

**Response from the Nanotechnology Industry Association to the call for evidence on
'Nanoscience and nanotechnologies: opportunities and uncertainties' Two-year review of progress on
Government actions**

The Nanotechnology Industries Association, the NIA, was formed in late 2005 by a group of companies from a variety of industry sectors including healthcare, chemicals, automotive and consumer products. Nanotechnology is a rapidly growing area of commercial activity, it is highly multi-disciplinary and cuts across a wide range of markets and industrial sectors.

The purpose of the NIA is to promote the responsible use of nanotechnology and raise awareness of its many applications among key audiences including the media, government, NGOs and other stakeholders. Initial aims of the association are:-

1. To bring together a representative network of UK companies to provide a focal point for the media, government and other stakeholders to hear an industry view on critical issues related to nanotechnology
2. To produce timely industry perspectives for Government and to provide input to assist government in policy development on nanotechnology

The unique feature of the NIA is that it provides a purely industry-led perspective derived from the views of the collective membership. This enables those seeking comment from industry to have one port of call and avoids the need to approach individual companies for statements on specific issues.

This response addresses the three aspects requested by the CST, namely

- The extent to which the Government has taken forward the commitments described in its Response.
- The timeliness and effectiveness of the actions taken by Government.
- Whether there have been significant developments in nanoscience/nanotechnology since February 2005 which raise new issues the Government did not address in its Response, and should now.

The industrial application of nanotechnologies

- R1 We recommend that a series of life cycle assessments be undertaken for the applications and product groups arising from existing and expected developments in nanotechnologies, to ensure that savings in resource consumption during the use of the product are not offset by increased consumption during manufacture and disposal. To have public credibility these studies need to be carried out or reviewed by an independent body. (Section 4.5: paragraph 32)**

It is accepted that the development of life cycle methodologies is still at an early stage for many products due to the inherent difficulties of such assessments, but great strides have been made in areas such as the automotive industry and following the WEEE directive. However, for applications and products that are not part of larger activities there is a lack of life cycle models and those that are being developed are a long way from being accepted as standard practice. It is therefore too soon to establish an independent body but the indications that further work is required was welcomed. However, there has been little evidence that further work has been commissioned in this area to generate the appropriate methodologies. The recent DEFRA calls for review projects including that of lifecycles is a start but this is very recent. The NIA considers this an important area and is considering this as part of the hazard assessment methodology that it is developing.

- R2 Where there is a requirement for research to establish methodologies for life cycle assessments in this area, we recommend that this should be funded by the Research Councils through the normal responsive mode. (Section 4.5: paragraph 33)**

It is felt that the Government response to this recommendation did not involve committing to any identifiable actions. It would have been useful to examine collating the current state of the art in this area from work done by the Research Councils, under EU programmes and internationally. From this a better appreciation of the gaps our understanding that could have enabled more targeted research to be undertaken would have been beneficial. There is little evidence that new projects have been initiated looking at life cycle assessment of nanotechnology based products.

Possible adverse health, safety and environmental impacts

- R3 We recommend that Research Councils UK establish an interdisciplinary centre (probably comprising several existing research institutions) to research the toxicity, epidemiology, persistence and bioaccumulation of manufactured nanoparticles and nanotubes as well as their exposure pathways, and to develop methodologies and instrumentation for monitoring them in the built and natural environment. A key role would be to liaise with regulators. We recommend that the research centre maintain a database of its results and that it interact with those collecting similar information in Europe and internationally. Because it will not be possible for the research centre to encompass all aspects of research relevant to nanoparticles and nanotubes, we recommend that a proportion of its funding be allocated to research groups outside the centre to address areas identified by the advisory board as of importance and not covered within the centre. (Section 5.6: paragraphs 55 & 56)**

The formation of the Nanotechnologies Research Coordination Group was welcomed as a mechanism to provide more coordinated targeting of Government resources. This was accomplished quickly and the NRCG set of working groups to make recommendations on research priorities in the key areas, which was also welcomed. However, progress by these working groups has been very slow with little input from outside Government on the industrial needs and no sign of the publication of any recommendations. The review being undertaken by EPSRC of their nanotechnology portfolio was also welcomed and the intent to establish a focused programme will provide a better means to coordinate research within the EPSRC remit. A similar exercise by the other Research Councils would be welcomed. The lack of any additional funding for this area is disappointing.

The 1st Report from the NIDG, “Characterizing the potential risks posed by engineered nanoparticles”, was a welcome overview of current Government funding in 2005. The two priority areas identified by the Government were welcomed, but it is not clear that further funds have been targeted at these areas. The two reports commissioned by DEFRA to identify exposure and hazard data needs respectively for addressing the risks presented by nanoparticles and nanotubes are a welcome first step. The environmental release of nanoparticles for research purposes has been discouraged by the Government and the industry welcomes this. The proposal by SNIRC was a welcome initiative but it is noted that the only aspect to be funded by DTI has been the information service and not for further research.

- R4 Until more is known about environmental impacts of nanoparticles and nanotubes, we recommend that the release of manufactured nanoparticles and nanotubes into the environment be avoided as far as possible. (Section 5.7: paragraph 63)**

The NIA supports a precautionary, factual and risk based assessment of the environmental impacts of nanoparticles and nanotubes prior to the release of manufactured nanoparticles and nanotubes into the environment. There needs to be a distinction made between free

nanoparticles and nanotubes and those that are incorporated into another media. The comments regarding research funding above also apply.

- R5 Specifically, in relation to two main sources of current and potential releases of free nanoparticles and nanotubes to the environment, we recommend:**
- (i) that factories and research laboratories treat manufactured nanoparticles and nanotubes as if they were hazardous, and seek to reduce or remove them from waste streams. (Section 5.4: paragraph 41)**
 - (ii) that the use of free (that is, not fixed in a matrix) manufactured nanoparticles in environmental applications such as remediation be prohibited until appropriate research has been undertaken and it can be demonstrated that the potential benefits outweigh the potential risks. (Section 5.4: paragraph 44)**

The NIA welcomed the Government stance and supports a responsible approach to the release of nanoparticles into the environment in that it should be avoided as far as possible. This a position that the Government has continued to advocate, however, the comments on the research programme above also apply to this recommendation. The review of regulation mechanisms concluded that existing regulation was sufficient to cover existing manufacture and this is welcomed by the NIA. It was important that this activity was undertaken rapidly and this has been done.

On the area of environmental remediation there is little evidence of the substantial progress expected in this area.

- R6 We recommend that, as an integral part of the innovation and design process of products and materials containing nanoparticles or nanotubes, industry should assess the risk of release of these components throughout the lifecycle of the product and make the relevant regulatory authorities. (Section 5.4: paragraph 42)**

The NIA agrees that hazard and risk assessments need to be undertaken early and it is good practice to do this. In many fields this information is made available as part of the regulatory approval process. The comments about research above also apply here.

- R7 We recommend that the terms of reference of scientific advisory committees (including the European Commission's Scientific Committee on Cosmetic and Non-food Products or its replacement) that consider the safety of ingredients that exploit new and emerging technologies like nanotechnologies, for which there is incomplete toxicological information in the peer reviewed literature, should include the requirement for all relevant data related to safety assessments, and the methodologies used to obtain them, to be placed in the public domain. (Section 5.3.2b: paragraph 30)**

The intent to introduce a Voluntary Reporting Scheme will contribute to the recommendation that such information is made available to the regulatory authorities. Industry has reservations about this scheme that have been communicated to DEFRA, particularly in regard to the confidentiality and subsequent use of the information provided by industry, but progress on this recommendation has been made.

Regulatory issues

- R8 We recommend that all relevant regulatory bodies consider whether existing regulations are appropriate to protect humans and the environment from the hazards outlined in this Report and publish their review and details of how they will address any regulatory gaps. (Section 8.5: paragraph 48)**

The publication of the DEFRA commissioned scoping study report on environmental regulations identifies potential gaps in regulation, however, a detailed assessment of these gaps is required before any firm conclusions can be drawn as to whether any new regulation is required. The finding by the HSE that current HSE legislation is adequate is also welcomed, this prompt assessment was very timely. Recent ITTs from DEFRA on this topic is a start but it is slow considering the time since the publication of the report.

- R9 We recommend that regulatory bodies and their respective advisory committees include future applications of nanotechnologies in their horizon scanning programmes to ensure any regulatory gaps are identified at an appropriate stage. (Section 8.5: paragraph 50)**

Many Government departments have included nanotechnologies as part of their horizon scanning activities and some have even established specific groups to monitor developments. A concern is that these activities will be reduced as budgets come under pressure as the CSR gets underway.

- R10 We recommend that chemicals in the form of nanoparticles or nanotubes be treated as new substances under the existing Notification of New Substances (NONS) regulations and in the Registration, Evaluation, Authorisation and Restriction of Chemicals (REACH) (which is currently under negotiation at EU level and will eventually supersede NONS). As more information regarding the toxicity of nanoparticles and nanotubes becomes available, we recommend that the relevant regulatory bodies consider whether the annual production thresholds that trigger testing and the testing methodologies relating to substances in these forms should be revised under NONS and REACH. (Section 8.3.2: paragraphs 18 & 19)**

The progress on this item is recognised as being intimately linked to pan European activities. The NIA considers that the current framework for REACH is sufficient to cover nanomaterials and it is unlikely that any new regulation will be required.

R11 Workplace:

- (i) **We recommend that the Health & Safety Executive (HSE) review the adequacy of its regulation of exposure to nanoparticles, and in particular considers the relative advantages of measurement on the basis of mass and number. In the meantime, we recommend that it considers setting lower occupational exposure levels for manufactured nanoparticles. (Section 8.3.1: paragraph 11)**

The promptness of the HSE in undertaking an initial review of its regulatory coverage was welcomed. Subsequent projects on Assessment of Exposure and Control Measures to Airborne Nanoparticles for Workers and Researchers in Laboratories in Universities and The Manufacture and use of Nanoparticles and Nanotubes: A Landscaping Study are a step in the right direction. The comments about research above also apply here.

- (ii) **We recommend that the HSE, Department for Environment Food and Rural Affairs and the Environment Agency review their current procedures relating to the management of accidental releases both within and outside the workplace. (Section 8.3.1: paragraph 12)**

The HSE has issued guidance notes in this area which is welcomed. The EA has not provided readily obtainable advice on specifics of nanotechnology incidents. The recent launch of an advice service funded by the DTI and delivered by the IOM is very welcome, but it has taken until now to instigate this activity. Also the help desk service that will provide information bulletin service to HSE is a positive step but it is unclear if this service is available outside the HSE – wider dissemination would be useful.

- (iii) **We recommend that the HSE consider whether current methods are adequate to assess and control the exposures of individuals in laboratories and workplaces where nanotubes and other nanofibres may become airborne and whether regulation based on electron microscopy rather than phase-contrast optical microscopy is necessary. (Section 8.3.1: paragraph 13)**

The HSE has continued to take a positive approach to review and consult on assessing current methods. However, the research programme to address the gaps has not materialized.

R12 Consumer products:

- (i) **We recommend that ingredients in the form of nanoparticles undergo a full safety assessment by the relevant scientific advisory body before they are permitted for use in products. Specifically: we recommend that industry submit the additional information on microfine zinc oxide that is required by the SCCNFP as soon as reasonably practicable so that it can deliver an opinion on its safety. (Section 8.3.3: paragraph 24 & 23)**

Information has been submitted to SCCNFP by industry but there has been no opinion has been delivered to date.

- (ii) **We recommend that manufacturers publish details of the methodologies they have used in assessing the safety of their products containing nanoparticles that demonstrate how they have taken account that properties of nanoparticles may be different from larger forms. (Section 8.3.3: paragraph 25)**

The intent to introduce a Voluntary Reporting Scheme will contribute to the recommendation that such information is made available to the regulatory authorities. Industry has reservations about this scheme that have been communicated to DEFRA, particularly in regard to the confidentiality and subsequent use of the information provided by industry, but progress in this recommendation has been made.

- (iii) **We recommend that the ingredients lists of consumer products should identify the fact that manufactured nanoparticulate material has been added. (Section 8.3.3: paragraph 26)**

The considered approach to labeling is welcomed and is being considered in the wider context of increased information on labeling. It is understood that the BSi NT1 committee is proposing a PAS on this topic, however, there needs to be a very good understanding of why and when a label needs to identify a product that contains nanoparticles. There are many manufactured nanoparticles generated through colloid chemistry that occur in existing products and have been approved for use, and it is not clear how these are to be considered/addressed.

- (iv) **We recommend that the EC's new Scientific Committee on Emerging and Newly Identified Health risks gives a high priority to the consideration of the safety of nanoparticles in consumer products. (Section 8.3.3: paragraph 27)**

A synthesis report from the Committee has been issued that deals with the results of assess potential risks of nanotechnology products. The next steps following on from this report are awaited with keen interest by the NIA.

- (v) **In the light of the regulatory gaps that we identify we recommend that the EC (supported by the UK) review the adequacy of the current regulatory regime with respect to the introduction of nanoparticles into consumer products. In undertaking this review they should be informed by the relevant scientific safety advisory committees. (Section 8.3.3: paragraph 28)**

The approach by the Government of integrating this activity with the activities at the European level is welcomed and progress in being made with the relevant EU DGs.

- R13 We recommend that the Department of Health review its regulations for new medical devices and medicines to ensure that particle size and chemistry are taken into account in investigating possible adverse side effects of medicines. (Section 8.3.4: paragraph 29)**

See comments above under R12 (v). The recent reduction in MRHA involvement in standards activity relating to nanotechnology is disappointing.

- R14 We recommend that manufacturers of products that incorporate nanoparticles and nanotubes and which fall under extended producer responsibility regimes such as end-of-life regulations be required to publish procedures outlining how these materials will be managed to minimise human and environmental exposure. (Section 8.3.5: paragraph 32)**

Visibility of activity in this area has not been sufficient to comment.

R15 Measurement:

- (i) **We recommend that researchers and regulators looking to develop methods to measure and monitor airborne manufactured nanoparticulates liaise with those who are working on the measurement of pollutant nanoparticles from sources such as vehicle emissions. (Section 8.4.2: paragraph 40)**

The HSE projects on Assessment of Exposure and Control Measures to Airborne Nanoparticles for Workers and Researchers in Laboratories in Universities and The Manufacture and use of Nanoparticles and Nanotubes: A Landscaping Study are a step in the right direction. The comments about research above also apply here.

- (ii) **We recommend that the Department of Trade and Industry supports the standardization of measurement at the nanometre scale required by regulators and for quality control in industry through the adequate funding of initiatives under its National Measurement System Programme and that it ensures that the UK is in the forefront of any international initiatives for the standardisation of measurement. (Section 3.3.5: paragraph 60)**

The development of the Measurement for Emerging Technologies Programme is a step forward. The positioning of the UK as Chair and Secretariat of the ISO TC/229 on Nanotechnologies is a significant step. Activity is progressing well at the pace that aligns with CEN and ISO protocols and will be supported by the NIA where appropriate.

- R16 We recommend that the research councils and the Arts and Humanities Research Board (AHRB) fund an interdisciplinary research programme to investigate the social and ethical issues expected to arise from the development of some nanotechnologies. (Section 6.8: paragraph 31)**

It is not apparent if any progress has been made on commissioning research into the social and ethical issues.

- R17 We recommend that the consideration of ethical and social implications of advanced technologies (such as nanotechnologies) should form part of the formal training of all research students and staff working in these areas and, specifically, that this type of formal training should be listed in the Joint Statement of the Research Councils'/AHRB's Skills Training Requirements for Research Students. (Section 6.8: paragraph 33)**

This does not appear to have been as a specific requirement included in the Joint Statement.

Stakeholder and public dialogue

- R18 We recommend that the research councils build on the research into public attitudes undertaken as part of our study by funding a more sustained and extensive programme of research into public attitudes to nanotechnologies. This should involve more comprehensive qualitative work involving members of the general public as well as members of interested sections of society, such as the disabled, and might repeat the awareness survey to track any changes as public knowledge about nanotechnologies develops. (Section 7.2.3: paragraph 19)**

The Government has made use of existing activities to undertake some activity in this area as mentioned in their response as well as the NEG, which is welcome, but these programmes are coming to a close soon and it is unclear what will happen then.

R19 We recommend that the Government initiates adequately funded public dialogue around the development of nanotechnologies. We recognise that a number of bodies could be appropriate in taking this dialogue forward. (Section 7.6: paragraph 49)

The establishment of The Nanotechnology Engagement Group project and Nanodialogues are a positive move to increase public dialogue. However, there needs to be improved dissemination of the outputs of these initiatives.

R21 We recommend that the Chief Scientific Advisor should establish a group that brings together representatives of a wide range of stakeholders to look at new and emerging technologies and identify at the earliest possible stage areas where potential health, safety, environmental, social, ethical and regulatory issues may arise and advise on how these might be addressed. (Section 9.7: paragraph 32)

The establishment of the S&T horizon scanning Centre within the OST has been accomplished however, looking at the impact of nanotechnologies is not apparent in the activities of the Centre. Information regarding specific projects is not easy to obtain.

General Comments

There is concern that there are a number of areas that impact on the Governments' ability to continue to take forward its commitments that were outlined in the Response, these include:

- Pressures on funding available to address the issues raised, particularly for research programmes, as the CSR gets underway.
- The impact that the amalgamation of Innovation Group with the OST will have on directing resources into nanotechnology.
- The end of the specific MNT funding within the technology programme on nanotechnology could have an impact on delivering outputs.
- Overall there needs to be improved dissemination of the launch and progress of the activities identified in the Government response.
- Some actions have been taken forward rapidly and proactively but this is not universal across the activities. The impression is that if activities were in place or at the advanced stage of planning then they have proceeded well, however, new initiatives or initiatives requiring new funding have been slower to materialize.
- Industry has recognised that it has responsibilities and has been proactive in addressing the issues. The establishment of the NIA is one action that has been initiated and the support of the DTI is appreciated.
- An overriding concern has been the low level of communication of Government activities and progress. It is often either restricted to a limited group close to the activity or promulgated in a passive way such as uploading a report to the internet that is difficult to find. There needs to be a more proactive communication strategy with interested parties and this is an area where the NIA may provide a channel to improve this.

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