUTION IN THE MANAGEMENT OF TECHNOLOGICAL RISK, Volume I: A Synthesis Report of case studies.*

[2] Oberdoerster *et al., Environ. Health Perspect.* **113** (2005) 823-839.