

**MEMORANDUM OF ADDITIONAL EVIDENCE TO THE SCIENCE
AND TECHNOLOGY SELECT COMMITTEE**

1. This memorandum sets out Defra's additional written evidence to the inquiry being undertaken by the Committee into nanotechnologies and food, as requested in the letter from the Clerk to the Science and Technology Sub-Committee I of 15 April.
2. Defra officials have spoken with the Clerk of the Committee to clarify the information requested and understand the information below reflects those discussions.
3. The Communication from the European Commission to the European Parliament, the Council and the European Economic and Social Committee on the 'Regulatory Aspects of Nanomaterials' accompanies this Memorandum, but as a separate document.

D) DETAILS OF RECENT AND CURRENT EHS RESEARCH PROJECTS FUNDED BY DEFRA

PROJECT TITLE	DESCRIPTION
Environmental Nanoscience Initiative programme (Phase 2)	ENI-2 aims to develop an interdisciplinary research programme between the UK and USA to develop models that will support our understanding of environmental exposure, bioavailability, fate and risks of nanomaterials. It is intended that the research will cover a wide range of disciplines including detection and risk analysis. This second phase builds successfully on the first which concentrated on developing UK capacity in nanotechnology research. ENI-2 will utilise synergies and a wider skills base to enhance the value and impact of the programme outputs and ensure a truly multi-disciplinary approach to nanotechnology research. Work is ongoing to finalise the contract with a planned letting date later this year.
An outline scoping study by the Institute of Occupational Medicine to determine whether high aspect ratio nanoparticles (HARN) should raise the same concerns as do asbestos fibres	Concerns about the potential health effects of high aspect ratio nanoparticles (HARN) are based primarily on toxicology studies of industrial fibres including asbestos. The objectives of this study are: i) to undertake a scoping study to review the existing literature on industrial fibres and HARN to determine whether they should raise the same concerns as do asbestos fibres and ii) to set out a research strategy to determine whether health concerns about HARN are well-founded.
A study by the Institute of Occupational Medicine to identify physicochemical factors controlling the capacity of nanoparticles to penetrate cells of the respiratory epithelium, especially those of first contact on inhalation of the particles.	The Cell Pen project investigated the mechanisms of particle movement across the respiratory epithelium to try to establish the resulting possible toxic effects in and beyond the lung. The project advised on i) Identifying which features of nanoparticles/tubes/fibres are important in particle-cell interactions, considering the potential role of nanoparticle (NP) chemistry, structure, mass, numbers, shape, surface area, surface charge and surface functionalisation; ii) Suggested how they may be modified to enhance or reduce their capacity to enter cells; and iii) Suggested how interactions between NPs and cultured human cells might be studied.
EMERGNANO: a review by the Institute of Occupational Medicine of completed and near-completed environment, health & safety research on nanomaterials & nanotechnology	This report was commissioned by Defra as a way of taking stock of the research work on nanotechnologies since the 2004 Royal Society and Royal Academy of Engineering report ¹ . The EMERGNANO report has assessed global research undertaken since then and mapped the knowledge gained against the UK NRCG's 19 research objectives. The report identifies where research gaps remain.
Identification of physiochemical factors controlling the capacity of nano-particles to penetrate cells of the respiratory epithelium – A study by Imperial College Consultants Ltd	For some susceptible individuals inhaling high levels of air pollution containing nano-sized particles, may lead them to develop heart and lung problems. This suggests that breathing in very small, nanosized engineered particles might also cause heart and lung problems. This work aims to discover how inhaled engineered nanoparticles reach the delicate air sacs of the lung, and how they interact with the cell barriers that protect us. The research uses human epithelial cells to look at whether the nanoparticles interact with and/or are internalised by the cells, what properties of the particles might make them reactive and what cellular processes are involved.
Research into the likelihood and possible pathways of human exposure via inhalation arising throughout the lifecycle of a selection of commercially available articles containing carbon nanotubes – Central Science Laboratory	This study follows recent research findings from the University of Edinburgh which demonstrated that some types of carbon nanotubes (CNTs) may present health hazards similar to those of asbestos. This further study will collate all available information in regard to potential hazards of CNTs, possible route(s) of exposure, and will use the available data and modelling approaches to estimate the extent of human inhalation exposure to CNTs throughout the lifecycle of some selected CNT products. The information generated will help identify the critical stages within the lifecycle of selected CNT products that may pose risk to human health or the environment.

¹ 2004 Royal Society and Royal Academy of Engineering Report 'Nanoscience and nanotechnologies: opportunities and uncertainties'

An evaluation of the UK skills base for toxicologists and ecotoxicologists - Plymouth University	There are concerns about the capacity of the scientific community to respond to current and emerging demands for toxicological and ecotoxicological assessments and whether there are enough scientists working at the bench (toxicologists, chemists, biologists) and experts involved in regulation and policy to support this activity. The aim of this project is to identify the current status of the scientific community, areas of expertise, and identify the gaps in skills, knowledge or recruitment. The analysis will identify whether there are gaps in provision, and areas where investment may be needed in future training and/or recruitment.
Imperial College study to identify physiochemical factors controlling the capacity of nanoparticles to penetrate cells of the respiratory epithelium, especially those of first contact on inhalation of the particles	An important area of research is to evaluate the mechanisms of action of engineered nanomaterials and one key aspect of the reactivity of nanosubstances is their interaction with cells and membranes. This work aims to determine (a) which combination of factors influence nanoparticle uptake and/or translocation by human alveolar epithelium; (b) the fate/cellular location of internalized nanoparticles and whether particle uptake is active or passive; and (c) whether nanoparticles influence the functional integrity of the alveolar epithelial barrier.
PROSPEcT: UK contribution to the OECD Nanomaterials sponsorship programme	The <i>PROSPEcT</i> LINK project is the UK's contribution to the OECD sponsorship programme and aims to undertake a detailed characterisation of two nanomaterials of commercial relevance to the UK – cerium oxide and zinc oxide. The data generated, and test methodologies employed will go a long way towards the ecotoxicological hazard assessment for these nanomaterials. In addition the data generated will be used to help establish QSARs (Quantitative Structure Activity Relationships) for predictive safety evaluations of novel nanomaterials.
An examination of the nature and application among the nanotechnologies industries of corporate social responsibility in the context of safeguarding the environment and human health – Cardiff University (BRASS)	This research project will attempt to ascertain how much dependence is currently being placed on corporate social responsibility and how effective CSR, as currently employed by the UK nanotechnologies industries and researchers, is in limiting the exposure to public health and environmental risks. The project will also attempt to identify exemplar models of CSR and ascertain where failure by industry stakeholders to adopt a responsible approach is resulting in potential risks to public health and the environment.

II) COMPARISON FIGURES ON AMOUNTS SPENT BY THE UK, EUROPEAN UNION AND UNITED STATES OF AMERICA, ON NANOTECHNOLOGIES ENVIRONMENTAL HEALTH AND SAFETY RESEARCH

The recent Defra commissioned EMERGNANO project identified the following levels of expenditure by the UK, EU and USA over the period 2004-2008:

	Number of studies	Amount spent (2004-2008)
UK	44	£3.3m
EU*	114	£63.1m
USA	165	£37m

* includes the UK figure, plus work from Switzerland.

III) NOTE ON REGULATIONS AND AUTHORISATION PROCEDURES GOVERNING FERTILISERS

There are three tiers of regulatory controls which ensure that all fertilisers for sale in the UK are safe for use. These are set out in 2 areas of primary fertiliser legislation, namely fertilisers which may be freely sold anywhere in the European Union (EC Fertiliser Regulation 2003/2003), and other fertilisers (The Fertilisers Regulations 1991). The third tier covers Health & Safety regulations which apply to all products manufactured or used in the UK. All manufactured fertilisers (including those containing nanomaterials) are required to comply with all of these regulations and legislation. We are not aware of any current plans for manufactured nanomaterials to be included in fertilisers by manufacturers.

The EC Fertiliser Regulation 2003/2003 defines the composition and definition of all fertilisers, which have been approved as EC Designated fertilisers. All EC Designated fertilisers can be traded freely within the EU. Every [importer](#) and [manufacturer](#) must ensure any fertiliser intended for sale in the EU complies with this Regulation.

The Fertilisers Regulations 1991 (as amended) specify the labelling and packaging of the product and place a responsibility on the manufacturer to declare the nutrient content of the product. The Regulations include a series of Schedules listing type designations of fertilisers.

Additional controls exist for Ammonium Nitrate (AN) fertilisers and these are set out under the 'Ammonium Nitrate Materials (High Nitrogen Content) Safety Regulations 2003'. They require that all imports into Great Britain of relevant Ammonium Nitrate material from outside the EU are to be notified to Defra.

**DETAILS OF THE TASK FORCES AND RESEARCH OBJECTIVES UNDER THE
NANOTECHNOLOGY RESEARCH CO-ORDINATION GROUP (NRCG)**

Task Force	Research Objectives (by most relevant Task Force)
1. Metrology, characterisation and standardisation	<p>RO 2 To identify the most suitable metrics and associated methods for the measurement and characterisation of nanoparticles.</p> <p>RO 3 To develop standardised, well-characterised reference nanoparticles.</p> <p>RO 4 To understand the properties of nanoparticles in the context of their ignition and explosion potential, and assess/develop methods for evaluating this.</p> <p>RO 9 Optimisation, development and application of technologies that enable the measurement of exposure to nanoparticles in soil and water.</p>
2. Exposure, sources, pathways and technologies	<p>RO 5 Further identification of sources of nanoparticles.</p> <p>RO 6 Optimisation and development of technologies that enable the measurement of occupational and environmental exposure to nanoparticles via air.</p> <p>RO 7 Understanding the fate and behaviour of nanoparticles in air.</p> <p>RO 8 Development of exposure control devices.</p> <p>RO 10 Research to understand the environmental fate, behaviour and interaction of nanoparticles in soils and water.</p>
3. Human health hazard and risk assessment	<p>RO 11 Research to establish a clear understanding of the adsorption of nanoparticles via the lung, skin and gut and their distribution in the body (i.e. toxicokinetics), identifying potential target organs/tissues for toxicity assessment.</p> <p>RO 12 Research to establish a clear understanding of inter and intra-cellular transport and localisation of nanoparticles and their cellular toxicity.</p> <p>RO 13 To establish a clear understanding of whether oxidative stress, inflammatory effects and genotoxicity apply to nanoparticles.</p> <p>RO 14 Research to establish a clear understanding of the deposition, distribution, toxicity, pathogenicity and translocation potential and pathways for nanoparticles in the airways and lung and their potential impacts on the cardiovascular system and brain.</p> <p>RO 15 Given the current use of nanoparticles in consumer products there is a need to further our understanding of dermal uptake, penetration and toxicity in the skin.</p> <p>RO 16 To develop testing strategies for human health hazard assessment and assess how fit for purpose current test methods are as applied to nanoparticles.</p>
4. Environmental hazard and risk assessment	<p>RO 17 Research to establish the uptake, toxicity and effects of nanoparticles on groundwater and soil microorganisms, animals and plants, especially in the context of remediation.</p> <p>RO 18 Research to establish the mechanisms of toxicity, toxicokinetics and in vivo effects of nanoparticles to key ecological groups (including invertebrates, vertebrates (e.g. fish) and plants). A key aspect of such work should be the facilitating of knowledge transfer from human toxicological studies to inform ecotoxicology.</p> <p>RO 19 Define endpoints to be measured in ecotoxicological studies and assess how fit for purpose current standard tests for persistence, bioaccumulation and toxicity are when considering nanoparticles. This should lead to the defining of a suite of standard PBT protocols for use in environmental hazard assessment.</p>
5. Social and ethical dimensions of nanotechnologies	<p>RO 1 To understand the social and ethical implications of nanotechnologies through a programme of public dialogue and social research.</p>

IV) DETAILS OF THE FOURTEEN OECD SPONSORSHIP NANOMATERIALS

The materials for the sponsorship programme were selected as a representative set of either commercially available, or soon to be available nano materials.

The table² below shows the materials and which countries have agreed to work on them.

Sponsorship material	Lead sponsor ¹	Co-sponsor ²	Contributors ³
Cerium oxide	UK, USA, BIAC	Australia, Netherlands	Germany, Switzerland, EC
Zinc oxide	UK, BIAC	USA, BIAC	Australia, Canada
Fullerenes (C ₆₀)	Japan, USA		Denmark, China
SWCNTs	Japan, USA		Canada, France, Germany, EC, China, BIAC
MWCNTs	Japan, USA	Korea, BIAC	Canada, Germany, France, EC, China, BIAC
Silver nanoparticles	Korea, USA	Australia, Canada, Germany, Nordic Council of Ministers	France, EC, China
Iron nanoparticles	China,	BIAC	Canada, USA, Nordic Council of Ministers
Carbon black			Denmark, Germany, USA
Titanium dioxide	France, Germany	Austria, Canada, Korea, Spain, USA, BIAC	Denmark, China
Aluminium oxide			Germany, USA
Silicon dioxide	France, EC	Belgium, Korea, BIAC	Denmark
Polystyrene			Korea
Dendrimers		Spain	USA
Nanoclays			Denmark, USA

Where:

1 = Lead sponsor assumes responsibility for conducting or co-ordinating all of the testing determined to be appropriate and feasible to address the endpoints for Phase 1 of a listed nanomaterial. A Joint lead may be developed depending on the degree of participation committed toward addressing endpoints.

2 = Co-sponsor conducts some of the testing determined to be appropriate and feasible to address the endpoints of Phase 1 for a specific listed nanomaterial.

3 = A contributor provides test data, reference or testing materials or other relevant information to the lead and co-sponsors.

² The most recent table as provided by the OECD Working Party on Nanomaterials, December 2008.