The Responsible Nano Code

Responsible Futures

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The following response has been prepared on the basis of comments made by Fellows of The Royal Academy of Engineering with experience in the area of risk assessment and management, and members of the Academy's Teaching Engineering Ethics working group.

1. The idea of a voluntary, aspirational code for companies working with nanotechnologies is a laudable one. It is important and valuable to have a code reflecting the commitment of a company to responsible practice and not just a legalistic code that sets out penalties for bad practice. It is also encouraging to see the promotion of what is essentially a code of ethics for a particular sector of industry. The appreciation of the need for aspirational statements of good practice in addition to legal codes is a welcome one. Nevertheless, there will still be need for legislation, as there will no doubt always be organisations who fail to act responsibly and there should be penalties for so doing. It is hoped that the release of this code will not negatively affect the development of legislation.

2. It is also welcome that the code will be a living document that can be updated and adapted as circumstances change. A code of responsible practice can only be useful if it is sensitive to the best and most current understanding of what constitutes good practice. In an emerging area of technology knowledge of risks and how to deal with them will grow rapidly, allowing the code to be made more specific where necessary. Although the code has value in its current broad form, it should no doubt become more detailed as particular lessons are learned.

3. There are some weaknesses in the code as it is presented. One Academy Fellow's reaction to the principles was 'Motherhood and apple pie': few people would object to them. As a result the code may be seen as lacking substance and organisations may not take sufficient notice of it, feeling that it makes no demands that they would not already perceive themselves as meeting. It might also strike stakeholders as simply a PR exercise, given that it is so agreeable and wide-ranging.

4. Given that the code is voluntary, there must be some motivation for organisations to adhere to it. This is especially the case when properly adhering to the code could have an impact on the organisation – for example, following principle two ("each organisation should proactively engage with its stakeholders and be responsive to their views in its development or use of products using nanotechnologies") could have a significant impact on a company's research and development work.   There must be a way of judging whether a company adheres to the code or fails to, and a way to recognise a company's successful adherence to the code, or lack of it. This is essential since the power of the code, being voluntary and not having any penalties for transgression, will depend on there being a disadvantage in failure to comply.

5. Similar work has been done elsewhere, for example the US FDA's report on Nanotechnology of July 2007 and DuPont and Environmental Defense's Nano Risk Framework. It is assumed that such work has been taken to account in drafting the responsible nanocode to share thinking and to establish accord where appropriate.

6. It is of paramount importance that lessons are learnt from risk management practices elsewhere. Nanotechnology is not fundamentally different from other emerging technologies with respect to the uncertainties it presents and tried and tested risk management processes should always be employed. Good risk assessment and management methodologies are quite general and differ only in the data fed into them concerning the specific materials being handled. There will be

uncertainty about the data concerning the materials, but experts in risk assessment are well-versed in assessing the impact of this uncertainty and the tolerability of these impacts. Similarly, the Health and Safety Executive and the Environmental Protection Agency have the ability to enforce and appraise risk assessments and they should be able to do this for nanotechnologies as they do for other areas. In many ways this code does not contain anything that a general code for chemical processing would not cover, but that is appropriate given that it is really a matter of fulfilling established risk management procedures that are generic to any areas of engineering and technology involving risk. Claiming that special processes are needed for nanotechnology conveys the message that there is something particular to fear here. This is likely to be counterproductive to the motivations behind the code – maintaining a rational dialogue with stakeholders on controlling risks.

7. It is also the case that stakeholder engagement is important not only to nanotechnology, but to all of an enterprise's activities. Any engagement should be part of a wide stakeholder-consultation process that includes consulting with the general public. In this particular code, the public should be explicitly included amongst stakeholders in the principles as well as in the indicators. There is some vagueness in the code as to who counts as a stakeholder. Since the code requires that all stakeholders be consulted, it is important that organisations can identify who constitutes a stakeholder for this purpose. Furthermore, firms will need guidance on what to do if they are unable to involve all stakeholders in discussions, or fail to do so. Will they be judged to have failed to adhere with the code?

8. It is agreed that a member of the board or governing body of a company should have responsibility for setting overall strategies with regard to its use of nanotechnologies. Board members should be trained in the relevant technologies and their safe use and the board should ensure that the employees responsible for preparing and approving risk assessments are competent and independent of commercial pressures (ie, the organisation should have an internal regulator). However, risk management should remain at managerial level. Any risk management strategies should permeate all levels of an organisation, so while risk management strategies or policies are set at board level, these strategies should be translated into procedures that are meaningful for all management and operational levels. The overseeing of such procedures should be the remit of managers.

9. The code makes no mention of balancing risks and benefits. In an area such as nanotechnology where the risks are largely unknown, there must be confidence that there are significant benefits in using nanotechnologies to justify those risks. Boards of companies should carry out risk-benefit analyses before undertaking to use nanotechnologies. Once it is confirmed that there are clear benefits, then risk management policies should be developed.

10. In general, the principles seem to focus on production and not at all on distribution and disposal. There is also no mention of responsibility for auditing to ensure that the appropriate procedures have been followed. Suggestions are given in the annex below for incorporating these considerations into the principles.

11. Finally, should the code list *indicators* of good practice, or are the listed 'indicators' instead *criteria* of good practice? This depends of course on how prescriptive the code is intended to be. Whilst, as stated above, there is value in an aspirational code, if there are no clear demands on organisations committed to the code it is difficult to judge when it is being followed; and without the possibility of making such a judgement it will be difficult to motivate organisations to commit seriously to acting in accord with the code.

<u>Notes on the principles and indicators</u>

Some suggested amendments to the code are indicated below.   Undoubtedly the code will go through various stages of drafting and these are offered as some suggestions for possible additions or refinements. Some suggestions for additional indicators are also offered. The changes and additions are highlighted in yellow.

Principle One:

Each Organisation should ensure that responsibility for guiding, managing ==and auditing== its involvement with nanotechnologies resides with the Board or governing body

Comment: is it appropriate to mention 'managing' here? The role of the board is to set strategies and develop policies rather than management. The board should have ultimate responsibility for auditing the processes involved in the development, distribution and disposal of products using nanotechnologies.

Principle Two:

Each Organisation should proactively engage with its stakeholders==, including the public,== and be responsive to their views in its ==development, distribution or use== of products using nanotechnologies

Comment: the public should be explicitly included amongst stakeholders. The distribution, and indeed sale, of nanotechnologies are also important subjects for public engagement.

Principle Three:

Each Organisation should identify and minimise sources of risk for workers handling products using nanotechnologies, at all stages in the production, ==distribution and disposal processes== or in industrial use, to ensure high standards of occupational health and safety

Comment: Distribution and disposal processes will also involve risk and should be explicitly included.

Principle Four:

Each Organisation should carry out thorough ==and demonstrable== risk assessments and minimise any potential public health, safety and environmental risks relating to its products using nanotechnologies

Comment: it was thought worthwhile to add this clause which was implied, but better explicitly stated.

Principle Five:

Each Organisation should consider and respond to any social and ethical implications and impacts in the development or sale of products using nanotechnologies

No comments

Principle Six:

Each Organisation should adopt ==publicly acceptable and understood== responsible practice in the sales and marketing of products using nanotechnologies

Comment: it was thought worthwhile to add this clause which was implied, but better explicitly stated.

Principle Seven:

Each Organisation should ==openly and cooperatively== engage with suppliers and/or business partners to encourage and stimulate their adoption of the Code and so assure its own ability to fulfil its Code commitments

Comment: it was thought worthwhile to add this clause which was implied, but better explicitly stated.

Potential Indicators of Good Practice

Principle One:

Each Organisation should ensure that responsibility for guiding and managing its involvement with nanotechnologies resides with the Board or governing body

Some indicators of good practice:

1. Responsibility for nanotechnology and accountability for implementation of the Code resides with the Board or governing body ==with a named board member taking the lead on behalf of the corporate body for implementation of the code.==

2. A published policy, approved at the highest level, for the responsible management of nanotechnology. This is likely to demonstrate, among other things:

    - A commitment to understanding, assessing and mitigating any health, safety, environmental, social and ethical issues associated with the company's involvement
    - A commitment to transparency in its involvement with nanotechnologies,
    - A commitment to listen and take account of stakeholders' concerns, ==including those of the general public==
    - A commitment to supporting the development of ==and adherence to== effective regulatory frameworks should that be deemed necessary by the appropriate bodies

3. Explicit incorporation of nanotechnology-specific risks into standard risk management processes and continuous assessment of nano risk as part of mainstream risk management strategy.

4. Disclosure that explains clearly how the organisation evaluates opportunities and risks when deciding which nanotechnology-enabled products are

appropriate to bring to market.

Principle Three:

Each Organisation should identify and minimise sources of risk for workers handling products using nanotechnologies, at all stages in the production process or in industrial use, to ensure high standards of occupational health and safety

Some indicators of good practice

1. No default assumption that the risks associated with nanotechnologies are the same as those involved with existing materials.

2. Given current uncertainties about the behaviour and predictability of some nanomaterials, organisations should demonstrate the development and adoption of procedures and tests that provide high standards of protection for staff.

3. Specific consideration of working with nanotechnologies within occupational health and safety policies and programmes.

4. References to the relevant standards and protocols used (it is likely, given current uncertainties, that organisations will need to apply measures in excess of historically accepted practice. This is also required by law).

5. Disclosure of policy, indicators and actions with declared milestones in the event of breaches of safety guidelines, including whistleblowing procedures.

Principle Four:

Each Organisation should carry out thorough risk assessments and minimise any potential public health, safety and environmental risks relating to its products using nanotechnologies

Some indicators of good practice:

1. No default assumption that the risks associated with nanotechnologies are the same as those involved with existing materials and that risk assessment methodologies used on similar materials at a larger scale are therefore also adequate.

2. Processes to identify and evaluate and minimise any risks to the general public, users or the environment from the development, use or disposal of products incorporating nanotechnologies.

3. Demonstration that the organisation has taken steps to identify knowledge gaps in this area and taken action to address them.

4. References to other standards/protocols the company has used in assessing product safety and actions taken in the absence of appropriate legislation.

5. Sharing information on risk mitigation methodologies and disclosure of results to government agencies, regulators, even competitors etc, to enhance the global understanding and development of appropriate risk assessment methodologies. Where issues of commercial sensitivity arise, organisations should work to find appropriate ways to communicate in this area.

6. Where existing regulation, standards and guidelines have not yet taken developments in nanotechnology into account, demonstration of how the company contributes constructively to the development of appropriate regulation and standards.

7. Where information or research is lacking, which would be a barrier to the responsible development of the technology, companies may, for example, proactively support government research initiatives or initiate/partner independent research to bridge these gaps.

8. Disclosure of policy and actions that would be taken in the event of negative product impact, including whistleblower procedures and protections.

9. Disclosure of such an event occurring, of its impact and of actions taken.

Suggested additional Indicator:

10. Clear risk management plans in which responsibilities are owned by the relevant responsible manager (i.e. not a centralised Risk Manager, whose role should be an audit and procedural one). Each manager being responsible for a particular aspect in the process and thus owns the risks in his/her area (be it a design aspect, manufacturing, in-service support etc.) Also have independent Safety Assessors, whose regular reports are seen by the Project Director and the Lead Safety Board member).

NB: Organisations likely to adopt this Code will be working at various stages in the product lifecycle. However, even if an organisation is not supplying the end consumer, it should demonstrate consideration of the issues which may arise for all stakeholders as it may be in the strongest position to address them. A process of 'one up and one down' is often used in circumstances such as this, where businesses share knowledge one level down the chain and one level up.

Principle Six:

Each Organisation should adopt responsible practice in the sales and marketing of products using nanotechnologies

Some indicators of good practice:

1. The organisation adopts and publishes a specific policy outlining its approach to sales, advertising, public relations and promotion of products containing nanotechnologies.

2. The 'nano' term is used appropriately when promoting products – *e.g.* the nano-prefix should only be used in products which are enhanced through the use of nanotechnologies.

3. Product effectiveness claims are substantiated by sound specific scientific research which is accessible to all stakeholders (though the importance of and the difficulties posed by company confidentiality issues are acknowledged)

4. The organisation provides easily accessible information to its customers and other stakeholders about its products that contain nanotechnologies. This may take the form of information on websites or product leaflets, labelling or public disclosure initiatives and mechanisms to assess and respond to such comments from the public.

5. The organisation has mechanisms to ensure that it can identify and trace products using nanotechnologies in its supply chain

Submitted by: **Prepared by**:

Mr Philip Greenish CBE   Dr Natasha McCarthy
Chief Executive   Policy Advisor
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