The Responsible NanoCode

The market for nanotechnology is rapidly expanding and has been predicted to be associated with 15% of all manufactured goods by 2014, worth roughly $2.6 trillion and equating to 10 million jobs worldwide [1].
This growth is occurring against a relatively slower pace of research into the risk [2], toxicology [3], fate and ecotoxicology of manufactured nanomaterials [4]. The risk governance of nanotechnology applications in food and cosmetics has recently been detailed and the need for a voluntary code was highlighted in order to earn a 'licence to operate' in an attempt to avoid a restrictive cycle developing in the nanotechnology debate [5].

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A nanoscale particle *(for example see Figure 1)* has at least one dimension in the range of 1nm to 100nm (note 1nm =10^{-9}m). In this range, materials can have substantially different properties compared to the same substances at larger sizes, due to the significantly increased ratio of surface area to mass as well as the role of quantum effects which become significant towards the lower end of this range, leading to significant changes in several types of physical properties [6].

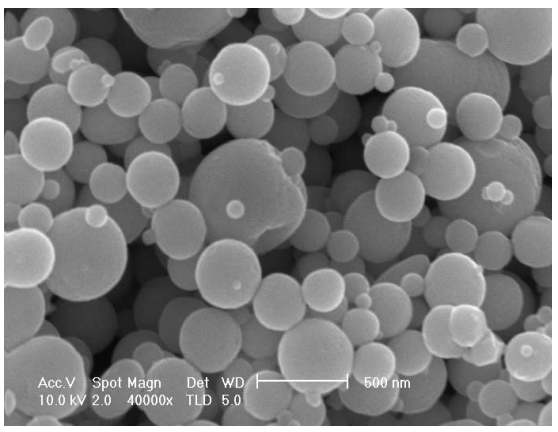


Figure 1. Scanning Electron Micrograph of PZT (lead zirconate titanate)

DEVELOPMENT OF THE RESPONSIBLE NANOCODE

In 2006, the Royal Society, Insight Investment and the Nanotechnology Industries Association began a partnership to develop a voluntary code of conduct for businesses involved in nanotechnologies as a result of concerns raised by the Royal Society. Alongside this, the investment community, notably Insight Investments, had also identified potential investment issues. It was believed that it was important that the business community participated in the development of a Code of Conduct related to the safe use of nanotechnology and nanomaterials based products. Later on the Nanotechnology Knowledge Transfer Network also joined the partnership.

The code was developed by an independent working group comprising experts from business, non-governmental organisations and academics:-

Companies:- BASF, Johnson & Johnson, Johnson Matthey, Oxonica, Smith & Nephew, Tesco, Thomas Swan and Unilever.

Academics/Scientists: Institute of Occupational Medicine, Edinburgh Napier University, University of Sheffield and University of Cardiff.

Unions/NGOs:- Amicus, Which? and Practical Action.

It was not intended that this Responsible NanoCode should replace or prevent the development of future regulation for nanotechnologies; however, given the absence of comprehensive appropriate legislation, it aimed to provide clear guidance about the expected behaviour of companies in relation to their nanotechnology activities. It was believed that the Code and the process of its development might assist with the evolution of such legislation by clarifying the principles that could underpin more detailed, verifiable, regulations.

The Responsible NanoCode, like other principles-based codes, illustrates expected behaviours and processes rather than the standards of performance. The Responsible NanoCode was not intended, however, to be an auditable standard; it does not detail levels of performance expected of companies, nor does it give guidance on definitions, characterisation and measurement. The voluntary code was aimed at promoting best practice within this emerging industry (i.e. from research and development to manufacturing, distribution and retailing) with the overall aim that compliance with the Responsible NanoCode would be seen as a beneficial exercise for a company enabling them to demonstrate responsible use and growth.

Seven Principles were defined to reflect all aspects of business, as below:-

Principle One - Board Accountability

Each Organisation should ensure that accountability for guiding and managing its involvement with nanotechnologies resides with the Board or with an appropriate senior executive or committee

Principle Two - Stakeholder Involvement

Each Organisation should identify its nanotechnology stakeholders, proactively engage with them and be responsive to their views

Principle Three - Worker Health and Safety

Each Organisation should ensure high standards of occupational health and safety for its workers handling nano-materials and nano-enabled products. It should also consider occupational health and safety issues for workers at other stages of the product lifecycle

Principle Four - Public Health, Safety & Environmental Risks

Each Organisation should carry out thorough risk assessments and minimise any potential public health, safety or environmental risks relating to its products using nanotechnologies. It should also consider the public health, safety and environmental risks throughout the product lifecycle

Principle Five - Wider Social, Ethical Environmental & Health Impacts

Each Organisation should consider and contribute to addressing the wider social, environmental, health and ethical implications and impacts of their involvement with nanotechnologies.

Principle Six - Engaging with Business Partners

Each Organisation should engage proactively, openly and co-operatively with business partners to encourage and stimulate their adoption of the Code

Principle Seven - Transparency and Disclosure

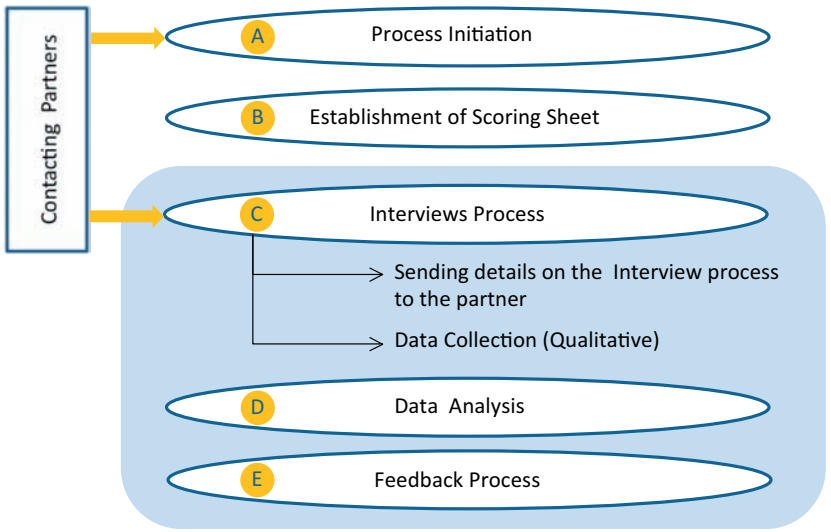
Each Organisation should be open and transparent about its involvement with and management of nanotechnologies and report regularly and clearly on how it implements the Responsible Nano Code

Companies that use the Code are encouraged to demonstrate their adherence to the principles of the Responsible NanoCode on a 'comply or explain' basis.

Previous codes adopting this approach lay down rules or guidance and companies are encouraged to publicly explain how they either comply with them or why they do not, usually through statements in their annual or social reports. It was also the intention of the working group to develop a code that has international relevance, reflecting the increasingly trans-boundary nature of manufacture and use of such technologies.

As part of the international launch of the Code, a consultation process was conducted in Europe, USA and Australia. As an example, an interactive session was held in Washington DC to launch the Code at an event organised by the Project for Emerging Nanotechnologies of the Woodrow Wilson Center for Scholars.

These consultations provided opportunities for experts to offer their initial views and to comment on the Code. In addition, it was possible for interested parties to submit comments directly via the Code's website.



Scheme 1. Methodology of the pilot study for the benchmarking process of the responsible NanoCode

Principle 1: Accountability
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1.1 Please discuss your level of accountability
Examples, Evidence
Tick the statement corresponding to your activities
Organisation has **published an account** of how it assigns responsibilty for environmental, social issues.
Organisation has **assigned explicit responsibility** for addressing environmental, social, etc. issues related to nanotechnology development to a Board Director or executive
Organisation has **not assigned responsibility** for environmental, social, etc. issues to a named body or individual.

Figure 2. A section of the interviewee version of the Evaluation Framework Questionnaire

A useful mnemonic to reflect the Code's key factors is noted below:-

NanoCode promotes best practise by the following 7 guiding principles;

Accountability of the Board for managing their nanotechnology.

Nanotechnology stakeholders are to be identified & their concerns met.

Occupational health & safety of all workers to be of a high standard throughout the lifecycle of the product(s).

Carry out thorough risk assessments & minimise any potential public health, safety and environmental risks.

Organisation to consider & address the wider social, environmental, health & ethical issues of their nanotechnology.

Develop the open engagement of business partners with the NanoCode.

Ensure an organisation is transparent about its nanotechnologies and how it adopts the Responsible NanoCode.

EXAMPLES OF GOVERNMENTAL RESPONSES TO NANOTECHNOLOGY

The responses of governments to nanomaterials varies [7], for example, Canada has announced a mandatory safety reporting scheme for companies producing nanomaterials, becoming the first country in the world to do so. Companies and institutions that manufactured or imported more than 1kg of a nanomaterial in 2008 will be required to submit all of the information they have - physical and chemical properties, toxicological data, and methods of manufacture and use. In the USA, the Environmental Protection Agency (EPA) considers many nanomaterials as chemical substances and, as such, they are subject to the standard regulatory practices under environmental law. Two notable exceptions are fullerenes and carbon nanotubes.

In the UK, a Mini Innovation and Growth Team comprising representatives from several Knowledge Transfer Networks prepared a report called "Nanotechnology: a UK Industry View" [8], which collected issues and concerns from the UK nanotechnology industry and academia and produced a series of recommendations for the UK Government, focussing on where it was believed that Government could make a significant difference. The Responsible NanoCode was referenced in this report which was presented to the UK Government in January 2010.

The report has formed part of an evidence collecting process prior to the Government launching its UK Nanotechnologies Strategy: Small Technologies, Great Opportunities which was launched on 18th March 2010 [9]. This Strategy sets out how Government will take action to ensure that UK residents can safely benefit from the societal and economic opportunities that nanotechnologies offer, whilst addressing the challenges that they might present.

In a recent report on Nanotechnologies and Food [10], the House of Lords Science and Technology Committee recommended 'that the Government, in collaboration with relevant stakeholders, support the development of voluntary codes of conduct for nanotechnologies in order to assist the continuing development of effective legislation for this rapidly emerging technology. The Government should work to ensure that voluntary codes are of a high standard, are subject to effective monitoring processes and are transparent.' This comment from the House of Lords Committee has therefore endorsed the value of a voluntary code such as the Responsible NanoCode.

BENCHMARKING THE RESPONSIBLE NANOCODE

Cranfield University were appointed to progress this initiative by benchmarking the Responsible Nanocode *(Scheme 1)*. This has involved interviewing companies and academics to gather information and to find demonstrable evidence of compliance covering their accountability, stakeholder relationship, worker health and safety, health, safety and environmental risks (non-worker), wider social, environmental, health and ethical issues, engaging with business partners, transparency and disclosure.

This benchmarking project has illuminated any knowledge gaps concerning for example health and safety, human or environmental exposure and ethical issues. Identifying such knowledge gaps greatly assists the development of robust methods for the ecotoxicity and environmental hazard assessment of manufactured nanoparticles under realistic scenarios.

The aim of this benchmarking project has been to interact closely with the developing nanotechnology industry to try and proactively address concerns and reinforce good practices and thereby help evolve the voluntary, principles-based Code of Conduct to a point where it will be adopted by businesses across the supply chain.

BENCHMARKING STUDIES

Benchmarking the Responsible NanoCode sought to ensure that the research and development as well as industrial application of nanotechnologies are performed in a transparent and responsible manner throughout organisations. These include:

- Research laboratories (including universities)
- Small and medium enterprises
- Large manufacturers
- Retailers and branded goods companies

The benchmarking activity provided an awareness of the risk maturity issues surrounding nanotechnology and provides an example of good practice for industry and research within the UK and EU.

The pilot study focused on both the testing and refining of the evaluation frameworks developed by the working group, to ensure the code is appropriate for a range of organisations. This pilot study involved a series of face to face interviews with a range of organisations and this process naturally helped to improve the evaluation frameworks *(Figure 2)*. In parallel, the collection and analysis of data gathered in the benchmarking interviews provides a picture of the practices among nanotechnology organisations in the UK.

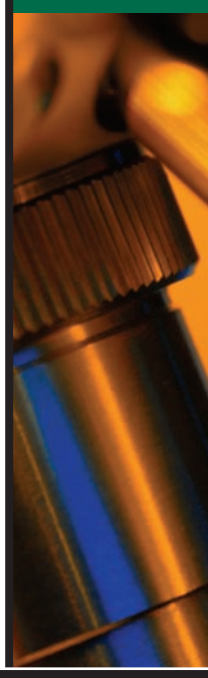
A copy of a typical evaluation questionnaire is available at http://www.cranfield.ac.uk/sas/risk/nanocode/

Although this pilot study was limited in scope, it was interesting to note that senior executives from the companies benchmarked valued participating in the process and one was quoted as saying 'this has reinforced our efforts on addressing the key issues related to safe manufacture and use of nanomaterials and helped us focus on best practices.'

CONCLUSIONS

The Responsible NanoCode was developed by a working party comprising large and small companies, academics, NGOs and unions and provides a very simple model for the responsible management of a nanotechnology-based business. Its acceptance by the nanotechnology industry is both encouraging and demonstrative of its potential for large and small companies alike.

The benchmarking process at Cranfield (www.cranfield.ac.uk/sas/risk/nanocode) provides endorsement for companies and aids the continuous improvement within these companies.



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