The Centre For Business Relationships, Accountability, Sustainability and Society

Report for Department of Environment, Food and Rural Affairs

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

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Abbreviations Used

B2B	Business-to-Business
BERR	Department for Business, Enterprise and Regulatory Reform
CEO	Chief Executive Officer
CIA	Chemical Industries Association
CNT	Carbon nanotube
CSO	Civil Society Organisation
CSR	Corporate Social Responsibility
DEFRA	Department of Environment, Food & Rural Affairs
ESRC	Economic and Social Research Council
LCA	Life cycle analysis
MNC	Multinational company
NGO	Non-Governmental Organisation
NIA	Nanotechnology Industries Association
NM	Nanomaterial
NRF	NanoRisk Framework
NSP	Nanoscale particle
NST	Nanoscale Science and Technology
QD	Quantum dot
SME	Small or Medium sized Enterprise

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Executive Summary

This report was commissioned by the Department of Environment, Food and Rural Affairs and has been undertaken by the ESRC Centre for Business Relationships, Accountability, Sustainability and Society of Cardiff University. It aims to provide a clearer understanding of the role which corporate social responsibility (CSR) currently plays in influencing the activities of companies involved in the nanotechnologies industry in the UK, and how CSR may contribute to protecting society from any health and environmental risks which may emerge from nanotechnology applications in the future.

Structure of the Research

Findings are based on three phases of research, which comprised:

*Phase 1***:** A review of the literature on risks associated with nanotechnology and the role of CSR. Two key elements of the literature review were to amalgamate all current transnational and national standards and codes of conduct relevant to nanotechnology sectors and the identification of general CSR criteria to be utilised in Phase 2.

Phase 2: an online survey of global nanotechnology companies and products either currently on the market or in development led to a sample of 78 companies based in the UK, or with substantial Research & Development (R&D) and/or manufacturing capacity in the UK, being selected for an online survey of CSR reporting. This study employed quantitative and qualitative content analysis of these documents to examine the breadth and depth of CSR reporting across six areas of material concern.

Phase 3: a programme of 22 interviews (7 public and 15 private sector) to examine attitudes towards and assumptions about CSR activities relevant to the aims and objectives of the research. If Phase 2 of the research concerned primarily what companies reported publicly about their CSR activities, Phase 3 aimed to assess as far as possible how companies and public sector actors understood the extent and depth of industrial activities in relation to CSR. It also included a roundtable event to allow interview participants and other stakeholders to offer feedback on preliminary findings, and to reflect further on the potential regulatory role of CSR.

Findings

Assessing these data in the light of the conceptual frameworks it utilises, the report finds that the UK nanotechnologies industry remains in an early stage of development, with progress very uneven across different sectors. Some commercialisation of products is evident in fields like medical diagnostics and electronics, but most production of novel materials is still concentrated within industrial R&D.

One key finding from the research is that the scope of individual companies' current CSR activities is *significantly affected* by their *size* and *the degree of commercialisation in their sector*. Two key areas where size and sector make a particularly significant difference are:

- *Stakeholder engagement*: wide engagement is not generally undertaken by smaller companies. Further, companies also have mixed opinions about its value: some see wide engagement as a valuable pedagogical device for ensuring public acceptance of nanotechnological products. Others see it as an expensive and in the last instance unnecessary activity.
- *CSR reporting*: levels are very low among smaller companies and those engaged in B2B activities and nanotechnology R&D (for example, 86% of micro-companies and 73% of SMEs failed to report online on their CSR-relevant activities at all).

Nonetheless, the majority of the 15 companies we interviewed are engaged with precautionary approaches to risk in the workplace, driven by existing regulations. Elsewhere, some gaps in current practices are evident:

- Assessment of risks at other stages in the product lifecycle is highly variable in scope and depth, and its extent is dependent on several factors:
  - company size;
  - data gaps;
  - difficulties with risk assessment methodologies;
  - costs;
  - availability of specialist expertise; and
  - the extent of business collaboration in producing and collating data.
- Lifecycle risk management faces serious obstacles, the problem of orphan products is perhaps not being widely addressed, and the role of stakeholder engagement is currently limited

The report also identifies a number of drivers and inhibitors whose interaction is held to affect how far and how widely CSR uptake has occurred, and which might continue to exert a strong influence in the future. As well as company size and sector, these concern:

- The extent to which CSR values are embedded within a company from senior management on down;
- The extent to which the market is seen as an arbiter of public acceptance of new technological applications;
- The perceptions within the company of costs of voluntary regulation;
- The extent to which both CSR and some forms of technical expertise are available to the company;
- Intellectual property issues; and
- The extent to which industry codes of conduct are seen as being of value.

Recommendations

The report makes several recommendations in Section 8.2, relating to what tools may be needed in order to promote voluntary regulation as a response to the regulatory uncertainty surrounding nanotechnologies. Regulators should:

- Promote an effective industry code of conduct;
- Facilitate access for all companies to CSR and wider technical expertise;
- Encourage collaborations between companies to develop CSR practices to "crystallise" industry code of conduct, with the aim or promoting sectoral differentiation of practices and principles where appropriate;
- Encourage sharing of CSR expertise within existing supply chains.

1 Introduction

1.1 Research Needs

This report aims to provide a clearer understanding of the role which corporate social responsibility (CSR) currently plays in influencing the activities of companies involved in the nanotechnologies industry in the UK, and how CSR may contribute to protecting society from any health and environmental risks which may emerge from nanotechnological applications in the future.

It has been suggested that regulators face considerable difficulties in regulating nanotechnologies effectively, due to the wide variety of applications that employ nanoscale science and to gaps in toxicological and other data relevant to potential human health and environmental impacts. The benefits of voluntary regulation are seen as lying chiefly in the contribution it may make to anticipatory and proactive management of emerging risks, and in integrating different areas of concern. An example of such a view is the EU's "Nanotechnology Action Plan" (EC 2005), where respecting ethical principles and integrating societal considerations into the development of nanotechnologies is seen as important at every stage of development.

This report provides below a comprehensive analysis of how CSR is currently viewed by nanotechnology companies and public agencies involved in governance. Building on data obtained via range of investigative methods, the report concludes with some recommendations to policymakers regarding the potential future regulatory contribution of CSR and how this may be promoted and developed.

1.2 Aims and Objectives

The primary aim of this research is to assess the current penetration of CSR approaches into the nanotechnologies industry, together with what drivers and inhibitors may influence the future development of voluntary approaches to regulation. Specific objectives were as follows:

1. To conduct a comprehensive review of the role of CSR policies, statements and strategies within the nanotechnologies industry. This is intended to provide the basis for:
    - Identifying current practices and adequacy of modes of CSR within the industry;
    - Identifying, where relevant, any existing gaps within practices;
    - Providing an analysis of current measures from legal to self-regulatory and their effectiveness;
    - Mapping current products and key industry players.

2. To interview a range of key companies on matters relating to risk management and risk assessment and to identify drivers, inhibitors and motivational pressures influencing the practices of companies within this industry and whether there are distinct drivers across the industry as a whole or whether there are sectoral differences.
    - To follow the interview phase with a 'round table' event of key stakeholders, held at DEFRA in London, in order to provide feedback on desk based and interview findings and provided the industry, researchers and policy makers to respond to findings to date, as well as to contribute further to the research via a scenarios exercise and subsequent discussion.

3. To conduct final analysis and to synthesis the gathered data to provide:
    - A set or drivers and inhibitors that influence the practices of industry including factors which motivate the marketplace activity, modes of governance, the role of media and public perceptions, legal liability and the role of scientific protocols;
    - A life-cycle assessment of the role of CSR and assessment procedures from pre-market, manufacture, use to disposal, it will also consider the priority of factors involved in decision making and how where practicable companies undertake assessment of risks without the full knowledge of potential risks;

- An assessment of the temporal assessment of the future uses of nanoproducts after commercialisation;
- A range of targeted recommendations to identify the most effective means to manage potential environmental and human health risks associated with nanotechnologies and to provide, where applicable, exemplar models of practice.

1.3 Scope of Report

The report is divided into 7 sections. Section 2 outlines the methodological background to the project, including its basic conceptual framework. In Sections 3 and 4, we present an analysis of the results of the research, relating findings to key technical aims related to the project's main aims and objectives. There we examine, *inter alia:*

- The extent to which companies report on their compliance and beyond compliance activities;
- At what level of specificity this reporting operates;
- What mechanisms of external assurance and oversight are in place;
- How far companies consider CSR to be capable of making a valuable contribution to protecting society from health and environmental risks; and
- What assumptions are made by actors from the private and public sectors about the opportunities and obstacles which surround CSR.

Sections 5 through 7 draw on these results in giving an overview of drivers and inhibitors which may affect future uptake of CSR, and gaps in current practice. Finally, section 8 draws a number of conclusions from the foregoing results and provides a number of recommendations which are intended to address some of the issues raised in sections 5 through 7.

The report also includes eight annexes, which contain in detail the evidence to support our analysis. In particular, Annex 3 deals with the on-line review of CSR documents published by identified companies, whilst Annex 6 contains a breakdown of data from both the public and private sector interviews. Finally, Annexes 7 and 8 provide details of the scenarios created for the round table event, together with an analysis of discussions and feedback from the event.

2 Methodological Background

2.1 Conceptual Framework

The conceptual background which informed our analysis of the results from these two phases identifies a baseline understanding of CSR, which conceptualises companies as social entities, not just private ones, whose responsibility to comply with certain norms of behaviour extends beyond the expectation that it should make profits for its shareholders. A company can have a range of impacts on society through its profit-seeking activities, and therefore it has certain obligations to contribute to the management of these impacts.

One might isolate three steps to continuous improvement in the business practices by which these impacts are looked after:

(a) Ensure compliance with legislation to the fullest extent;
(b) To proactively manage impacts beyond the level of compliance with existing regulation; and

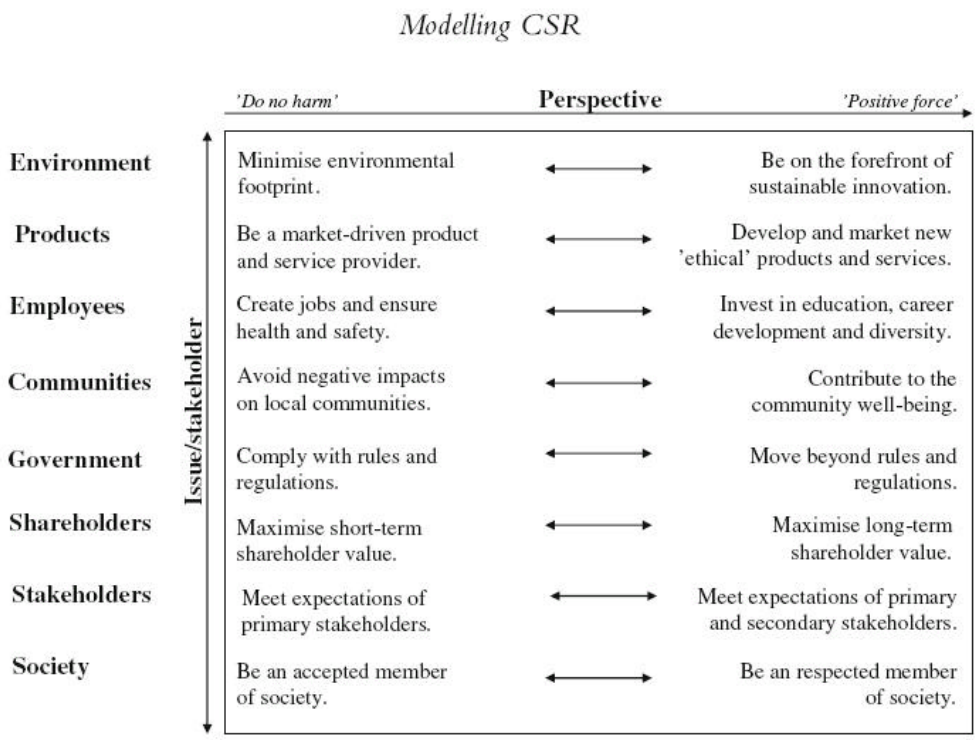
(c) Ensuring that reporting on these activities takes place (with a preference for external audits).

One way of thinking normatively about how this might operate (which informs phases 2 and 3 of the research, and our conclusions and recommendations) is to see a need to develop a dynamic ongoing relationship between high level values, concrete policies and regular reporting on key performance indicators.

This ideal of continuous improvement has to be qualified, however. What *actually* becomes the subject of improvement is, some scholars have argued, one of two models of CSR performance. In other words, there are two contrasting directions in which CSR values, policies and reporting can move.

The recent EU-funded RESPONSE study (RESPONSE 2007) of firms' attitudes to CSR has identified two main orientations of CSR – towards *minimisation of risks* both to the business and to society across the spectrum of a company's activities on the one hand – "do no harm" – and towards adding added *positive dimensions of social value* to the company's business activities - the company as "positive social force" (see Figure 1 below).

Figure 1: Corporate Social Responsibilities as a continuum (Pedersen 2009)



The research is structured into three distinct but interrelated phases.

2.2 Phase 1: Literature Review

Initial work on this project was directed at producing an exhaustive literature review of academic, policy, and 'grey' literature relating to the role of CSR as a self regulatory tool for the nanotechnologies industry. This was crucial not only to shape the main work on

identifying current scope of CSR within the industry but also to identify general CSR Criteria for application in Phase 2. This literature review is appended to this report (see Annex 1) and that part of the review touching upon the framework of CSR is to some degree replicated in the main body of this report.

The literature review examined research on: (a) NST risk and uncertainty; (b) regulatory developments in the UK, EU and USA; (c) CSR thinking on areas of direct relevance to the NST industry; and (d) current international and national CSR standards and guidelines (see Annex 2). From this, six material CSR criteria (see Table 1 below) were identified which were postulated as areas of concern which companies and regulators should address to develop a comprehensive and integrated approach to "responsible innovation".

Table 1: Material CSR Criteria

Environmental Impacts	Including statements around specific environmental impacts of current activities, but also definitions and programmes of sustainable development
Health and Safety	What measures are undertaken to safeguard the safety of workers and the safety of consumers?
Access	Is IP shared with developing countries? To what extent are upstream commitments made to sharing other benefits and promoting development (NB this excludes corporate philanthropy, defined as sharing of profits)
Social acceptance and understanding	To what extent are a range of internal and external stakeholders included consulted and/or informed about the company's activities and future plans?
Legal compliance and liability	What declarations are made about compliance with legal statutes, regulatory regimes (including statements about judgements of liability made against the company)
Risk management	Is information provided about general approaches to risk management and responsible innovation within the company (such as LCA, product stewardship, precautionary approaches)? This is in addition to specific statements about safeguarding consumers and employees, or the environment – it concerns whether systems of risk analysis are explicitly discussed.

2.3 Phase 2: Online CSR Survey

Phase 1 was followed by an online survey of global nanotechnology companies and products either currently on the market or in development. The purpose of Phase 2 of the research was to examine how companies involved in the nanotechnology industry in the UK reported online on their CSR activities. From this survey, 78 companies based in the UK, or with substantial R&D and/or manufacturing capacity in the UK, were selected as the basis for an online survey of CSR reporting (producing a sample of 68 documents during the period September – November 2008). This study employed quantitative and qualitative content analysis of these documents to examine the breadth and depth of CSR reporting across six areas of material concern that were identified in Phase 1 (see Table 1).

Online statements from 78 companies, all of whom advertise their interest in nanotechnology either through membership of industry associations or through broader research programmes, formed the basis of this study. Because of the jurisdictional remit

of the DEFRA project, all these companies are ones either based within, or with substantial research and development capacity based within, the UK. As the focus of the project concerns a broad-based concept of what constitutes CSR, these documents were not limited to annual reports, but also included policy statements and published codes of conduct. Companies tend to incorporate more than one form of commitment in reporting their CSR activities. These can range from general guiding values, through specific policy guidelines, to quantitative performance targets designed to aid continuous improvement.

Companies were categorised as either:

- *Micros* (typically making use of university-originated IP, with <10 staff);
- *SMEs* (>10 and <250 employees);
- *Large* (over 250 employees but based in one country); or
- *Multinational/MNC* (with substantial production, research or distribution operations in more than two countries).

They were further categorised according to their positioning in the supply chain.

The unit of analysis for the study was explicitly taken to be individual sentences within documents, as sentences typically form the unit of analysis for studies of CSR statements even when this is not explicitly stated (Tilt 2001, 196). Declarative statements containing information either about general commitments, specific policies or quantifiable goals and measures of progress were counted across 7 individual thematic categories (see Table 1 and Table 2). The classification of these statements was further broken down to indicate whether they applied specifically and explicitly to NST-related activities or were more general in scope, and whether they applied mainly to the company on whose behalf the statement was made, or whether the information provided concerned the supply chain with which the company does business.

Table 2: Examples of Declarative CSR Statements

Examples of *general* declarative CSR statements	"We support efforts to improve access to medicines around the world, in both developing and developed countries." (*Access*) "We are committed to reducing our impact on climate change." (*Environmental Impacts*)
Examples of *specific* declarative CSR statements	"To help us better understand patient needs we have set up advisory boards in the US and Europe with representatives from a wide range of patient groups." (*Social Acceptance and Understanding*)
Examples of *quantified* declarative CSR statements	"We set new targets to reduce our climate change impact (CO_2 equivalent emissions) and energy use in operations, and transport from 2006 levels by 20 per cent per unit of sales (based on a constant exchange rate) by 2010 and by 45 per cent by 2015." (*Environmental Impacts*)

Statements were coded as "general", "specific" or "quantified", and frequency statistics for these three categories of statement were used to provide "profiles" for different categories of company across the various material CSR concerns, with the aim of mapping the kinds of normative commitment upon which different categories of company report. Only statements which related directly to the material concerns outlined above

were recorded. These material concerns were taken to reflect the different dimensions which would have to be included in order to build a comprehensive and integrated approach to "responsible innovation". No account was taken of philanthropic initiatives, or community initiatives which did not relate specifically to stakeholder engagement or access considerations as outlined above.

In addition, a qualitative analysis was undertaken to identify examples where companies have begun to develop (either individually or in concert with others) systems of stakeholder, risk and responsible innovation management. These may potentially be useful both in responding to potential NST hazards, should any emerge, and in shaping the future direction of NST development in ways which reflect material CSR concerns about access, social acceptance, environmental protection and product stewardship through a product's lifecycle. This analysis also considered, by way of comparison with examples from the main sample, the NanoRisk Framework (NRF) developed by DuPont and Environmental Defense, and the CENARIOS "nano-risk assessment tool" developed by Innovationgesellschaft GmbH in Switzerland, and AssuredNano's certification standard of the same name (at the time of writing, full documentation was not yet commercially or publicly available). For the purposes of this study, DuPont's CSR contribution was considered as an extreme outlier, given the unique nature of the NRF, and was not included within the main survey.

A complete analysis of on-line statements is located at Annex 3.

2.4 Phase 3: Public & Private Sector Interviews

This phase consisted of a programme of 22 interviews (7 public sector and 15 private sector) to examine attitudes towards and assumptions about CSR activities relevant to the aims and objectives of the research.

If Phase 2 of the research concerned primarily what companies reported publicly about their CSR activities, Phase 3 aimed to assess as far as possible how companies understood the extent and depth of their own activities in relation to CSR, and to relate these understandings to those of government and public agencies.

Seven interviewees from public agencies and government departments were identified with the assistance of DEFRA. 50 private companies were initially contacted, with contactees being identified through the foregoing online CSR study, through previous research on current products, via personal contacts, and via further online research (see Annex 5). A series of 15 semi-structured interviews with representatives of companies of different categories, sectors and positions in supply chain was undertaken as a result. In both the public and private sector interviews, a set of interview questions were used as a loose script for each interview (see Annex 4). Some difficulties were encountered. 13 companies (26%) declined to participate, with business confidentiality being widely cited as reason for not participating, along with time and costs for SMEs of participating (several companies have been contacted by a number of researchers recently, as the industry does not comprise a large number of companies). Four companies (8%) responded by stating that they were not, technically speaking, involved in nanotechnology. 15 (30%) companies did not respond despite various attempts to contact them,, with a majority of these being companies involved in manufacturing consumer products containing nanomaterials, some of whom did not have accurate contact details on their websites.

Limitations of Data

The interview sample, whilst including companies from a broad cross-section of the UK nanotechnologies industry, does not necessarily enable a comprehensive comparison between companies from similar sectors to be made. For example, while such comparisons are to some extent possible between companies engaged in producing specialty chemicals, the lower representation of e.g. the food, cosmetics and pharmaceutical sectors make comparison difficult.

However, given that information from consumer-facing large and MNC companies in the cosmetics and pharmaceutical sectors is widely available online and has been documented under Phase 2, extrapolating from the available interview data to a broader picture of practices in these sectors is arguably justifiable, with caveats.

Interview data for the public and private sector interviews was coded and analysed according to different but complementary analytical foci (see Table 3 and Table 4 below), which reflected the general stated aims and objectives of the research (see p. 7 above, and Annex 6 for a complete breakdown of interview data according to these foci).

Table 3: Analytical foci for public sector interviews

Public Sector		
1. Government role in promoting responsibility in nanotechnologies industry.	2. Contribution of different regulatory approaches.	3. Extent of evidential gaps and application of precaution
4. Drivers within the industry that might encourage the uptake of CSR	5. Companies' concerns regarding present and future markets for their products	6. Views on role of codes of conduct
	7. Examples of CSR in industry/gaps in practices	

Table 4: Analytical foci for private sector interviews

Private Sector		
1. Role of foresight/ anticipatory risk management	2. Nature and extent of pre-market research/isolation of employee risk factors	3. Sources of influence on company practices from within the industry
4. External sources of pressure which influence	5. Technical questions about manufacture, use	6. Temporal extent of risk assessment and

practices	and disposal which influence product development	research and actions resulting from these assessments
7. Extent and nature of stakeholder engagement practices	8. Extent to which monitoring procedures for products containing nanomaterials differ from those not containing nanomaterials	9. Influence of modes of governance on attitudes to CSR

2.5 Roundtable Event

Following the phases 2 and 3 of the research, a roundtable event, hosted by DEFRA in London, was held to which were invited public and private sector stakeholders who had participated in Phase 3. The main part of the event consisted of a scenarios exercise (see Annexes 7 and 8). This involved participants discussing and reflecting on three potential scenarios for the next decade of nanotechnological development ("Low consensus, high cost", "High consensus, slow growth", "High disruption, high growth"), and on the role that voluntary regulation might play in changing the shape of these futures. These scenarios were developed by the research team, based on work done on the EU-funded Nanologue project, to reflect the initial conclusions of this project regarding current strengths and weaknesses in CSR practice in the industry, and what factors might play a role in driving or inhibiting CSR take-up.

3 Profiling Current Modes of CSR

3.1 Regulatory context

Based on Phase 1, it is evident that various national and regional jurisdictions are, at the present time, pursuing modes of "soft" regulation which make a place for voluntary action. These have included, for example, the voluntary reporting schemes to collect information from industry on existing uses of nanomaterials in the UK (UK Government 2008b) and the USA (Environmental Protection Agency 2008). In the UK, the Royal Society, Insight Investment and the Nanotechnology KTN have set up a working group called Responsible NanoCode, which has produced a principles-based code of conduct for the industry that stresses the need for effective and comprehensive risk assessment, wide stakeholder engagement, and transparency, and which aims to be promoted on the basis of a benchmarking model (Responsible NanoCode 2008). The German Chemical Industries Association (VCI) has published a set of guidelines to help companies understand the responsibilities pertaining to nanomaterials under the EU's new REACh regulations (VCI 2008). For its part, the EU's "Nanotechnology Action Plan" (EC 2005) promotes the integration of CSR concerns with private sector activities both at a high level and throughout business practices.

However, some have argued that the promotion of voluntary approaches faces difficulties: some suggest that voluntary initiatives do not produce high-quality data unless they include effective incentives, are properly transparent, and are made mandatory after an introductory period of some years (Hansen and Tickner 2007). Whether there is currently any great appetite across the nanotechnologies industry for collaboratively developing frameworks of best practice is difficult to determine on the basis of existing research.

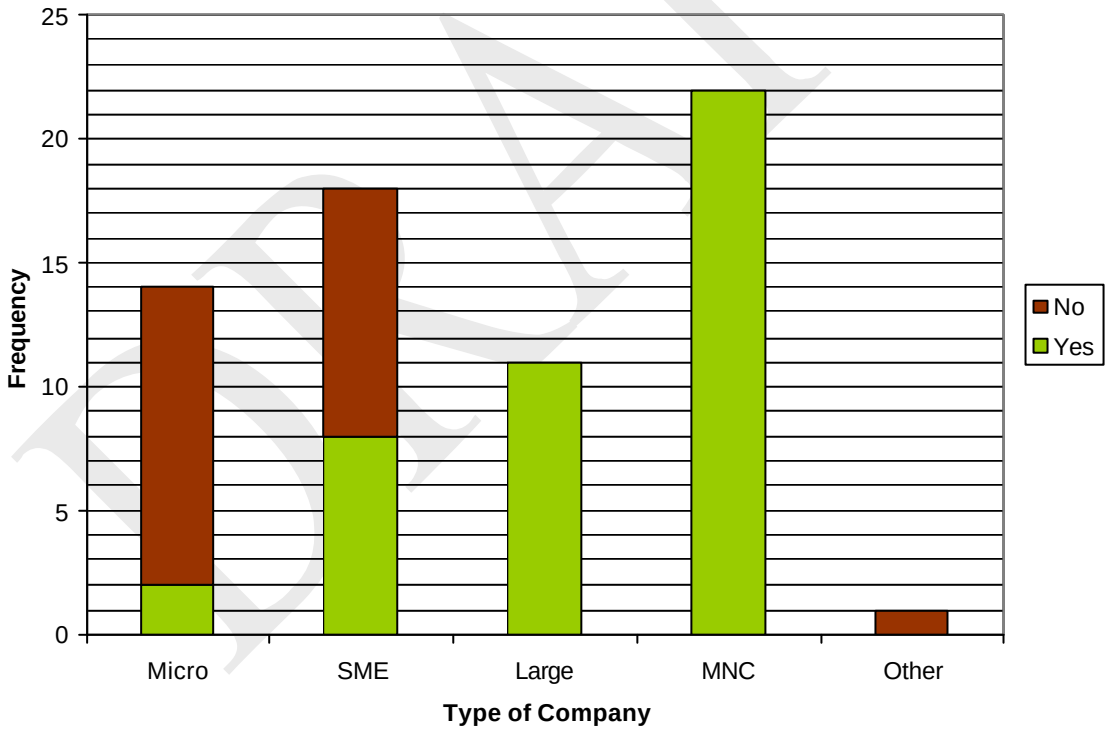
Drawing specifically on Phases 2 and 3, a number of key findings were observed in this regard. One of the key findings of the study was that most companies who engage in CSR

see it as a tool to reduce risks and operational cost; only companies with very high social performance rankings – a subset for the most part of the set of all large and multinational companies - think about CSR as a means to drive product innovation and to contribute to social values beyond those with a financial dimension.

3.2 Levels of reporting

From analysis of on-line statements, 86% of micro-companies and 73% of SMEs failed to provide either a code of conduct, policy statement or annual report that addressed one or more areas of material general CSR concern identified in the survey (see Figure 2 below). Moreover, there were very few documents that made explicit reference to a company's nanotechnology activities, only 12% (8 out of 68 submissions across 43 submitting companies) overall. There was in general no explicit and detailed discussion in any of the documents examined of nanotech-related activities across any of the material CSR criteria on which the survey focused. In general, it was assessed that micro-companies and SMEs who make submissions do not tend to refer to external CSR reporting standards or codes of conduct. In contrast, submissions by MNCs regularly referred to external standards (see Table 14, Annex 3) with ISO 14001 with the highest recorded number of references with 13 of the 68 submissions.

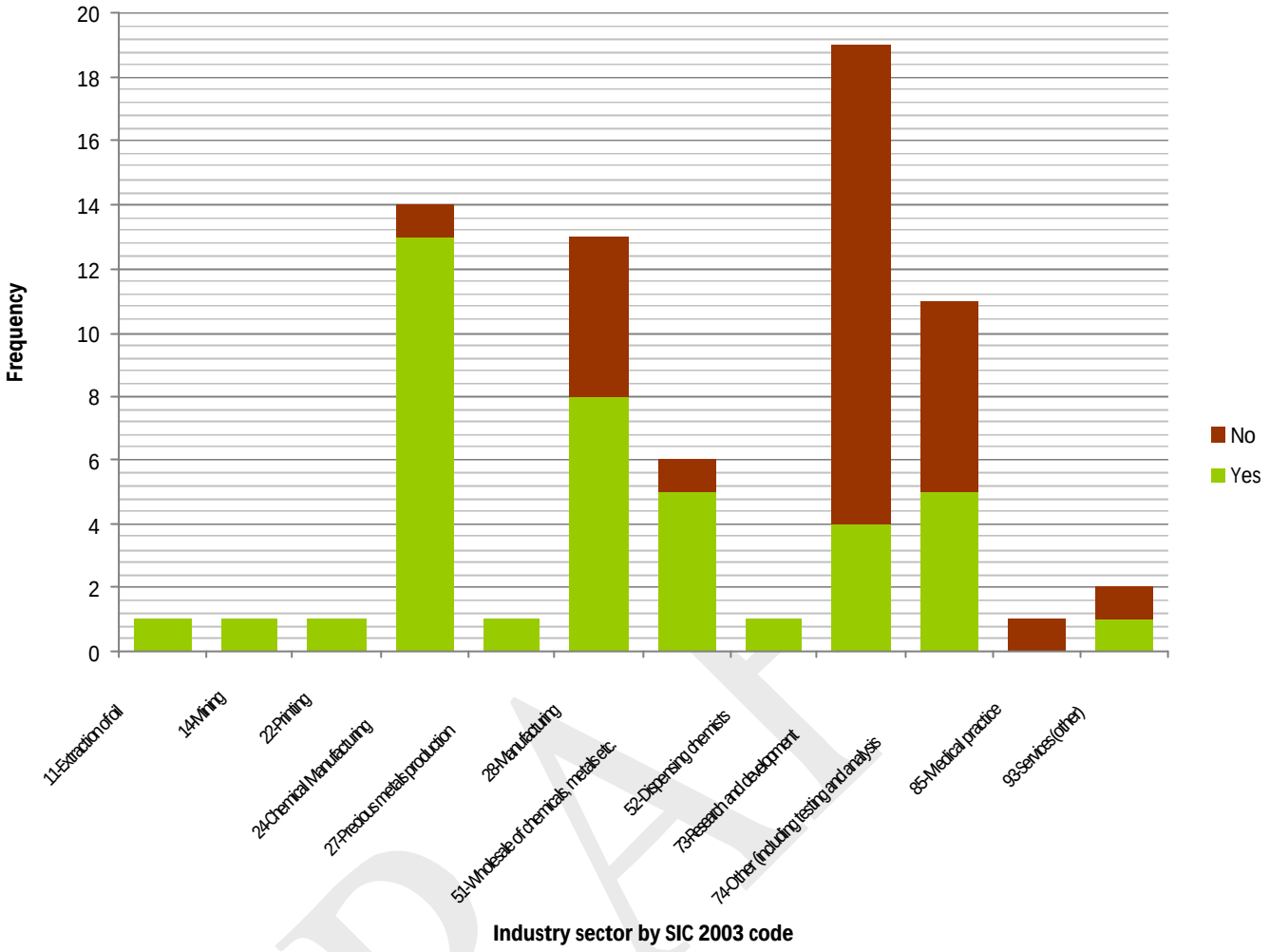
Figure 2: CSR Statements Available Online by Company Type



The sectoral profile (by SIC 2003 division) of the reporting sample shows that the lowest level of reporting was among companies engaged primarily in R&D, including research on nanomaterials and nanostructures. This sector sees a heavy representation of micro companies (see Figure 3 below).

Use of third-party auditing for CSR reporting is widely recognised as essential to build trust and credibility (see e.g. GRI 2006). However, those micro-companies and SMEs who make submissions do not tend to refer to external CSR reporting standards or codes of conduct. Some degree of auditing is more common among MNCs, but even here is far from universal (6 out of 22, 27%).

Figure 3: Provision of CSR documents by industry sector (n=71)



3.3 Extent to which NM-specific monitoring procedures are used

In the workplace, NMs are treated largely in accordance with existing risk management protocols developed in response to existing regulation, although in some cases NMs are treated according to additional protocols and with extra toxicology and risk assessment being done. Products incorporating nanomaterials are made to meet the same standards as apply to other comparable products, although in consumer-facing sectors, regulations are seen as stringent enough to ensure that adequate pre-market research is done.

3.4 Influence of modes of governance on attitudes to CSR

Our Phase 3 interviews showed that companies were more or less unanimous in seeing the impacts of taking mandatory regulation beyond what exists at present as potentially very destructive. Nonetheless, regulatory uncertainty was also seen as destructive – although uncertainty was not itself widely seen as a strong incentive for companies to self-regulate. Further, to place measures, which are currently beyond compliance, into part of a mandatory regime (e.g. LCA for new NMs), or extending REACh to all new NMs, were seen as particularly disproportionate.

Companies were keen for better and more formal modes of engagement with regulators to be in place, allowing more information to be exchanged, but also saw codes of conduct, perhaps endorsed by government, as a big step forward. Companies tended to be confident that the current regulatory situation would not change too much in ways which

might have a negative impact on their business, although consumer-facing companies saw it as holding some potential threats, notably through EU-based labelling legislation, which was seen as a blunt instrument. The cosmetics company we interviewed in particular has acted in anticipation of this by demanding more public communication from the EU on the balance of risks *and* benefits on e.g. sunscreens. Their argument for taking this action was that labels would be interpreted by consumers primarily as warnings.

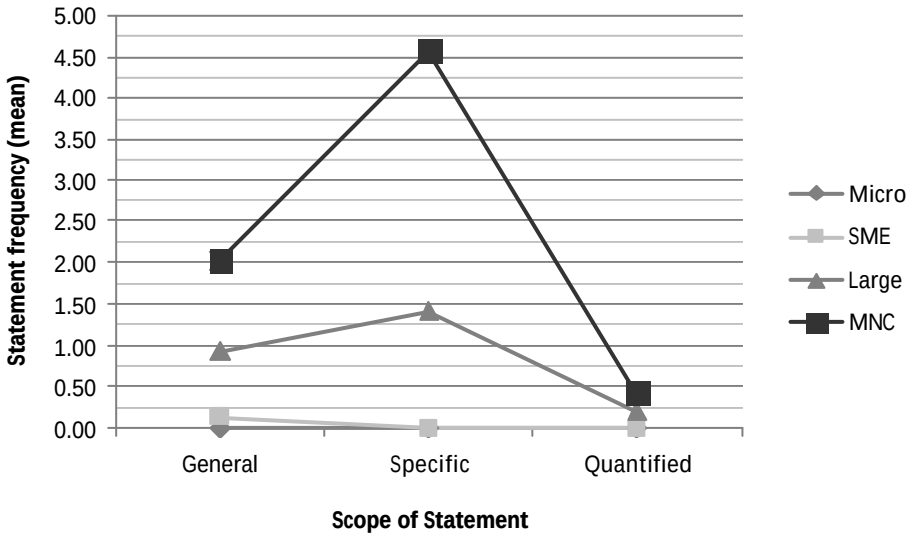
3.5 Extent and nature of stakeholder engagement practices

Results from Phase 2 suggest that wider stakeholder engagement activities are very uncommon among smaller companies. In addition, Phase 2 results show that even among larger companies there is limited evidence of systematic approaches or of the setting of specific performance targets in this area (see

Figure 4 below). Further, little evidence was found to indicate that access to technologies in the developing world is an issue much addressed in general CSR documents, although one pharmaceutical company we interviewed in Phase 3 indicated that public perceptions of inequalities in access to products have been a major factor in their revision of their stakeholder engagement practices. This was borne out by evidence from Phase 2, where companies involved in the medical/pharmaceutical sectors tended to be most interested in more upstream, systematic and consultative modes of engagement. Within the submissions from these companies, it was evident that in many cases these approaches reflected responses to previous negative publicity.

From our Phase 3 interviews, it is evident that B2B companies, small and large, tend to view stakeholder engagement as difficult, costly, and being best undertaken through intermediaries (media, government, industry bodies). Across all sectors represented in the interviews a frequent assumption appears to be that the rapid commercialisation of beneficial products is seen as a key route to positive public perceptions, irrespective of the impacts of stakeholder engagement activities. Along with this view tends to come the assumption that it is *individual products* that are the subject of acceptance and rejection, rather than *whole technologies*, unless these technologies are created as an object of specific concern through e.g. the advocacy action of CSOs.

Figure 4: Stakeholder Engagement Profile by Company Type (n=68)



4 Extent of LCA Approach

4.1 Foresight

Little evidence of systematic proactive management of product risks/product stewardship approaches is available from the online CSR submissions of smaller companies. Even larger and multinational companies tend not to frequently set themselves quantifiable reporting targets in this area.

Nonetheless, there is strong evidence from Phase 3 that activities which fall under different analytical foci (see Table 4 above) and which reflect, to varying degrees, a "do no harm" interpretation of CSR (see Figure 1 above) are engaged in by all the companies we interviewed. This is despite there being notable differences in levels of reporting on CSR among different categories of company and sectors (see section 3 above). Notable exceptions were the three pharmaceutical and medical diagnostics companies we interviewed, whose responses contained marked elements of a "positive social value" approach, to varying degrees (with the strongest indicators provided by larger companies). The orientation towards risk minimisation extended from strategic foresight activities, through occupational health measures, to the employment of risk assessment protocols for products.

There is, therefore, some evidence of anticipatory approaches to risk being employed across different dimensions of companies' activities. Some examples of areas into which companies' current foresight activities and thinking extend include:

- The extent to which different approaches to product stewardship might be feasible for NST-engaged companies of different sizes and sectors.
- Some evidence among SMEs that a lack of regulation and a need to anticipate risk can drive innovation.
- Views that anticipating specific risks and uncertainties associated with products can sensitize companies to potential areas of regulatory change.
- A general sense that the role of industry or sectoral codes of conduct in making this kind of risk management more systematic may be valuable.

The majority of companies we interviewed, across different sectors, claimed to employ precautionary occupational health risk protocols, focused on minimisation and monitoring of exposure within the workplace. Five of the smaller companies we interviewed (and two of the multinationals) attributed their precautionary commitments in part to values and attitudes held by directors or senior management which reflect their experience in larger technology companies or university research centres, which have become embedded within the working practices (the "DNA") of the company. Larger companies tend more to describe well-established systems, e.g. "risk banding", that have evolved across the full range of their operations in response to existing regulations.

Smaller companies, working at the cutting edge of technologies, are closer to emerging risks

Smaller companies, working at the cutting edge of technologies in many cases, are perhaps closer to emerging risks, and potentially highly sensitized to them. Examples exist of specific and extensive pre-market human and environmental toxicology

being developed by individual companies, with some companies suggesting as a result of their experiences that existing toxicology protocols tend to be unsuitable for NST purposes, and better ones would encourage more pre-market research.

4.2 Technical questions

Although smaller companies tend to represent CSR as relatively inaccessible to companies like them due to high costs, they undertake anticipatory assessments of the risks and uncertainties which surround potential product development options in a way similar to that taken by larger companies. Most companies we interviewed tend to distinguish between:

i) Products with established benefits which are expected to be accepted by consumers or business customers;
ii) Products surrounded with known uncertainties which can be dealt with by established precautionary protocols; and
iii) Products where persistent and difficult to resolve scientific uncertainties make them unacceptable business risks.

4.3 Temporal extent of risk assessment and research

One area where costs undoubtedly may impose considerable limitations on what measures are possible for smaller companies is temporally extended risk assessment and management – through LCA, product stewardship and so on. With respect to LCA, it is true that, given the early stage of development of most sectors, many gaps affect the feasibility of LCA, particularly in relation to data and modelling, even for larger companies. However, costs of performing LCA for products and, often, a lack of access to relevant expertise are anticipated to make implementation difficult for smaller companies.

Lifecycle costs:

"And if there's legislation to say you must deal with end of life., you will stop companies such as us manufacturing our product, because

Although they may not currently report on their activities in this regard, our interviews show that approaches to product stewardship are being explored by smaller companies, especially those who have experience of industry codes such as Responsible Care. For larger, consumer-facing companies, temporally-extended risk management is typically seen as essential to the company's business. LCA is seen as extremely important, and bespoke analytical tools are available for the assessment of products, often developed by industry associations. Nonetheless, gaps in toxicological data, together with the early stage of product development in many cases, are seen as major – if not insuperable – obstacles for the use of LCA in nanotechnological contexts.

Liability for orphan products has not been widely considered by smaller companies, but where it has, the problem is seen as related to IP ownership passed up or down the supply chain.

5. Drivers

5.1 External Pressures

If small and large companies show capacity for foresight and precautionary practices to avoid and/or mitigate business risk, there are clear differences between their attitudes to

external pressures to adopt CSR measures, which appear to reflect their different positions in the supply chain.

Many companies we interviewed see business risks from negative public perceptions, and relate these to inadequate communication by industry, government and media, with some also citing the distorting effects of CSO activities. This is reflected in views of wider engagement as being essentially about educating the public – not in terms of enabling people to understand the science, but to appreciate the benefits of particular products.

But outside larger consumer-facing companies, there is little evidence (with some exceptions) that perceived external pressures are driving changes in practice, particularly where communication with stakeholders beyond peer companies, business customers and employees are concerned (out of 13 non-consumer facing companies of all sizes interviewed, only four showed signs of extending engagement beyond this circle).

CSR in the supply chain:

"[…] we basically have a range of material that doesn't use any cadmium and that really is a big deciding factor for Japanese companies to work with us because they just don't like any heavy metal in their products." (company M)

5.2 Size and sector

It is undoubtedly true that both the degree to which companies are involved in activities which address material CSR criteria, and the extent to which they report on them, are heavily influenced by their size and sector of operation. Profiles for all CSR criteria analysed in Phase 2 demonstrate that much higher levels of general, specific and quantifiable statements are produced by large companies and MNCs, and that overall there is more integration of codes of conduct, specific policies and performance targets in the reports produced by larger businesses. The need to survive in the short term may trump longer term views (cf. Baker 2003): "one of the real challenges for CSR is specifically for small companies where a long term - a long timeframe is six months" (Company G). Without extra capacity (such as might be provided by a department dedicated to dealing with CSR practice, for example), smaller companies face major difficulties developing comprehensive and integrated approaches to CSR. Further, B2B companies, of all sizes, and those involved primarily in R&D activities, are less likely to report or engage in CSR.

5.3 Supply chain pressure

A common concern for smaller companies is that, compared with larger companies, they face cost pressures and an associated shortening of their temporal frame of reference which may reduce their capacity for developing "beyond compliance" approaches. A major concern for many of these companies is, first and foremost, "getting the technology to work" in ways which are functionally useful and add value to products. Determining what technologies may add value to products is, for example, a significant concern for smaller (and indeed, for larger) companies. Navigating markets and finding likely customers is also a source of time and financial costs for small companies, an effect in many cases of the sheer number of potential uses for novel materials.

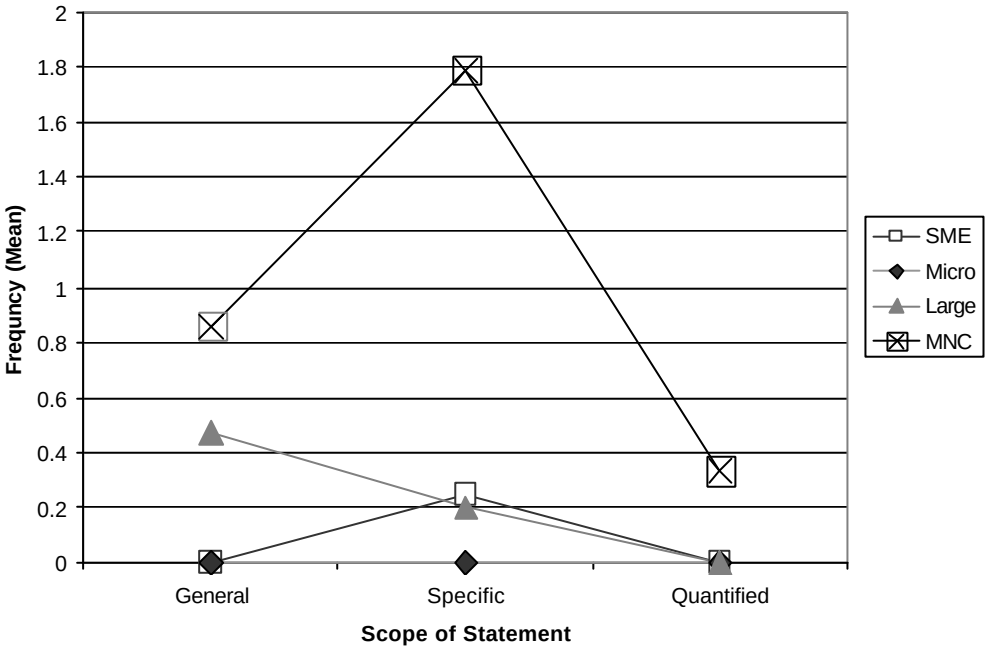
Nonetheless, some of these pressures may themselves be important sources in motivating CSR. For example, small manufacturers of NMs typically seek collaborations and investment from larger companies, often beyond the EU. The CSR requirements of operating within these supply chains may often be significant, forcing companies to treat the costs of going beyond compliance pragmatically as business costs. Seeking ways of

adapting to the requirements of the supply chain is a crucial way in which smaller companies can reduce their business risk.

The majority of CSR documents from larger companies analysed in Phase 2 make clear that commitments from suppliers to follow certain EHS standards or practices are required by their larger customers. As Figure 5 below indicates, our data suggests that multinational companies in particular (who naturally tend to source materials from a wide range of suppliers) often have a marked focus on specific supply chain policies. This was borne out by the interviews we conducted: the need for smaller companies, particularly in the speciality chemicals sector, to develop collaborations with larger companies to develop products creates expectations among smaller companies that certain best practice standards as well as regulatory compliance will be required of them. In some cases, this led to changes in business models and manufacturing processes:

> *[…] we basically have a range of material that doesn't use any cadmium and that really is a big deciding factor for Japanese companies to work with us because they just don't like any heavy metal in their products. […]So that's going to be again another, another key issue for us to work with that in terms of lifetime and performance and everything else that they outperform I guess the cadmium based materials. (Company M)*

Figure 5: Statements on Supply Chain requirements by Company Type (n=68)



5.4 Embedded Values

A range of companies small and large pointed to the influence that direction from senior management can have on CSR activities. For MNC companies, a change of CEO was seen as an event which could have an enormous influence on perceptions within the company. Smaller companies traced the influence of experienced directors or other members of senior management within working practices in the company. This was particularly apparent in relation to the implementation of precautionary measures in the workplace, where attitudes were also buttressed by the natural orientation

CSR in the DNA?

"So you know, we live it. We don't need to be told it, we live it." (Company K)

of "overcautious" scientists (Company M). It was also apparent, however, in general attitudes towards long-term liabilities. As one SME noted,

> *it's no use trying to hype up the technology, make a quick exit, get those original shareholders, make those original shareholders money and then leave the, if you like, the next generation of shareholders or owners with a long-term liability.(Company G)*

The importance of such values as a way of expressing a fundamental connection between the normative assumptions of companies and those of the society in which they operate was also stressed by several interviewees. As one remarked: "no responsible company should be in a position that says we want to take more risks than the societies in which our customers are based are willing to actually tolerate" (Company G).

5.5 Freedom to operate

Public sector interviewees tended to assume that reputation and publicity are two key drivers in causing companies to adopt CSR measures, due to their effect on company's position in the market. Companies tended to concur, interpreting these factors as necessary components of their "licence to operate", which required them to anticipate future shifts in regulation and to satisfy themselves that their products and practices complied with current regulations. Proactive attitudes to environmental and health implications were seen as bringing key benefits to the industry, by helping to head off the threat of costs being imposed through future legislation, and other business risks: *"being ahead of the game and understanding what the issues area in terms of both our customers and our staff, that's far better than being told later*" (Company K). This was also one of the main drivers behind companies' feelings about wider public engagement, which they expressed in terms of the need to help the public understand the actual benefits of nanomaterials and nano-enabled products. A connection between market advantage and CSR was made by most companies interviewed.

5.6 Coordinated guidance and assistance

Where companies reported having access to guidance, information, expertise and financial assistance for developing CSR policies through contacts they happened to have within and outside industry, this was seen as having been a major incentive to adopt a more CSR-based approach. To make it more likely that CSR measures would be adopted across the board, several companies suggested that it was necessary for government (and in some instances, industry bodies) to take a more coordinated approach to providing information, guidance, and in some cases funding for the support of CSR activities. These measures could include the following:

i) Providing a research framework which helps companies focus EHS research on specific areas where data and modelling gaps exist;
ii) Setting firm guidelines (on the model operated by the EPA) regarding "risk banding" for the production of NMs and NSPs, so that a transition from precautionary mode to full toxicological assessment is triggered by scaling up production;
iii) Code-of-conduct based guidance formulated in concert with CSOs and government to help companies (particularly in the food sector) deal with uncertainty;
iv) Well-publicised provision of coordinated advice and support to early stage companies to understand risk issues; and

v) Seed money to help smaller and larger companies in the same and in different sectors to collaborate on toxicological research.

6. Inhibitors

6.1 Lack of access to CSR expertise

This is a problem noted by several smaller companies (from different sectors), and seen as a serious stumbling block. Going beyond compliance – whether this concerns individual material concerns like stakeholder engagement, anticipatory risk management, EHS issues, or integrating these issues in a framework which can drive subsequent reporting – is seen as extremely difficult due to a lack of coordinated support, in terms of information, guidance and extra capacity.

6.2 Cost perceptions

Although much of the R&D necessary to drive NST development was being done by smaller companies, these companies are perhaps least able to bear the costs of implementing proactive CSR measures, particularly where long-term risk management, e.g. through LCA and product stewardship, might be a matter of concern. This point was made emphatically by two companies we interviewed closely involved in industrial R&D. In relation to cost problems, one interviewee noted that cost may deter companies from even trying to find out about CSR, as it appears not to be something companies like them can engage in: "they don't want to hear" (Company G).

High degrees of safety testing, LCA research and monitoring were all seen by one of these companies as much more feasible for sectors where there are large mark-ups on products: such an approach, it was suggested, *"does not work at all on anything else bar the pharma industry; never has, never will"* (Company K). In general, at least some perception of CSR beyond basic compliance as having high costs was almost unanimous among smaller companies interviewed, with some seeing in particular the pressures that would derive from future regulatory costs (particularly with REACh now exerting additional pressure) as potentially crippling for the whole European NST industry if the future development of regulation was not undertaken with particular sensitivity to the needs of smaller companies.

6.3 Lack of effective regulatory engagement

Smaller companies we interviewed noted that making sure compliance is possible for companies is a major contribution of itself, which means ensuring that they are aware that they should comply with existing regulations. Noting that there may be around 4.5 million small companies in the UK, one interviewee wondered

> *how many of those companies actually have a comprehension or understanding of what the regulations really mean and how they affect their business. There's not enough education done I think on engaging people to actually help them understand what their obligations really are. (Company N).*

If such awareness exists, then it may itself be a driver of further CSR activities. Without such awareness, however, further steps may be very difficult.

6.4 Intellectual Property Right Issues

Although business confidentiality issues were not widely discussed by interviewees, some interesting comments were made about the specific role played by intellectual property in stimulating growth in emerging technologies and the pressures that this could exert on companies to avoid e.g. opportunities for public engagement and other voluntary

measures in case commercial commerciality was compromised. Labelling was mentioned as one area in which IP issues of this kind could act as a barrier, and two companies in particular (K, L) noted that data gathering exercises such as voluntary reporting schemes, together with public engagement exercises, would face difficulties:

> *[…] this is still very much an experimental type technology because you can make massive changes in functionality very easily. Then you know, you have to hold the IP close and I think that's what the NGOs find somewhat difficult to get their heads round (Company K).*

6.5 Competing standards

As was evident from Phase 2 of the research, a number of codes of best practice and codes of conduct are becoming available. There was significant concern among both private and public sector interviewees that perceived or actual competition among these frameworks might slow down the take-up and implementation of CSR. A collective action problem might result, with companies waiting to see which of the available standards would become "the only game in town" (Public 7). It was widely thought that the industry and public profile of any standard or code would be the key to its success. Participants in the Scenarios Exercise and some companies interviewed in Phase 3 suggested that government backing, provided perhaps via a set of well-publicised criteria thought necessary for any standard to be effective might be a way forward.

6.6 Effectiveness of standards

Some interviewees noted that for any voluntary standard to be effective and to attain a high profile, it has to include strong oversight mechanisms. The problem of oversight is frequently mentioned in literature on CSR initiatives as a cause of perceived ineffectiveness (e.g. Gunningham 1995). Without such oversight, it was thought that any voluntary standards would be ineffective. Overcoming this problem was seen as very difficult: one company suggested that a full and thorough implementation of independent and professional oversight via review committees which did not include stakeholders would be one way forward: "you almost want professionals who have no axe to grind" (Company G).

6.7 "The market will decide"

As noted in section 3 above, one of the key assumptions evident behind the responses of several smaller B2B companies (six in total) we interviewed was that the primary criterion for increased penetration of nanotechnologies would be the commercialisation of products that consumers would buy (rather than the acceptance of whole *technologies*). Two companies alluded to the public acceptance of mobile phones as an example of how this market–led dynamic might operate. If such a dynamic is widely accepted as the primary mode through which societal concerns become alleviated, or at least neutralised, then there is less incentive for smaller companies to extend their CSR activities beyond risk minimisation in the workplace and compliance with standards in the supply chain.

7. Gaps

7.1 Inadequacies of data

There was widespread recognition among companies interviewed that persistent data gaps continue to provide cause for concern. With respect to human health, these include the nature of potential hazards and characterisation of reference materials, but also include uncertainties about the best approaches to acute and chronic exposure modelling, toxicological methods more widely, and testing protocols. These gaps also extend to

environmental exposure, where fates of NMs, complex interactions with the environment and latent effects continue to be of concern.

7.2 Life cycle analysis

These data gaps present a particular problem for wider adoption of lifecycle approached to risk management. Here, in particular, the lack of modelling capability for complex interactions between NMs and the environment or human body is felt particularly keenly by smaller companies, particularly in the food sector. Another issue is that many products or materials remain at a very early stage of development, and so filling data and methodological gaps remains attendant on further development. It was evident from our interviews that larger consumer-facing companies had more capacity, as well as access to more data, but here the problem was seen as one of fostering further industry/academic/government collaboration, given that "nobody has been able to put all of the pieces together" (Company C).

7.3 Orphan products

Discussions of orphan products and successor liability in interviews were marked by little evidence that smaller companies had considered this issue in depth. Two SMEs and micros dealing with innovations in electronic components or spun out from universities interpreted this issue in relation to IP arrangements. In the event of the company's dissolution, one company saw IP and liabilities returning to the university, with the other interpreting them as being taken on by larger customers who had incorporated N's proprietary technology in their mobile devices, textiles etc.

7.4 Stakeholder engagement

Generally and for the most part, both private and public sector interviewees (with some exceptions, mainly in the public sphere) saw the role of CSR in terms of risk minimisation, "do no harm". It is here that the problem of ELSI, the economic, legal and social impacts, of emerging technologies and the proper place of these considerations in the activities of companies becomes relevant. As one interviewee noted,

> *the question is: what is the purpose of regulation? And I think […] that, in the debate, that fundamental question is often lost and my view of regulation is it's […] effectively society's willingness to accept risk (Company G).*

As recent studies (e.g. Gavelin, Wilson et al., 2007) of the various upstream public engagement exercises undertaken in response to the Government's *Outline Programme for Public Engagement on Nanotechnologies* suggest, one dimension of public concern, which may have a significant affect on acceptance of technologies (as it arguably did with GM: see Kearnes, Grove-White et al. 2006), is the extent to which uncertainty is openly discussed in relation to both the risks and benefits of emerging technologies. If regulation reflects societal acceptance of risk, then it may also be thought of as representing society's acceptance of persistent uncertainty also. These persistent uncertainties may, over time, crystallise around technologies and not just individual products, due to various factors which may include but are not necessarily reducible to CSO advocacy activities (see e.g. Kearnes and Wynne 2007).

In this light, there is perhaps a significant disconnect between the observation made by several participants in the roundtable Scenarios Exercise, that latent health and environmental impacts of new technologies (not products) may, in any event, be unforeseeable, and the views of stakeholder engagement held by the majority of public and private sector interviewees, as summarised in Section 3 above. These views can be seen as a reflection of the drivers and inhibitors discussed previously, in so far as they

represent wider stakeholder engagement as difficult and costly, but also often as a necessary means of communicating benefits of specific products (as opposed to technologies) to consumers. Treating stakeholder engagement as, primarily, a means of communicating certainties may reflect assumptions about how best to minimise business risk *and* societal risk – by getting across "the facts" about products. But upstream engagement has, as one of its aims, transparent discussion about uncertainty and how it can be managed and responded to.

8. Conclusions and Recommendations

8.1 Conclusions: Current Scope of CSR

There are several key conclusions to be drawn regarding the current scope of CSR in the nanotechnologies industry, which indicate both strengths in the industry as well as significant gaps in practice:

- The UK industry remains in an early stage of development, with progress very uneven across different sectors. Some commercialisation of products is evident in fields like medical diagnostics and electronics, but most production of novel materials is still for industrial R&D. The scope of individual companies' CSR activities is therefore significantly affected by their size and the degree of commercialisation in their sector.
- Two key areas where size and sector make a particularly significant difference are in stakeholder engagement and CSR reporting:
    - Wide stakeholder engagement is not widely undertaken by smaller companies. Further, companies also have mixed opinions about its value: some see wide engagement as a valuable means of ensuring public acceptance of nanotechnological products. Others see it as an expensive and in the last instance unnecessary activity, as the market is seen as being a more reliable mechanism for ensuring products with demonstrable benefits are successful.
    - Public documentation and reporting of activities is very low among smaller companies.
- Most companies interviewed are highly engaged with precautionary approaches to risk in the workplace, driven by existing regulations.
- Assessment of risks at other stages in the lifecycle is highly variable, and its extent is dependent on several factors: company size, data gaps, difficulties with risk assessment methodologies, costs, availability of specialist expertise, and the extent of business collaboration in producing and collating data.
- A wider sample of companies would be necessary to fully assess how far these issues affect different sectors, but it is evident that outside large companies, lifecycle risk management faces serious obstacles, and that the problem of orphan products is perhaps not being widely addressed.

8.2: Recommendations: Future Scope of CSR

1) Promote an effective industry code of conduct: to assist in overcoming regulatory uncertainty, the promotion of an effective code of conduct (which provides both high-level and concrete guidance on how to address areas of material CSR concern) is essential. This is necessary in order to avoid the potential for competition between different codes of conduct in the near future. Forms that such promotional activity might take might include:

- Setting out requirements that any such code should include (both in procedural terms, e.g. being developed by multiple stakeholders, and substantive terms, e.g. to include reporting requirements, regular external auditing, adoption of proactive and systematic models of stakeholder engagement);
- Promoting being benchmarked against the code as a condition which suppliers of goods and services to public organisations should meet; and
- Focusing on encouraging adoption by larger companies in order to exploit their supply-chain influence on smaller companies.

2) Facilitate access to CSR and wider technical expertise: it is essential that benchmarking against any such code should be adequately incentivised for smaller companies, with access to regulatory information, CSR consultancy expertise, toxicological/risk management expertise, and possibly financial assistance. Bodies such as NanoKTN could conceivably play a key role in encouraging the sharing of expertise.

3) Encourage sectoral differentiation: the development of principles and guidelines to make a code of conduct a concrete source of guidance for different sectors should be pursued, which may require the setting-up of sector-specific working groups to allow guidance to "crystallise" in forms suited to the specific conditions which obtain in different sectors (a recommendation which was also made by participants in the Roundtable Exercise). Companies who have already developed, or are developing positive models of CSR and/or technical risk assessment and management expertise should be used to energise activity.

4) Encourage sharing of CSR expertise within existing supply chains: it is not only pressure to be benchmarked against codes of conduct that should be exploited by regulators. Transfer of CSR knowledge and experience down the supply chain, with sharing of resources, should also be encouraged. Exemplar models of practice should be formulated.

Beyond these recommendations, however, wider questions should perhaps still remain very much on the agenda for regulators. The degree of involvement in and reporting on CSR activity is highly variable, as suggested in this report, and dependent on interactions between a range of drivers and inhibitors. Does it therefore make sense to conceptualise a more responsible future as one in which more and more companies adopt CSR policies, gradually adopting high-level value commitments which are realised in specific policies and assessed against quantifiable performance targets?

Which model?

Is it enough for emerging technologies companies to seek to "do no harm"?

According to this view, more effective voluntary regulation requires incremental improvements in different areas of CSR concern to close CSR gaps. But even if these gaps are closed, it is possible that such a view would be seriously mistaken. We stated earlier (see p. 8 above) that business' own understandings of CSR tend to fall somewhere on a continuum between "do no harm" and adding "positive social value". To assess the future contribution which CSR may make to regulating nanotechnologies, it is also necessary to ask which kind of CSR we will get, if incremental improvements go on being made, and what kind emerging technologies might need.

This point is particularly pertinent with respect to how best to address public concerns (which may as yet be at a low level, based on recent research on public awareness of NST). If effective regulation of emerging technologies involves building consensus about what kinds of risks and uncertainties society is prepared to accept, then it may be asked whether enacting policies that reinforce the assumption that CSR is about "minimising risk" may be for the best.

Annexes

Annex 1: Literature Review

Introduction

> *At this point in time, the assessment of the social, juridical and ethical consequences of nanotechnology relies more on hypothetical or even speculative assumptions than on rigorous scientific analysis. (Renn and Roco 2006, 154)*

Governments have responded to the rapid development of nanoscale science and technology (hereafter NST) by proposing a variety of regulatory approaches. The major difficulty they face is how to develop an adequate and proactive regulatory approach for highly uncertain risks, in situations where strong scientific evidence of risks is not available, although plausible risk scenarios may be (Hansson 2004). A proactive approach, which promotes *ex ante* responsibility for managing and mitigating uncertain risks, is arguably not built into either traditional risk regulation, or the precautionary approach that is currently built into EU law. The reactive nature of traditional risk regulation may trap regulators in a "vicious spiral" of being unable to regulate while waiting for evidence of risk to arrive (Dorbeck-Jung 2007, 268-9). At the same time, the standard precautionary approach is itself dependent on scientific evidence, and cannot protect against risks of which we are ignorant (Marchant 2003, 1800). Given that a proactive approach presents regulators with these difficulties, the promotion of voluntary regulation and corporate social responsibility (hereafter CSR), based on measures such as codes of conduct, promulgation of best practice, and data-sharing, has come to form part of the approach advocated by the US, UK and German governments, along with the European Commission. The aim is to produce a system which is both flexible and efficient at gathering information, as well as fostering a "culture of responsibility" (European Commission 2008a, 7)

In this review, we survey the areas of uncertainty with which any regulatory system will have to cope. These comprise both the potential risks of current applications of NST on human health and the environment, and the possible consequences of future applications which may become possible as the technology develops. Importantly, the uncertainties faced by regulators are not just a matter of "data gaps" which affect our understanding of e.g. the toxicological properties of current nanomaterials; they also arguably derive from "moral gaps" which are opened up by the potential economic and social consequences of NST research (Dorbeck-Jung 2007, 267). We then end with a brief survey of how the regulatory context in the European Union, United Kingdom and United States contains provisions for voluntary regulation, before going on to examine corporate social responsibility criteria which are germane to NST applications, and how current international and national CSR frameworks articulate some of these general criteria.

Future Potential: Uncertain Benefits and Risks

In deciding what regulatory approaches might be best suited to oversee the development of nanotechnologies, it is necessary to weigh visions of the potential benefits which may flow it against anticipations of the risks which may result (Wolfson 2003). However, the keyword here is "anticipation". Manipulating matter at the nanoscale exploits the novel properties which particles and structures with at least one dimension of at most a few hundred

nanometres can have. But these novel properties, and how they might be exploited in the future, are by their very nature the source of much uncertainty and ignorance (Swiss Re 2004; Nel, Xia et al. 2006, 622-3). Many properties are thus ambivalent or ambiguous in terms of their potential for risk (Renn and Roco 2006, 163-4; Swierstra and Rip 2007, 17). At the moment, much of nanotechnological research concerns what has been called "passive" technology (Roco 2004), generally involving the engineering of particles in order to produce novel material structures and compounds, including for example carbon nanotubes, quantum dots, and nanoscale metal oxides, which can then be incorporated into other applications and products (Allianz 2007, 28-9). In the future, it is postulated that the skills and knowledge gained through the early development of nanotechnology will lead to radical innovations in the creation of complex nanostructures, which will in turn enable systems incorporating numerous individual nanoengineered components to be built (Renn and Roco 2006, 156-7). The potential of such developments for revolutionising materials science, computing, environmental management, medicine and other fields is seen as immense (Anton, Silberglitt et al. 2001). Nanotechnology is often represented as a technology that could enable other existing approaches to engineering (including information technology and biotechnology) to converge, with far-reaching results (Bainbridge 2007).

Whether such expectations about future generations of nanotechnological evolution can be fulfilled is highly uncertain, and will depend upon scientific developments and wider social conditions which are entirely unpredictable from the standpoint of the present (Keiper 2007). Concerns about the potential negative economic, social and ethical consequences of future innovations have nevertheless been widely articulated in response to the continuing development of "first wave" nanotechnology, and have included the impact of advanced nanotechnology on the economies of developing countries (Correa 2005; ETC Group 2005; Hunt 2006), the possible impact of technological convergence on accepted definitions of human nature (de S. Cameron 2006), and the development of new generations of nanotechnological weaponry (Gatti and Montanari 2008), as well as the now-familiar (and widely discredited) apocalyptic scenarios of biospheric destruction ("grey/green goo") (Joy 2000; ETC Group 2003).

Some suggestions about potential regulatory responses to the uncertain futures of nanotechnology have proposed dealing with such concerns directly as a necessary element of risk management (International Risk Governance Council 2006), and as a means of securing the social acceptability of NST research into an uncertain future (Siegrist, Keller et al. 2007). The possibility of "concern assessment" (as opposed to traditional "risk assessment") in the face of novel technological development has emerged against a background of new interest from government, industry and commentators in the potential of stakeholder engagement for allowing social concerns and ethical debate to be publicly articulated (Renn and Roco 2006, 177; Gavelin, Wilson et al. 2007).

However, regulatory responses to the *current* uses of nanotechnology have themselves to deal with conditions which, over ten years since the founding of the US National Nanotechnology Initiative, are still characterised by widespread scientific uncertainty and ignorance about the potential risks of current nanotechnology applications (Bijker, de Beaufort et al. 2007). In toxicology, characterising the risk of a given substance generally requires a thorough description of its hazards and the potential for exposure of humans (and other organisms) to these hazards. Current uncertainty about risk is generated by a continuing lack of knowledge in both these areas. We now move to examine some of the areas of uncertainty and ignorance

which hamper the application of traditional risk assessment and management approaches to current NST developments.

Nanotechnology hazards: the status quo of current knowledge

Human health

There is no way to establish in some *general* way what the hazards associated with nanoparticles of different elements are. When particles of familiar elements such as aluminium and carbon are engineered at the nanoscale, it is true that some characteristic changes in properties are shared by nanoparticles of different elements, such as larger surface to volume ratios and changes in surface conductivity. It is also true that physical properties like these (as opposed to chemical ones) are seen as crucial in determining whether or not a particular nanomaterial is hazardous (Chatterjee 2008, 342). However, the specific variations in such properties across different nanomaterials, and in the ways in which these materials may interact with the environments in which they are employed, may be such that characterisation of hazards is not possible until a nanomaterial is made and used in a particular context (Uskokovic 2007, 46) or deployed in a particular environment (Klaine, Alvarez et al. 2008), as it is often interactions between ambient properties (such as the biological properties of the pulmonary or digestive system) with those of the nanomaterials in question that produce unforeseen outcomes. Further, any harmful effects produced by these complex interactions may only emerge over a long period of time. Finally, the properties which may cause problems tend to be ones which are not usually considered in toxicological testing regimes (Oberdorster, Maynard et al. 2005) and the amounts of nanomaterials which are ingested may be so small as to make measurement difficult (Englert 2007).

This means that describing the health hazards associated with even a single material is difficult. Take single-walled carbon nanotubes (SWNTs) as an example. SWNTs are widely used in a variety of applications, notably in sports goods such as tennis rackets for their high tensile strength and in electronics applications for their high conductivity. They are expected to become one of the most widely used products of the first wave of nanotechnology (Besley, Kramer et al. 2008). However, a growing number of studies have indicated that introduction of SWNTs into the body (particularly the lungs) can cause damage like that produced by asbestos fibres. Some have also suggested, however, that this effect may only be produced by longer SWNTs, and not by shorter ones (Donaldson, Poland et al. 2008).

Other notable hazards which have been indicated by animal studies have been the possibility of cell damage resulting from phenomena such as oxidative stress (Oberdorster 2004). However, there is as yet almost no dose-response data on such hazards (UK Government 2006, 42), and data on long-term hazards will have to wait until currently ongoing *in vitro* and *in vivo* studies (Thomas and Sayre 2005; IRGC 2006, 22-3) are completed. The importance of understanding the parameters which govern how NSPs can interact with the human body over time is vitally important given the strong possibility that some nanomaterials will not be expunged by the body's natural defences and may bioaccumulate over time (European Commission 2004, 18; SCENHIR 2006, 50). However, studies on bioaccumulation are still not far advanced (Allianz 2007, 4).

Environmental

Calls for greater priority to be accorded to ecotoxicological studies have repeatedly been made by commentators and government advisors over the last few years (NSTC 2006, 31-2; UK Government 2006, 88), in response to indications that the level of knowledge on the

potential environmental fates and ecological effects of nanomaterials has been even lower than on their possible effects on human health (Krug 2005). Questions have been raised about the levels of funding given to studies on ecological risks: for example, Service (2004, 1734) notes that the US National Nanotechnology Initiative claimed in 2004 that 11% of research funding was spent on environmental studies, but that in fact the majority of this money went on research into potential environmental applications of nanomaterials, not on toxicological studies of existing materials. Despite greater efforts being made in this area, knowledge remains piecemeal (Lubick 2008, 1821-2).

The priority of improving ecotoxicological knowledge is underlined by the need to understand what environmental fates are possible for easily-transportable nanomaterials (Kuzma 2007, 1087), which requires that their behaviour both in solution and as colloids should be understood (Klaine, Alvarez et al. 2008). It is also vital because of the variety of potential hazards which are beginning to be indicated by research. Much of this research has concentrated on the dangers which maybe posed to key aquatic species, such as daphnia and fish (Oberdorster 2004; Blaise, Gagne et al. 2008), although the significance of some earlier studies has been subject to debate (Stern and McNeil 2008, 15). However, numerous other lines of work have been opened up: some NSPs have been shown to inhibit root growth in plants (Hannah and Thompson 2008, 296), can bind pollutants in ways that alter their bioavailability, bioaccumulation and movement (Sutherland, Bailey et al. 2008, 823), and may be harmful to important soil microorganisms (Klaine, Alvarez et al. 2008, 1842-4).

Nanotechnology exposure: an overview

In characterising the potential risks posed by nanomaterials, the second key aspect after hazard is the degree to which human and environmental exposure may occur, and through what mechanisms of transport this exposure could happen. Nanoparticles could gain entry into the human body via a number of routes, including ingestion, inhalation and absorption through the skin (Hoet, Bruske-Hohfeld et al. 2004; Nel, Xia et al. 2006, 624-5). Research is continuing on the various pathways that free nanomaterials may take through the atmosphere and through aquatic and terrestrial environments, if released through e.g. a research laboratory accident or through product disposal.

As noted above, the properties of nanomaterials can vary depending on how they are produced and used. Exposure pathways can also vary throughout a nanoproduct's lifecycle, from manufacturing through use to disposal (Donaldson, Stone et al. 2004). The likelihood of exposure can be assessed using tools such as life cycle analysis (LCA). However, no LCAs for nanomaterials conforming to the relevant ISO standards have so far been produced (Bauer, Buchgeister et al. 2008, 912), with one reason being that data gaps concerning the nature of specific hazards affect our understanding of what possible exposure routes may exist at the various stages of a product's life (Aitken, Chaudhry et al. 2006, 305-6).

Toxicological research therefore continues to investigate whether or not workers, consumers and the environment may become exposed to free nanomaterials during, respectively, the manufacturing, use and disposal of free nanomaterials. For example, the potential for workers being exposed through inhalation to e.g. carbon nanotubes during the manufacture of either the nanotubes themselves or products incorporating them has been of great concern (Stern and McNeil 2008, 6), and to date has constituted one of the main areas of NST health risk research (Donaldson, Aitken et al. 2006). However, because of the knowledge gaps concerning hazards discussed in the previous section, to date, risk assessments on nanomaterial manufacturing processes have only been able to concentrate on the risks

attendant on the manufacturing processes themselves, not on the risks of exposure to specific nanomaterials themselves (Robichaud, Tanzil et al. 2005).

Use and consumption of nanomaterials brings with it a different set of concerns. As more and more nano-enabled products enter the market across different sectors (Brumfiel 2006), research is beginning to focus on the more widely used materials that are being incorporated into consumer items, such as nanosilver (Chen and Schluesener 2008; Friends of the Earth 2008, 27; Luoma 2008), as well as carbon nanotubes (Köhler, Som et al. 2008). As medical use of nanomaterials increases, questions surrounding the routes taken by nanoparticles through the body and their eventual fates will become more urgent. Research on these pathways and the kinetic properties of nanoparticles more generally remains scanty (Hagens, Oomen et al. 2007). Dermal exposure, through the use of e.g. TiO_2 in sunscreens, has also been investigated (Schulz, Hohenberg et al. 2002), with some studies showing that the typical size of metal oxide nanoparticles makes such a source of exposure unlikely (Nohynek, Dufour et al. 2008). As well as exposure to nanomaterials such as quantum dots through medical uses such as in drug delivery (Chan 2006), future research will need to examine the use of nanomaterials in food, which promises to become widespread (Chau, Wu et al. 2007; Chaudhry, Scotter et al. 2008; Friends of the Earth 2008).

The potential for migration of nanomaterials during use or disposal makes the transport and fate of potentially persistent materials such as nanotubes and metal oxides being a particular focus. Among the key anticipated environmental applications of nanomaterials are water purification (Bellobono, Morazzoni et al. 2005; Savage and Diallo 2006), pollution abatement and environmental remediation using e.g. iron nanoparticles (Zhang 2003), sensing of pollutants, pH and chemical warfare agents, oil-water separation, and the destruction of bacteria (including anthrax) (Theodore and Kunz 2005). The potential of such applications for releasing free nanoparticles and nanostructures into the environment necessitates extensive research on their potential for transport particularly through aquatic and terrestrial media. As a result, the potential for exposure of key aquatic species to nanotubes, fullerenes and metal oxides has been the subject of a number of studies (e.g. Cheng and Cheng 2005; Lovern and Klaper 2006; Blaise, Gagne et al. 2008). The potential for exposure of key species is even less well researched in relation to the foundations of ecosystems. Studies on soil microbes (critical for the health of terrestrial ecosystems) have suggested that nanomaterials could have serious effects (Throback, Johansson et al. 2007), but are few and far between, while studies on microbes within marine sediments and on marine invertebrates are nearly entirely lacking (Klaine, Alvarez et al. 2008, 1841).

Further, a key research need which threatens to hamper work into human and environmental exposure scenarios is for new instrumentation and testing methods which can detect nanoparticles distributed within real-world environments (Maynard, Aitken et al. 2006; Englert 2007).

Regulatory Responses: Making Room for Voluntarism

Being clear about the extent to which the current situation is characterised by uncertainty and ignorance, as well as clear risk, is vital to framing regulatory action. The International Risk Governance Council (IRGC) has suggested in an influential white paper that four categories of risk can usefully be applied in understanding the potential hazards posed by NST: simple, complex, uncertain and ambiguous (IRGC 2006). A subsequent report stressed that the present generation of mainly passive nanomaterials may pose at most complex risks, with

future generations of NST development (leading e.g. to the manufacture of active nanostructures and their incorporation in living systems) may create situations where the effects of using nanomaterials are highly uncertain or ambiguous (Renn and Roco 2006), both in terms of their toxicological impacts and their broader social consequences (for example, in the sphere of human enhancement). The assurance that further risk research will lead in the near term to sufficient characterisation of nanomaterial hazards has been criticised, however, on the grounds that the limitations of knowledge in the present, especially regarding the toxicological effects of persistent nanomaterials in the long-term through mechanisms such as bioaccumulation, make some of the more serious potential risks very uncertain indeed (Bijker, de Beaufort et al. 2007, 1218-19).

Calls for pre-emptive regulatory action have been widespread, and have varied enormously in the scope of action advocated. Some have called for moratoria on the production and release of nanomaterials (ETC Group 2003). Other commentators have called for voluntary precautionary measures on the part of researchers and industry to limit exposure, particularly of workers engaged in NST research and manufacturing, and particularly where nanotubes are produced (Mills and Fledderman 2005, 21; Köhler, Som et al. 2008). The Royal Society and Royal Academy of Engineering (RS/RAEng) report on the risks of NST (RS/RAEng 2004) proposed that nanomaterials should be regulated in a precautionary manner as novel chemicals, and that free nanoparticles should be removed from waste streams to limit environmental exposure. The question of whether nanomaterials are "substantially equivalent" to bulk forms of the same chemical remains a key question to which reviews of regulatory responses in different national jurisdictions have drawn attention (e.g. RS/RAEng 2004, 86; Ludlow, Bowman et al. 2007). The pertinence of this issue is marked, as various reviews of the literature (e.g. Uskokovic 2007, 53) and studies of current regulatory approaches (e.g. Franco, Hansen et al. 2007, 176) stress that case-by-case assessment of nano- and bulk versions of chemically identical materials have often demonstrated substantial differences between the two types, and that these differences can often be shown to be vitally important in determining how to manage risks. It can be argued, therefore, that a key requirement of regulatory responses is how to mobilise data-gathering on nanomaterials toxicology across the industrial and academic sectors where NST is developing, and how to use this data to produce best practice guidelines with respect to risk assessment and risk management. Further, to maximise the public acceptability of NST research, wide stakeholder engagement has been promoted. To fulfil all these requirements, several governments are encouraging industry and academia to develop flagship voluntary initiatives.

Governmental Responses

We now provide a necessarily brief survey of responses at the government level from the UK, EU and USA to the risks and uncertainties surrounding NST. A common theme across jurisdictions has been an incremental, step-by-step approach to the regulation of nanomaterials, concentrating on already defined exposure scenarios (e.g. in the workplace), utilising current regulations as much as possible, and avoiding blanket regulation across what is largely felt to be a difficult to define technological sector. Linking these approaches with effective transnational regulatory models (Marchant and Sylvester 2006), backed by comprehensive international databases of nanomaterials (Put 2004, 120; Allianz 2007, 36) is crucially important, with international product standards offering one regulatory model which could facilitate further development (Lee and Jose 2008, 117). The role of industry in the interim as a partner in helping to promote voluntary forms of regulation and in taking proactive precautionary action where necessary has also been emphasised. We briefly survey in section 5.ii the prospects for the development of voluntary regulation, before going on in

section 6 to look at some general CSR criteria which voluntary frameworks should incorporate, and in section 7 at how some extant examples of such frameworks embody these critieria.

European Union

In the EU, an incremental testing and regulatory programme (EC 2004, 23-4) is currently favoured. Part of this approach is to encourage industry to pursue stakeholder dialogue, build in life cycle risk assessment, and to take into account the wider impacts of its activities in line with CSR criteria (EC 2005). In order for this approach to work, however, commentators have argued that a number of modifications to the existing regime should be made (Franco, Hansen et al. 2007, 180-2): occupational exposure be limited as far as possible, free NSPs should be treated as inherently hazardous until shown otherwise and possible treated as new substances under REACh even if not produced in sufficient quantities to trigger assessment. Franco et al. also point out that for an incremental approach to work, more LCA analysis must be done, which requires overcoming the tendency for manufacturers to avoid disclosing product data. Recognising that crucial knowledge gaps and resultant research needs exist in the key areas discussed above, a report for the European Commission (EC 2008b) has suggested that existing regulation should nevertheless be able to cope with NST development for the moment.

United Kingdom

The UK Government agreed with the RS/RAEng that nanoparticles should be removed from waste streams and that their novel properties mean that they should require special testing (UK Government 2005b, 5-7). They also agreed with the RS/RAEng's conclusion (2004, 77) that a general moratorium on NST research would be inappropriate, and that a case-by-case, incremental approach would be required (UK Government 2005b; 2008a). In order to obtain more information on the scope of current nanomaterials production and to allow for the creation of lifecycle profiles, a voluntary reporting scheme was announced in 2006 by DEFRA (UK Government 2008b). The Government has also developed a framework for coordinating research funding to address outstanding research needs in metrology, hazard characterisation and exposure studies, as well as on the wider social and economic impacts of NST (UK Government 2007). Its commitment to extending public participation in addressing future NST development was initially articulated in 2005 (UK Government 2005a), with the initial result being a series of activities undertaken under the aegis of the Nanotechnology Engagement Group or NEG (Gavelin, Wilson et al. 2007).

United States

The EPA ruled in July 2008 that nanoparticles should be considered substantially equivalent to bulk forms of the same element, despite the continuing debate over whether it is the physical or the chemical properties of a given element that decide the risk potential of its nanoscale form (Chatterjee 2008, 342). The EPA's voluntary reporting programme, inspired by the UK's initiative, aims to fill existing data gaps on the potential hazards emerging within the life-cycle of individual nanomaterials, and is running alongside a programme of research aimed at addressing outstanding risk research needs (NSTC 2006). As with other jurisdictions, the USA has avoided a sector-specific set of new regulations. In this environment, it has been suggested that the regulatory approach in the USA may be pushed ahead by individual states taking responsibility for "end-of-pipe" regulatory measures in the absence of any proactive lead from the federal government (Powell, Griffin et al. 2008).

Voluntary Prospects

The various national and regional jurisdictions are also pursuing the possibility of voluntary regulation as a way of responding to ongoing uncertainty. Ongoing initiatives include voluntary reporting schemes to collect information from industry on existing uses of nanomaterials in the UK (UK Government 2008b) and the USA (Environmental Protection Agency 2008), together with the collaborative framework for dealing with risk developed between the NGO Environmental Defence and DuPont (EDF - DuPont 2007), all which emphasis the need to collect data to form lifecycle profiles of the risks of specific nanomaterials. The Royal Society, Insight Investment and the Nanotechnology KTN have set up a working group called Responsible NanoCode, to produce a principles-based code of conduct for the industry that stresses the need for effective and comprehensive risk assessment, wide stakeholder engagement, and transparency (Responsible NanoCode 2008). The German Chemical Industries Association (VCI) has published a set of guidelines to help companies understand the responsibilities pertaining to nanomaterials under the EU's new REACh regulations (VCI 2008).

However, voluntary approaches will have to overcome difficulties, with some commentators arguing that they do not lead to high-quality data unless they include effective incentives, are properly transparent, and are made mandatory after an introductory period of some years (Hansen and Tickner 2007). Whether there is currently any great appetite across the nanotechnologies industry for collaboratively developing frameworks of best practice is difficult to determine on the basis of existing research.

For example, a recent survey of 40 companies in Germany and Austria manufacturing nanomaterials and/or products containing nanomaterials originating with others indicated a near complete lack of any voluntary risk management framework for nanomaterials (Helland, Scheringer et al. 2008), with 30 of the 40 reporting that they did not actively investigate the possibility of human or environmental exposure of the materials they produced or used (ibid., 642). Similarly, a brief survey of 11 large companies from the chemical and consumer goods sectors conducted as an adjunct to the EU-funded Nanologue project found that only 3 had specific NST-related corporate social responsibility policies, and that both stakeholder dialogue and transparency were broadly lacking (Turk 2007).

Corporate Social Responsibility – General Criteria

For any business CSR is about balancing the need to make a profit with the need to be socially and environmentally responsible. CSR is a means for a company to proactively manage its impact on society and can provide opportunities for risk reduction and innovation. In its "Nanotechnology Action Plan" (EC 2005) the European Union stresses the importance of respecting ethical principles and integrating societal considerations into the development of nanotechnologies at every stage. Businesses need to take appropriate action to make use of opportunities and limit risks while involving and informing stakeholders. "CSR management also fosters innovation and risk reduction as stakeholders evaluate their own business activities and strategies and map out current and future requirements and concerns" (Schaller 2008).

The knowledge gaps which NST opens up provide space within which voluntary regulation may serve as a valuable way of putting flesh on the bones of a general commitment to precautionary handling of nanomaterials in workplaces, in the supply chain, and in the marketplace and beyond. Corporate social responsibility provides conceptual and practical

models for developing such a framework, with a view to promoting a culture of pro-active ethical responsibility within industry (Carroll 1991). The idea that to promote future-regarding corporate responsibility through a mixture of codes of conduct, best practice models and gradual acculturation is in line with arguments provided by some ethicists on the greater robustness of "virtue" or "care"-based theories of responsibility in the face of great technological uncertainty (e.g. Jamieson 1992; Keulartz, Schermer et al. 2004; Groves 2009).

Materiality

It is important for any industry to define and manage the most important CSR issues rather than take a general approach to identifying "material" issues. Given the complex and varied nature of the nanotechnology industry materiality will differ considerably from company to company. The industry has the opportunity to address material issues right at the beginning of developing CSR strategies. While the detail of which issues are material to each business will vary there are common concerns that the whole industry must address in any CSR strategy if it is to lead to any successful form of governance. Not all material CSR concerns are negative; a successful strategy should balance the potential gains from nanotechnology with careful assessment, mitigation and communication of risks.

Table 5: Negative and Positive Impacts of Key Material Issues

Material issue	Negative impacts	Positive impacts
Environmental Impacts	• Release of manufactured nanoparticles into the environment. • Life-cycle impacts of technology. • Problems at recycling and disposal phase. • Manufacture of nanoparticles could be energy and resource intensive.	• Efficiency gains in production due to cleaner manufacture and less resource use. • Nanotechnology-based environmental technology applications.
Human health	• Scientific uncertainty regarding the behaviour of nanoparticles in the human body.	• Opportunity for disease prevention (e.g. improved food safety).
Privacy/human rights	• Collection of increasingly sensitive data likely to raise questions about information provenance and distribution. • Concern for civil liberties from increasingly advanced surveillance capabilities.	
Access	• Fears that the developing world will not have good access to nanotechnology due to prohibitive costs. • Divide between the rich and the poor as only the rich can afford to take advantage of e.g. high-end medical applications.	• Potential to tackle environmental and health issues in the developing world. • Poverty alleviation?

Acceptance/understanding	• Little understanding/awareness in general public about nanotechnology and its potential impacts. • Concerns expressed regarding governance structures and corporate transparency.	• CSR can be used as a powerful communicative tool to improve understanding and acceptance.
Liability	• Difficult to establish a causal relationship between the actions of a company and the resulting impact. • Concern that liability frameworks are currently insufficient for the regulation of nanotechnologies. • Risk that nanotechnology may develop outside regulatory control.	• CSR may be able to bridge some of the gaps in legislation. • CSR as an enabler of innovation.

Stakeholder Engagement

It has become widely recognised that businesses are deeply enmeshed within various social networks, members of which can indirectly or directly affect or be affected by a company's operations. Voluntary strategies for proactively managing relationships with these "stakeholders" have been represented as advantageous to both business and society (Donaldson and Preston 1995), both in terms of increasing the social legitimacy of business and in accessing information which may be germane to a company's operations. In particular, good stakeholder relationships are seen as crucial in anticipating and managing conflict through negotiated solutions, thus obviating the possibility that a conflict may have to be settled through external agencies, such as the courts or government agencies (Freeman 1984). It has been argued that the practicality and clarity of stakeholder management-based understandings of CSR are extremely useful for promoting CSR to managers (Jamali 2008).

The need for businesses to pursue social engagement activities in the context of technological innovation (Wilsdon and Willis 2004) has been particularly stressed with regard to NST development (Kearnes, Macnaghten et al. 2006; Pidgeon and Rodgers-Hayden 2007), with the hope of learning lessons from the failures of public engagement surrounding GMOs and biotechnology in the 1990s (Barnett, Carr et al. 2006; Einsiedel and Goldenberg 2006). Munshi et al. (2007) identify 8 nodes of discussion or "stakeholder groups" that have been central to the development of dialogue around NST, but also note that "most discussions on this subject are not multidimensional, multidisciplinary, or fully open" (433). These key stakeholders are:

1. Technoscientists
2. Leaders of business and industry
3. Official or quasi-official bodies
4. Social science and humanities researchers
5. Fiction writers
6. Political activists
7. Science journalists and popular science writers
8. General public

Munshi et al. raise a number of key points that have a bearing on the development of CSR in the nanotechnology industry. Firstly, there is much definitional variation surrounding NST. Given that defining CSR is also a contentious issue the addition of another complicated layer of discourse to the CSR debate may prove problematic. There is a general lack of societal debate on the social implications of NST (Dunkley 2004), which leaves the social aspects underrepresented. This is compounded by the fact that discourse on the social, economic, legal and ethical implications of NST among social science and humanities researchers is in a very early stage of development. Munshi et al. (2007, 439) note that "[…] researchers have not produced literature yet, nor have they coalesced into functioning research communities".

Political activists and NGOs (so crucial to the endorsement or criticism of CSR) are wary of NST developments and have tended to take a negative stance. However, some activists have recognized that NST offers both potential benefits and risks and have called for the application of the precautionary principle as a way of managing nanotechnology (Montague 2004).

Like GM foods and bio-technology, NST has the potential to produce fear and confusion in the general public, particularly with regards to environmental and human health issues. There is a "lack of trust in business leaders to minimize nanotechnology risks to human health" (Cobb & Macoubrie 2004). The main problem at the moment is that there is a lack of awareness in the general public of what NST is and what the future holds in this area "few individuals are aware of this new science as the entire field…is a well-kept secret" (Dunkley 2004). Munshi et al. (2007) contend that it is businesses that need to convince the public of the benefits of nanotechnology; one way to do this is through CSR.

Munshi et al. (2007) raise two further points of interest. First, "[…]the power to define what is or is not nanotechnology rests with technoscientists […] It is this very power that privileges the technological aspects of a little-understood field over the social and cultural aspects" (p. 446). Crucially for CSR, "[i]t is in acknowledging social and cultural rationalities alongside technical and economic ones that policy makers can make the use of new technologies more equitable and socially and environmentally sustainable" (447).

CSR and Risk Management

The idea that CSR can be used as a means of reducing business risk is not a new one (see Wood 1991; Orlitzky & Benjamin 2001). Businesses with proactive CSR engage in managerial practices like environmental assessment and stakeholder management (Wood 1991) that tend to anticipate and reduce potential sources of business risk, such as potential governmental regulation, labour unrest, or environmental damage (Orlitzky and Benjamin 2001).

Husted (2005) offers a "real options" concept of risk management that could potentially be of benefit to an industry where the risks are both significant and also frequently unknown, and where "strategic adaptation by skilful, rigorous, and continuous management of unsystematic (business) risk lies at the very heart of strategic management" (Bettis 1983). Husted (2005: 176) argues that "[a]s a real option, CSR projects provide a way of reducing the downside business risk of the firm and are thus an essential element in the risk management of the corporation". CSR involves business decisions about the allocation of resources "careful analysis of the costs and benefits of CSR projects in terms of cash flows, using traditional techniques of valuation, often leads to the decision to forego such investments" (McWilliams

and Siegel 2001). However, in undertaking traditional cost-benefit analysis businesses often fail to take into account the value of strategic flexibility that certain CSR investments may create.

> *Options quite simply confer "preferential access to future opportunities". Real options include both the option to undertake activities or to acquire. They allow a person or a firm to defer a decision to commit resources until after the nature of an uncertain environment has revealed itself. If future conditions turn out to be poor, then decision makers can stop investment; if conditions turn out positively, investment may continue (Husted, 2005: 177).*

CSR may be used as an option to call upon the support and resources of stakeholders in times of crisis. A proactive CSR management system may provide a company with strategic flexibility that allows them not suffer too greatly when a risk is realized. Such strategic flexibility is crucial to the NST industry where so many of the risks are poorly understood; it could allow companies to take pre-emptive action.

Husted (2005) notes that CSR 'real options' may be divided into at least two kinds: "[d]irect benefits are derived from the creation of new products and services, which generate rents that are captured by the firm. Indirect benefits include the development of firm-specific assets that are of value to the firm, but require further steps in order to capture the rent potential of these assets. In the case of real CSR options with direct benefits, CSR may act as a vehicle for innovation, which may provide a test of a product or service before launching that product or service to a wider public" (Kanter 1999).

CSR and innovation

To be successful and innovative today, companies must consider the social and environmental impact of their operational processes, stimulate employees to be creative, and collaborate with their customers, suppliers and other business partners in designing and developing new products and services. The view that equates innovation exclusively with high technology and new products is slowly being abandoned and innovation is coming to be understood as a broad, continuous, systematic activity that takes place throughout the enterprise (Sawhney *et al.*, 2006; Hamel, 2006; Vila and MacGregor, 2007).

"Innovation is the process through which productive resources are developed and utilized to generate higher quality and/or lower cost products than had been previously available. […] [Innovation] requires the visualization of a range of potentialities that were previously hidden and that are now believed to be accessible. Thus, innovation strategy is in its essence, interpretative and therefore subjective, rather than 'rational' and objective."
(O'Sullivan, 2000: 393, 409)

The term "corporate social innovation" was first introduced by Kanter (1999: 125) who argues that companies should use social issues as a learning laboratory for identifying unmet needs and for developing solutions that create new markets. The term corporate social innovation can be defined as a way of "finding new products and services that meet not only the functional needs of consumers for tasty food or clean clothes but also their wider aspirations as citizens."(Patrick Cescau CEO of Unilever cited in Webb, 2007). Little explicit attention has been paid to the space or fit between CSR and innovation i.e. very few published works explicitly discuss CSR in conjunction with innovation (e.g., Midttun, 2007). Implicitly, however, much work in each of the general domains of CSR and innovation has overlapped, as in the case of sustainable development (Carpenter and White, 2004).

There are two types of innovation that may be driven by CSR:

1. Innovations aiming at social improvements (i.e. health, education, community development). Here the term social innovation can refer to product innovations with a social purpose.

Nanotechnology is widely recognised as a great opportunity for disease prevention (e.g. improved food safety); early disease detection (e.g. sensors for cancer detection) or medical treatment (e.g. controlled drug delivery by nanocapsules). There has also been considerable discussion about the potential benefits of nanotechnology in tackling issues affecting developing countries (Turk, 2007).

2. Environmental or eco- innovation at the heart of their work.

Sustainability innovations (also called eco-innovations, eco-design, eco-preneurship, or clean technology venturing) have been proposed as a source for "environmentally benign growth" (Dyllick, 1994: 60). Cleantech denotes new technology and related business models (such as CSR) offering competitive returns for investors and customers while providing solutions to global challenges through breakthrough product innovation (Hockerts & Morsing, 2008). Cleantech venturing is thus driven by two main forces: technology and competitiveness which are both superimposed on certain environmental or social problems in order to generate new ideas (*ibid.*). At present there is a strong belief that there will be environmental benefits from the introduction of nanotechnology and improvements could be delivered in the overall environmental performance of products through:

- efficiency gains in production due to miniaturization effects, e.g. cleaner manufacture with less emissions and less waste
- efficiency gains in use from the ability to build devices from the bottom up and improve efficiency and operation, e.g. better solar cells from molecular manufacturing
- nanotechnology-based environment technology applications, e.g. devices for waste water treatment (Turk, 2007).

Socially Responsible Design (SRD) (Davey *et al*., 2005) builds on existing design areas that overlap with areas of responsibility and sustainability such as Design for Environment, SRD takes an integrative approach to several existing design initiatives. The link with CSR is described as being the part of CSR that has an external focus; alternatively, SRD is described as “CSR in action”. A key message is that an understanding and implementation of design is necessary in order for companies to include CSR in the production of the products, processes, environments and services that create their image in the marketplace. The authors state that SRD “focuses attention on the products, environments, services and systems that can alleviate real world problems and improve quality of life.”

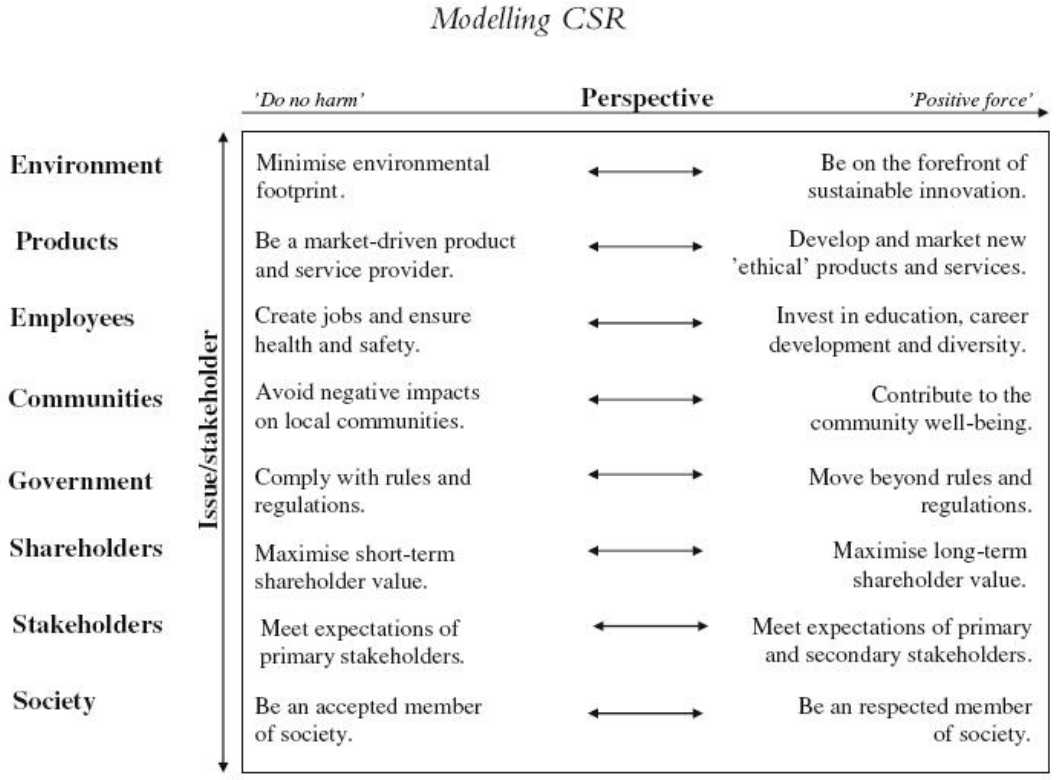
From the CSR point of view, interest has focused increasingly on certain corporate actions and processes where companies have no choice but to innovate on several levels, including products (where they have to satisfy the demand for socially responsible products) and processes (where they must pay attention to the implications of social responsibility across the whole supply chain) (MacGregor & Fontrodona, 2008).

However, as pointed out by Hockerts (2008), most companies remain focused on CSR as a tool to reduce risks and operational cost; only companies with very high social performance rankings think about CSR as a means to drive product innovation. Hockerts (*ibid.*) proposes that corporate social innovation requires the creation of knowledge structures that result from investments in corporate social performance. Blum-Kusterer and Hussain (2001) similarly find that regulation and technological progress are the two main drivers for sustainability innovations.

Conclusion

CSR is fundamentally about re-imagining the social contract between business and society. In order to understand and classify the pro-active activities of companies, it has been suggested that the CSR "imaginaries" (deeply embedded assumptions about the nature and limits of CSR) which underlie these activities should be mapped. Categorizing approaches to CSR, based on business' own interpretation of how it should deal with material CSR issues, has become one influential way of understanding to what extent CSR has penetrated a given industry, and with what emphasis. The recent EU-funded RESPONSE study has suggested (RESPONSE 2007), we could usefully consider two ways of thinking about the general orientation of a company's CSR activities. According to RESPONSE, companies can be placed somewhere on a continuum which has as its extremes contrasting CSR models: "Do No Harm" and "Positive Force". The first of these concentrates CSR activity on minimizing health and environmental risks – and with them, business risks. The second strives towards adding positive social value to the company's business activities in various ways. Examples of how these different approaches might play out across different material concerns are given below in Figure 6.

Figure 6: Social responsibilities as a continuum (Pedersen 2009)



Annex 2: CSR and Voluntary Initiatives: Current Transnational and National Frameworks Relevant to NST Development

Table 6: CSR and Voluntary Initiatives: Current Transnational and National Frameworks Relevant to NST Development

Transnational

Standard/Code of conduct	Description	Relevant principles
AccountAbility 1000 (http://www.accountability21.net/)	Launched in 1999, AA1000 is an accountability standard which specifies processes designed to improve accountability and performance through stakeholder engagement. It was developed to address the need for organisations to integrate their stakeholder engagement processes into daily activities.	AA1000 sees effective stakeholder engagement as being based on three principles: materiality (knowing which stakeholder concerns are important), completeness (understanding the meaning of these concerns) and responsiveness (responding effectively to concerns) (AccountAbility 2005, 27). It provides a comprehensive framework for planning and evaluating engagement activities which draws on these principles to construct an iterative process of planning, design, implementation and review. Stakeholders themselves should be included in evaluation and review processes (ibid. 49)
CENARIOS	TÜV SÜD's CENARIOS approach sets out general requirements for a company's overall risk management system.	Includes an adaptation of the typical risk matrix used in risk assessment (classifying risks according to seriousness of consequences and according to probability of risk event occurrence) which, given the lack of knowledge surrounding the probability of particular potential consequences of the introduction of an innovative technology, uses the seriousness of these consequences as the primary classificatory variable. Monitoring of information sources on product risk as the state of knowledge changes is included as a crucial ongoing part of the risk management system, recognising the extended temporal

		aspects of the risk management process. Features annual auditing to support award of accreditation, and established responsibilities of risk (TÜV SÜD GmbH 2008, 23) and production managers (TÜV SÜD GmbH 2008, 24) to ensure that processes and systems are continuously improved
DuPont and Environmental Defense Fund Nano Risk Framework (http://nanoriskframework.com/page.cfm?tagID=1095)	Agreed between a major MNC and a prominent NGO, this framework offers guidance on the key questions an organization should consider in developing NST applications. It allows users to address areas of incomplete or uncertain information by using reasonable assumptions and appropriate risk management practices. Further, it offers guidelines on how to generate information and iteratively update information as it becomes available, as well as offering guidance on how to communicate with stakeholders.	The framework offers a six-stage set of guidelines for risk assessment and management, designed for iterative use in the development of specific NST applications. The six stages cover the general description of the physic-chemical properties of nanomaterials, through life cycle profiling of potential hazards, evaluation of risks, assessment of risk management measures, organisational action (including the setting up of a process management structure), and ongoing review of progress.
European Commission Code of Conduct for Responsible Nanosciences and Nanotechnologies Research (http://ec.europa.eu/nanotechnology/pdf/nanocode-rec_pe0894c_en.pdf)	Published in 2008, this code of conduct is intended to provide EU member states and all stakeholders interested in NST with a set of guidelines that seek to promote responsible research. Member states are encouraged to use the code as the basis of concrete regulatory action, including encouraging voluntary regulatory measures within their jurisdictions.	Action by member states should encourage precautionary activity, together with forward thinking about potential future impacts of products, with the aim being the creation of a "general culture of responsibility" (EC 2008a, 7-8). A key priority of concern for states should be initiatives regarding the communication of benefits, risks and uncertainties related to NST research, and also measures designed to encourage private and public sector laboratories to share best practice concerning risk (with due respect for the protection of intellectual property).

Ethical Investment Research (EIRIS) (http://www.eiris.org/)	A not-for-profit organisation, EIRIS does not investigate companies' financial status but looks at their social, environmental and ethical policies and practices. It carries out independent research covering over 40 different areas including animal testing, military, environmental performance and human rights. Information from EIRIS is used in compiling the FTSE4Good Index Series (see below).	A comprehensive series of performance indicators used by EIRIS are provided in the document, *The State of Responsible Business* (Gordon 2007). These cover, for example, supply chain labour standards, supply chain systems, and monitoring and reporting of labour practices in the supply chain. These are based on the ILO Conventions, with basic and advanced scores being achievable depending on companies' degrees of commitment (ibid. 47-8. Environmental indicators are also provided, covering environmental policy, management systems, reporting and performance improvement (ibid. 55-6). The documentation also mentions NST as an emerging issues, noting that "[a] number of companies are involved in the research and marketing of nanotechnology products and, although some experts are warning of potential risks to health and the environment, confirmation of which could damage the reputation and value of such companies, it is clear that not all companies are reporting on how they manage such risks." (79)
FTSE4Good (http://www.ftse.com/ftse4good/index.jsp)	The FTSE4Good Index Series is a family of benchmark and tradable financial indices. FTSE4Good indices have been designed to measure the performance of companies that meet globally recognised corporate responsibility standards, and to facilitate investment in those companies. Uses the EIRIS framework.	Based on research from EIRIS (see above).
Global Reporting Initiative (http://www.globalreporting.org/Home)	The Global Reporting Initiative (GRI) is a multi-stakeholder process and independent institution whose mission is to develop and disseminate globally applicable guidelines for	The 2006 edition of GRI's *Sustainability Reporting Guidelines* states that they provide a framework which an organisation can use to show how it "influences and is influenced by expectations about sustainable development" (GRI 2006, 37-8)

	reporting by organisations on sustainability performance.	The guidelines set out several relevant reporting principles. They recommend that organizations should cover all significant sustainable development impacts (environmental, economic and social), and that reports should be inclusive of all stakeholders and responsive to their concerns. Processes of stakeholder engagement should be documented. As well as overall principles, the guidelines also provide a number of performance indicators concerning environmental impact, labour standards, social performance and responsibility for products. These should be addressed directly in reporting. *Environmental indicators* EN12 Description of significant impacts of activities, products, and services on biodiversity in protected areas and areas of high biodiversity value outside protected areas. EN14 Strategies, current actions, and future plans for managing impacts on biodiversity. EN22 Total weight of waste produced by type and disposal method. EN23 Total number and volume of significant spills. EN24 Weight of transported, imported, exported, or treated waste deemed hazardous under the terms of the Basel Convention Annex I, II, III, and VIII, and percentage of transported waste shipped internationally. *Labour practice indicators* LA8 Education, training, counselling, prevention, and risk-control programs should be in place to assist workforce members, their families, or community members regarding serious diseases.

		LA9 Health and safety topics should be covered in formal agreements with trade unions. *Social performance indicators* SO1 Includes reporting on the nature, scope, and effectiveness of any programs and practices that assess and manage the impacts of operations on communities. *Product responsibility indicators* PR1 Concerns life cycle assessment of health and safety impacts of products and services. PR2 Total number of incidents of non-compliance with regulations and voluntary codes concerning health and safety impacts of products and services during their life cycle, by type of outcomes.
Global Sullivan Principles (http://www.thesullivanfoundation.org/gsp/principles/gsp/default.asp)	The objectives of the Global Sullivan Principles are to support economic, social and political justice by companies where they do business, particularly with reference to the different dimensions of equality and tolerance. Organizations small and large are encouraged to endorse them. The GSP organization publicises case studies of best practice under the principles.	Relevant here are commitments to provide a safe and healthy workplace, to protect human health and the environment, and to promote sustainable development. The principles also commit endorsers to work with communities in which they do business to improve quality of life ("their educational, cultural, economic and social well-being"). Endorsers are also requested to encourage organizations with whom they do business to adopt and apply the principles.
International Council of Chemical Associations (ICCA) Responsible Care (http://www.responsiblecare.org/)	A long-standing code of conduct initiative from the chemical industry which began in Canada in 1985. The basic mechanism of the code is the adoption by companies of codes of conduct. Adherence to these codes allows organizations to sit on their country's	The basis of the initiative is a commitment to improving all aspects of health, safety and environmental performance in a company's activities, as well as establishing forms of open communication about its business with stakeholders. A key part of the RC initiative is the management systems-based guidelines on Product Stewardship, adopted in December 2007

	Responsible Care council.	(ICCA 2007). Adherence to Responsible Care commits companies to developing indicators against which improvements in their performance can be measured.
ILO Conventions (http://www.ilo.org/global/lang--en/index.htm)	A system of conventions focusing on the fundamental rights of human beings at work, which have been maintained since 1919. As well as being supported by formal compliance procedures, they also form the basis for numerous transnational voluntary codes of conduct.	Various conventions pertaining to health and safety contain stipulations which are relevant to the assessment and management of NST risks. Some examples follow. *C187, Promotional Framework for Occupational Safety and Health Convention, 2006a* Article 5.2.b states that employers shall "contribute to the protection of workers by eliminating or minimizing, so far as is reasonably practicable, work-related hazards and risks, in accordance with national law and practice, in order to prevent occupational injuries, diseases and deaths and promote safety and health in the workplace" *Convention C170 Chemicals Convention 1990* Employers shall ensure that "all chemicals are evaluated to determine their hazards". Article 6.1. states that employers shall maintain "[s]ystems and specific criteria appropriate for the classification of all chemicals according to the type and degree of their intrinsic health and physical hazards […]". Article 12 states that employers should "ensure that workers are not exposed to chemicals to an extent which exceeds exposure limits or other exposure criteria for the evaluation and control of the working environment established by the competent authority, or by a body approved or recognised by the competent authority, in accordance with national or

		international standards". Further, that they should "assess the exposure of workers to hazardous chemicals", and "monitor and record the exposure of workers to hazardous chemicals when this is necessary to safeguard their safety and health or as may be prescribed by the competent authority". Finally, it stipulates that they should "ensure that the records of the monitoring of the working environment and of the exposure of workers using hazardous chemicals are kept for a period prescribed by the competent authority and are accessible to the workers and their representatives."
ILO Tripartite Declaration of Principles Concerning Multinational Enterprises and Social Policy (http://www.ilo.org/public/english/employment/multi/download/english.pdf)	First adopted in 1977, the Declaration offers guidelines to governments, companies and employees' organisations on employment, training, conditions of work, and industrial relations. It is reinforced by the ILO Conventions, and regular surveys are conducted to assess its impact.	Multinational enterprises are enjoined to provide "adequate safety and health standards" for employees, "bearing in mind their relevant experience within the enterprise as a whole, including any knowledge of special hazards" (ILO 2001). Companies should share information with employees' organisations across the range of their operations, and particularly should "make known to those concerned any special hazards and related protective measures associated with new products and processes" (ibid. 8). Further, they should "cooperate in the work of international organizations concerned with the preparation and adoption of international safety and health standards" (ibid.)
ISO 14000 Series (http://www.iso.org/iso/iso_14000_essentials)	ISO is the world's largest developer of standards. ISO 14000 details accreditation criteria for environmental management systems.	In relation to environmental management systems, the key standard is ISO14001:2004, whose aim is to provide a framework for a holistic, strategic approach to setting out an organization's environmental policy, plans and actions. The standard provides generic requirements for an environmental management system (EMS). Its underlying rationale is that the requirements of an effective EMS are the same across organizations, regardless of the specific nature of their activities. The standard is based on an iterative approach

		to management.
OECD Guidelines for Multinational Enterprises (http://www.oecd.org/document/28/0,3343,en_2649_34889_2397532_1_1_1_1,00.html)	A set of guidelines and standards addressed by OECD governments to multinational businesses which are designed to stimulate and guide corporate social responsibility initiatives. Areas covered include employment and industrial relations, human rights, environment, information disclosure, consumer interests, and technology.	On employment, the guidelines enjoin businesses to "take adequate steps to ensure occupational health and safety in their operations". Environmental guidelines stipulate that businesses should "establish and maintain a system of environmental management appropriate to the enterprise", including "[c]ollection and evaluation of adequate and timely information regarding the environmental, health, and safety impacts of their activities". Further, taking into account cost and confidentiality issues, a business should "[p]rovide the public and employees with adequate and timely information on the potential environment, health and safety impacts of the activities of the enterprise, which could include reporting on progress in improving environmental performance". A precautionary approach to risk management is commended, with businesses being enjoined to "not use the lack of full scientific certainty as a reason for postponing cost-effective measures" to prevent the possibility of harm. In relation to innovation, the guidelines propose that MNCs should "where practicable", adopt "practices that permit the transfer and rapid diffusion of technologies and know-how, with due regard to the protection of intellectual property rights".
Social Accountability 8000 (http://www.sa-intl.org/index.cfm?&stopRedirect=1)	The social accountability system, SA8000, promotes the adoption of human-rights-based principles by retailers, producers and other organizations. Their goal is to encourage just	The primary relevant principles here concern health and safety practices in the workplace. The latest version of the SA8000 standard states that companies should, "bearing in mind the prevailing knowledge of the industry and of any specific

	and decent working conditions throughout supply chains.	hazards, […] provide a safe and healthy working environment and shall take adequate steps to prevent accidents and injury to health arising out of, associated with or occurring in the course of work, by minimizing, so far as is reasonably practicable, the causes of hazards inherent in the working environment" (Social Accountability International 2008, 6). Further, it stipulates that companies should "establish systems to detect, avoid or respond to potential threats to the health and safety of all personnel."
UN Global Compact (www.unglobalcompact.org/)	The Compact emerged from the 1992 Rio Summit under the Agenda 21 programme, and reflects principles established by the Rio Declaration, ILO standards, and the Universal Declaration of Human Rights. It seeks to advance responsible corporate citizenship in response to the challenges of globalisation.	In relation to the environment, Principle Seven states that "business should support a precautionary approach to environmental challenges", Principle Eight, that it should "undertake initiatives to promote greater environmental responsibility", and Principle Nine, that it should "encourage the development and diffusion of environmentally friendly technologies".

National

Framework/Code of conduct	National Jurisdiction	Description	Relevant principles
Assured Nano	UK (but potentially wider)	An accreditation standard which aims to offer reassurance that companies are proactively taking steps to look after EHS concerns surrounding NST. At the time of writing, this standard is still in the beta testing stage.	It is hoped that the standard will be equally applicable to research groups in universities as to manufacturers of nanomaterials or nano-enabled products. It is intended to be as applicable to a global multinational company as to an SME. Accreditation will be based on documenting existing good practice and helping build on this, rather than imposing e.g. heavy additional reporting requirements. Companies who gain the accreditation will be subjected to an annual audit.

EPA Nanoscale Materials Stewardship Program (NMSP) (http://www.epa.gov/oppt/nano/stewardship.htm)	USA (but potentially wider)	The main purpose of the NMSP is to encourage the submission of information from industry and academia on the properties and potential hazards of new nanomaterials. Submissions regarding materials that are either new or existing chemical substances (as determined by the TSCA Chemical Substances Inventory) are invited.	Submissions are invited under either the Basic or In Depth programmes. For inclusion in the Basic programme, participants may submit data on material characterization, hazard, use, potential exposures, and risk management practices relevant to specific nanomaterials. Participants who have already developed risk management plans may include this in their submission. Confidentiality and intellectual property protection measures are included in the scheme. At present, the nature of information required under the In Depth programme remains to be decided upon. The scheme will operate by inviting Basic programme participants to sponsor the development of additional data for characterising particular nanomaterials. Sponsors will be allowed to work with both other sponsors and other stakeholders in developing data development plans. The In Depth programme will be designed to link up with work undertaken by the OECD's Working Party for Manufactured Nanomaterials.

UK Voluntary Reporting Scheme for Engineered Nanoscale Materials (http://www.defra.gov.uk/environment/nanotech/policy/index.htm)	UK	Designed to canvass industry and academia for information on nanomaterials currently being developed, in order to assess any potential risks as a first step towards formulating any necessary regulation.	The scheme focuses on deliberately engineered nanomaterials that are "free" within any environmental media at any point during the material's life cycle (UK Government 2008b, 4). It is viewed explicitly as a starting point for data gathering, recognizing that "the data considered as desirable in order to determine the hazard, exposure and risk of engineered nanoscale materials is likely to change as our understanding of what is appropriate develops". Existing tests, for example, may not prove adequate for assessing nanomaterials (ibid. 5). As with the US scheme, the DEFRA scheme is designed to feed into the efforts of the OECD Working Group, with submissions being recorded by the Group. Business confidentiality still applies to this data, however, with only the name of the nanomaterials and its CAS number being recorded (ibid. 6).
ResponsibleNanoCode (http://www.responsiblenanocode.org/)	UK	Developed by the Royal Society, Insight Investment, and the Nanotechnology Knowledge Transfer Network (NanoKTN), the aim of the code is to translate CSR criteria into a voluntary, principles-based Code.	The Code is intended to be appropriate for organisations of all sizes, and aims "to stimulate organisations to consider all aspects of their involvement with nanotechnologies, including the broader social and ethical issues" (Responsible NanoCode 2008). Its key principles cover central CSR criteria, including accountability, the need for stakeholder involvement and engagement in risk management, occupational health and safety (for a company's own workers, but also including considerations of relevant issues for workers involved at other stages of a product's lifecycle), health and environmental impacts of a company's activities, understanding of wider social and economic impacts of its NST activities. Companies are also encouraged to formulate specific policies for marketing nanomaterials and for providing customers and other stakeholders with information about products containing them, as well as encouraging other businesses to adopt the code. In 2009 an independent group of stakeholders will be engaged

			in benchmarking a set of selected companies to see how closely they are adopting the code.
Verband der Chemischen Industrie (VCI), Responsible Production and Use of Nanomaterials	Germany	Formulated as a way of translating the principles of Responsible Care (see above), and particularly the ICCA's Product Stewardship framework (see above) into a form specific to the challenges facing the NST industry. It brings together a series of VCI publications which address the core RC principles.	Guidelines are provided to assist companies in understanding what data submission requirements exist with respect to nanomaterials under the EU's REACh regulations. Although REACh uses tiered production volumes of more than 1t per year as a trigger for test requirements, specific obligations under REACh and other legislation (such as Chemical Agents Directive 98/24/EEC) still apply to nanomaterials in respect of risk assessment, classification and labelling, and occupational health and safety, as well as the, continue to apply. "This means that manufacturers or importers must classify substances, or even specific products, according to the hazardous properties of the substances or products, label them if necessary, and provide specific safety information." (VCI 2008, 9). Further, recommendations are provided for how information sharing requirements of REACh can be met by distributing material safety data sheets throughout a company's supply chain. In addition, specific guidelines are included on establishing practices under the principles of Responsible Care (see above) voluntary precautionary approaches to occupational health and safety for nanomaterials, based on hazard assessment and including a consideration of substitution options, technical and organisational protection measures and personal protection. Finally, examples of stakeholder engagement exercises and roadmaps for the future development of risk management are included.

Annex 3: Analysis of On-line Corporate Reports, Codes and Policies

Introduction

The object of this exercise was to provide an overview of current online publication of CSR-related literature from a sample of 78 companies within different categories (university micro/micro, small, medium enterprises (SMEs), large and multinational) who have current research and commercial interests in nanotechnology. A major source of cases was the Nanotechnology Industry Association's Corporate Members' List.

Questions which the analysis aims to answer are:

a) How far companies of different types report on material CSR considerations which have been identified as likely to be of import to the development of CSR frameworks, codes of conduct and/or best practice around nanoscale science and technology.
b) Whether information on nanotechnologies (risks and opportunities) are publicly available through company statements,
c) Whether companies have sections or entire policies dedicated to nanotechnology within codes of conduct, CSR policy statements or annual reporting,
d) Whether current policies on product stewardship, responsible innovation and risk analysis i) extend the scope of risk management across the lifecycles of products (including R&D, manufacture, distribution and disposal), through the value chain and/or cover orphan/legacy products, and ii) explicitly include provisions to deal proactively both with *uncertainties* about the potential consequences of the introduction of a given product (deriving from limits on current knowledge) and the *risks* associated with its introduction.
e) How currently available standalone risk management frameworks for nanoscale science and technology (hereafter NST) might build on and extend existing CSR initiatives revealed by our survey.

With this in mind, the survey comprises two approaches. *First*, a quantitative content analysis has been undertaken in order to establish profiles for different industry sectors which indicate how different material criteria are reported on, and how far NST is currently a subject of reporting across these criteria. Secondly, a qualitative analysis of policy statements and reporting from across the sample was undertaken. The aim of the qualitative survey was to provide answers to questions d) and e) above, via two strands of analysis. Firstly, we examined current policies and practices which could be helpful for developing frameworks for responsible innovation. Secondly, we considered how far some persistent problems faced by voluntary CSR initiatives could be addressed by, on the one hand, the policies and practice we identified and, on the other, three examples of stand-alone NST risk management initiatives (i.e. AssuredNano, CENARIOS and the NanoRisk Framework), which are designed to help companies in implementing responsible risk management in the development of nanotechnologies.

Methodology

Content Analysis

Online statements surrounding corporate social responsibility from 78 companies, all of whom advertise their interest in nanotechnology either through membership of industry associations or through broader research programmes, formed the basis of this study. Because of the jurisdictional remit of the DEFRA project, all these companies are ones either based within, or with substantial research and development capacity based within, the UK. As the focus of the project concerns a broad-based concept of what constitutes corporate social responsibility, these documents were not limited to annual reports, but also included policy statements and published codes of conduct. The reasoning behind this was that to assess the degree to which existing approaches within the industry to CSR incorporate a degree of responsiveness to emerging material issues, it is necessary to understand the broad range of normative commitments to which companies lay claim in forming their own approaches to CSR, and to assess the degree to which these approaches incorporate more than one form of commitment. These different types of commitment represent different levels of specificity of commitment, from general guiding values, through specific policy guidelines, to quantitative performance targets designed to aid continuous improvement. The coding was undertaken by two coders, using a coding sheet of which a copy is provided below at the end of this Annex.

Document Categories

Codes of conduct typically contain minimum standards of behaviour to which employees are expected to conform (including bodies of law with which the company has to comply), and typically also provide examples of how to apply these standards in real-life situations. These standards are also typically represented as reflecting values which should guide all company activities. Some codes of conduct which are publicly available are less detailed and comprehensive, and simply state in general terms a set of guiding values.

Policy statements generally articulate concrete measures which are intended to structure business activities in ways that reflect guiding values, which may be stated externally, for example in a code of conduct. They range in scope from general commitments within particular areas of concern (e.g. “to reduce environmental impacts”) to quantitative targets (e.g. “to reduce emissions of volatile organic compounds by 10% by 2010”).

Annual CSR reports (which may be specifically devoted to concepts like CSR or “sustainable development”, or which may form a subsection of the company’s annual shareholders’ report) detail how a company is actually performing in relation to the commitments it has made elsewhere (in codes of conduct, policy statements, or both). A higher degree of specificity is required in such documents, with stress being placed on measurable indicators of success, which are stipulated as requirements within industry-wide codes of conduct like the ICCA’s Responsible Care initiative (ICCA 2007, 13-14). Annual reporting is itself also included as a requirement by many independent CSR frameworks such as the Global Reporting Initiative (Global Reporting International 2006).

Categories of Companies

Companies were categorised as either micros (making use of university-originated IP, with <10 staff), SMEs (<250 employees), large (over 250 employees but based in one country) or multinational (with substantial production, research or distribution operations in more than two countries). They were further categorised according to their positioning in relation to NST: does a given company make nanomaterials, nanoparticles or nanostructures, which are incorporated into products by others? Does it provide instrumentation for researchers or manufacturers? Does it make products which incorporate its own nanomaterials, or products which incorporate nanomaterials from another supplier? Does it act as a distributor for nanomaterials? Many companies of course fall under more than one category in respect of their business.

Categories of Statements

The unit of analysis for the study was explicitly taken to be individual sentences within documents, as sentences typically form the unit of analysis for studies of CSR statements even when this is not explicitly stated (Tilt 2001, 196). Declarative statements containing information either about general commitments, specific policies or quantifiable goals and measures of progress were counted across 6 individual thematic categories (see Table 7 and Table 8 below). The classification of these statements was further broken down to indicate whether they applied specifically and explicitly to NST-related activities or were more general in scope, and whether they applied mainly to the company on whose behalf the statement was made, or whether the information provided concerned the supply chain with which the company does business. Statements which referred to quantifiable measures of progress were ignored if they were merely historical (i.e. if they referred only to a point in the past and were not involved in making a comparison with present activities or future targets).

Table 7: Material CSR Concerns

Environmental Impacts	**Including statements around specific environmental impacts of current activities, but also definitions and programmes of sustainable development**
Health and Safety	What measures are undertaken to safeguard the safety of workers and the safety of consumers?
Access	Is IP shared with developing countries? To what extent are upstream commitments made to sharing other benefits and promoting development (NB this excludes corporate philanthropy, defined as sharing of profits)
Social acceptance and understanding	To what extent are a range of internal and external stakeholders included consulted and/or informed about the company's activities and future plans?
Legal compliance and liability	What declarations are made about compliance with legal statutes, regulatory regimes (including statements about judgements of liability made against the company)
Risk management	Is information provided about general approaches to risk management and responsible innovation within the company (such as LCA, product stewardship, precautionary approaches)? This is in addition to specific statements about safeguarding consumers and employees, or the environment – it concerns whether systems of risk analysis are explicitly discussed.

Table 8: Examples of Declarative CSR Statements

Examples of *general* declarative CSR statements	**"We support efforts to improve access to medicines around the world, in both developing and developed countries." (*Access*)** **"We are committed to reducing our impact on climate change." (*Environmental Impacts*)**
Examples of *specific* declarative CSR statements	"To help us better understand patient needs we have set up advisory boards in the US and Europe with representatives from a wide range of patient groups." (*Social Acceptance and Understanding*)
Examples of *quantified* declarative CSR statements	"We set new targets to reduce our climate change impact (CO_2 equivalent emissions) and energy use in operations, and transport from 2006 levels by 20 per cent per unit of sales (based on a constant exchange rate) by 2010 and by 45 per cent by 2015." (*Environmental Impacts*)

Taken together, frequency statistics for these three categories of statement have been used to provide "profiles" for different categories of company across the various material CSR concerns. We report on these profiles for several key CSR criteria in below).

Only statements which related directly to the material concerns outlined above were recorded. These material concerns were taken to reflect the different dimensions which would have to be included in order to build a comprehensive and integrated approach to "responsible innovation".[1] No account was taken of philanthropic initiatives, or community initiatives which did not relate specifically to stakeholder engagement or access considerations as outlined above.

In addition, a qualitative analysis was undertaken to identify examples where companies have begun to develop (either individually or in concert with others) systems of stakeholder, risk and responsible innovation management which may potentially be useful both in responding to potential NST hazards, should any emerge, and in shaping the future direction of NST development in ways which reflect material CSR concerns about access, social acceptance, environmental protection and product stewardship through a product's lifecycle. This analysis also considered, by way of comparison with examples from the main sample, the NanoRisk Framework developed by DuPont and Environmental Defense, and the CENARIOS "nano-risk assessment tool" developed by Innovationgesellschaft GmbH in Switzerland, and AssuredNano's certification standard of the same name (at the time of writing, full documentation was not yet commercially or publicly available). For the purposes of

[1] On this concept, originating in academic research on innovation, see for example Guston (2006) and Cordes (2004).

this study, DuPont's CSR contribution was considered as an extreme outlier, given the unique nature of the NRF, and was not included within the main survey. Our qualitative analysis considers four emerging problems which CSR policies will have to address, drawing on surveys of initiatives like the chemical industry's Responsible Care Charter, and provides a qualitative overview of how far existing CSR approaches might assist in providing solutions.

Results

Sectoral Profile of Sample

Table 9: Sectoral Profile of Sample by Company Type (n=71)

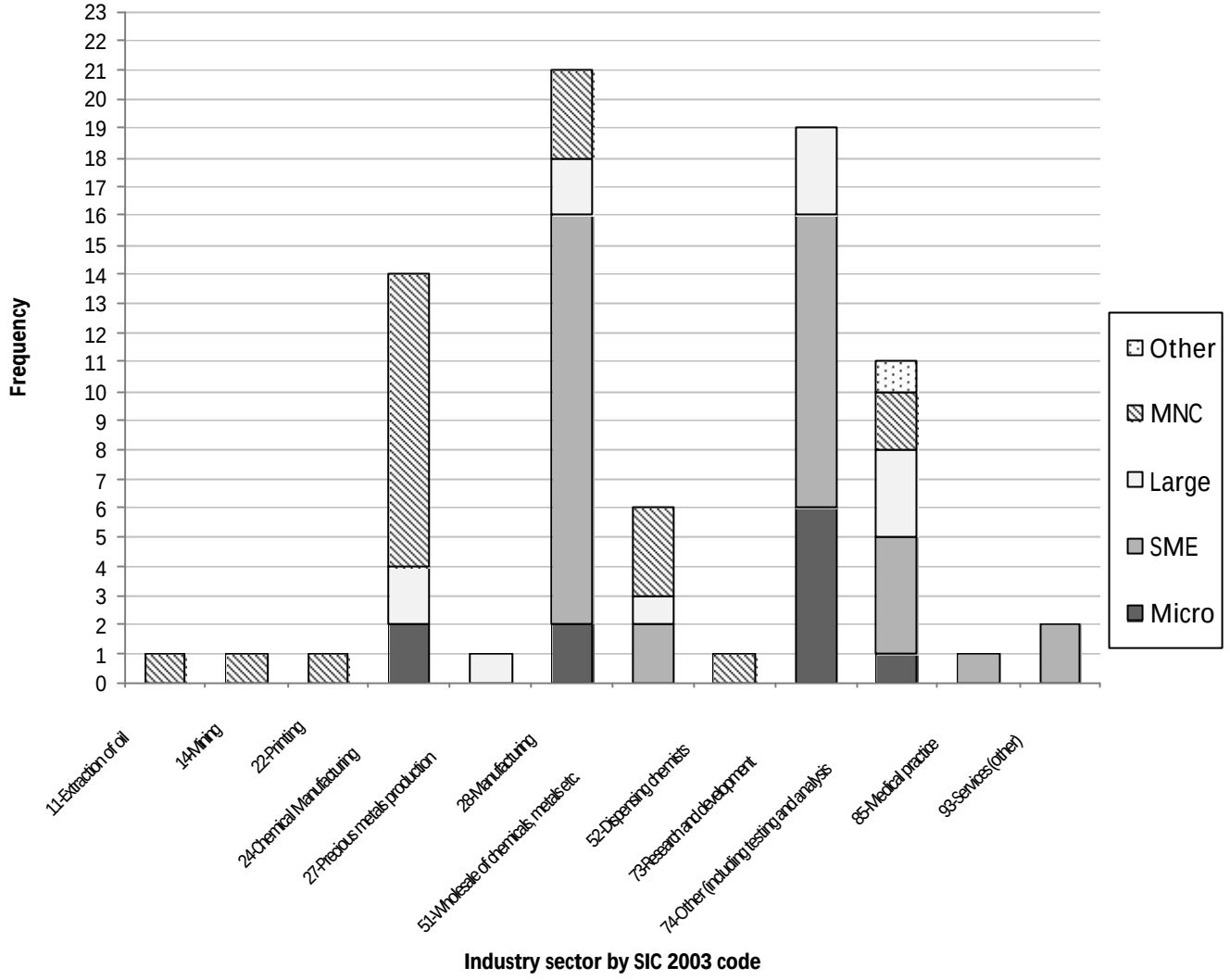
Sector (by SIC 2003 code)	Company Type					
	Micro	**SME**	**Large**	**MNC**	**Other[2]**	**Total**
11-Extraction of oil	0	0	0	1	0	**1**
14-Mining	0	0	0	1	0	**1**
22-Printing	0	0	0	1	0	**1**
24-Chemical Manufacturing	2	0	2	10	0	**14**
27-Precious metals production	0	0	1	0	0	**1**
28-Manufacturing[3]	2	14	2	3	0	**2**
51-Wholesale of chemicals, metals etc.	0	2	1	3	0	**6**
52-Dispensing chemists	0	0	0	1	0	**1**
73-Research and development	6	10	3	0	0	**19**
74-Other (including testing and analysis	1	4	3	2	1	**11**
85-Medical practice	0	1	0	0	0	**1**
93-Services (other)	0	2	0	0	0	**2**
Total	**11**	**27**	**11**	**21**	**1**	**71**

The sample population, broken down by sector (SIC 2003 codes were used, with companies engaged in manufacturing products which could contain nanomaterials grouped together) is represented in Table 9 above and Figure 7 below. SMEs and micro companies were concentrated largely in the manufacturing, R&D and testing/analysis sectors (in that order). Multinational companies were represented across a number of different sectors, with the largest concentration being in chemical manufacturing. It should be notes that large pharmaceutical companies are typically classified within the chemical manufacturing or wholesale of chemicals sectors.

[2] Used for companies where data on turnover and/or number of employees were not available.

[3] "Manufacturing" includes the following SIC code subcategories, all of which involve operations during which nanomaterials or nanostructures may be incorporated into final products: manufacture of metal products, of special purpose machinery/engines, of electronic components, of precision instruments, of auto accessories and other manufacturing.

Figure 7: Sectoral Profile of Sample by Company Type (n=71)



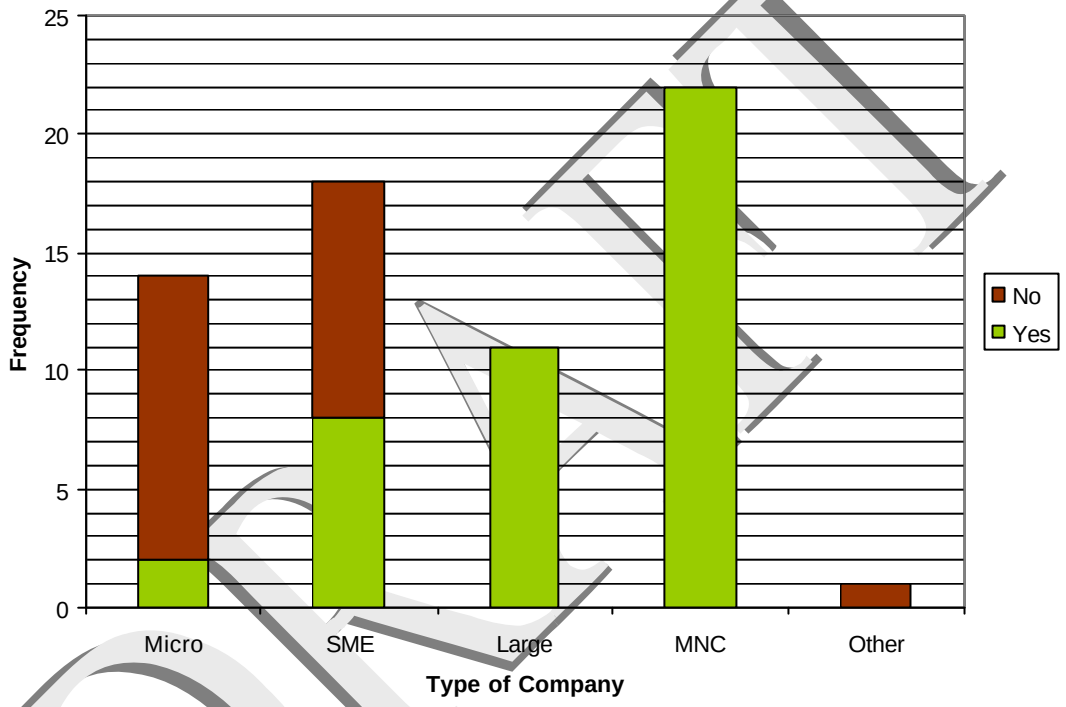
Level of Reporting

The first point to note with respect to the online statements we examined was that very few statements which could be placed in any of our three categories of document were made by either micro companies or SMEs. 86% of micros and 73% of SMEs failed to provide either a code of conduct, policy statement or annual report that addressed one or more of the areas of CSR material concern identified previously. By contrast, all large and multinational companies surveyed provided one or more of these documents.

Table 10: CSR Statements Available Online by Company Type (n=78)

Type	Yes	%	No	%
Micro	2	14	12	86
SME	8	27	22	73
Large	11	100	0	0
MNC	22	100	0	0
Other	0	0	1	100
Total	**43**		**35**	

Figure 8: CSR Statements Available Online by Company Type (n=78)



In terms of which types of documents each type of company provided, no micros or SMEs provided more than one each (see Table 11). Only 18% and 9% respectively of large companies provided two or three types of document, whereas 50% and 25% of multinationals respectively provided two or three.

Table 11: Types of Document Provided by Company Type

Type	One document type provided	%	Two document types	%	Three document types	%
Micro	2	100	0	0	0	0
SME	8	100	0	0	0	0
Large	8	73	2	18	1	9
MNC	5	25	10	50	5	25

Table 12: Numbers of Documents Published by Document Type (n=68)

Document Type	Frequency	Percent
Code of Conduct	15	22.1
Policy statement(s)	29	42.6
Latest Annual Report	24	35.3
Total	**68**	**100**

Figure 9: Numbers of Documents Published by Document Type (n=68)

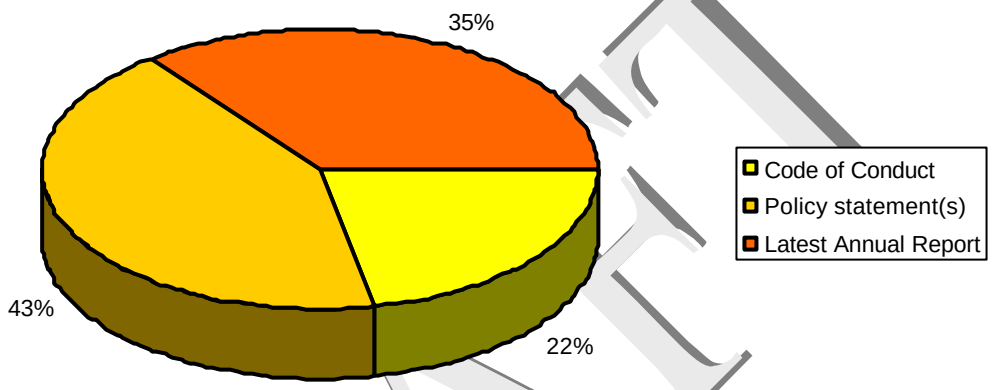


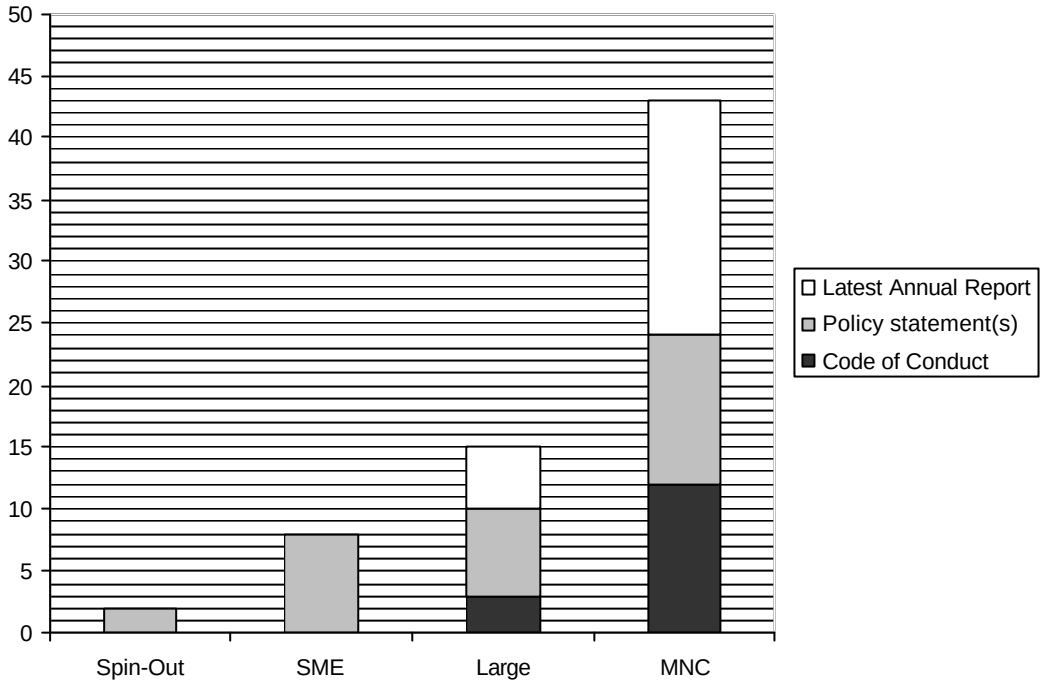
Table 13: Types of Document Submitted by Company Type (n=68)

	Type of Document			
Company Type	**Code of Conduct**	**Policy statement(s)**	**Latest Annual Report**	**Total**
Micro	0	2	0	**2**
SME	0	8	0	**8**
Large	3	7	5	**15**
MNC	12	12	19	**43**
Total	**15**	**29**	**24**	**68**

This profile of submissions fits previous evidence as to the well-attested difficulties faced by smaller companies in engaging in voluntary CSR measures, particularly with respect to reporting annual performance indicators. Gunningham (1995, 65-7) notes that the conflict between short-term profitability and the longer-term benefits (both business and societal) of voluntary environmental initiatives tends to be a difficult one for smaller enterprises to address. Higher profit margins and economies of scale make it easier for larger companies to bear the costs of introducing environmental measures. This is emphatically the case when we consider how far companies are able to systematically implement CSR, an indication of which is the number of companies

who are able to publish examples of all three types of documents listed in the *Methodology* section above. There appear to be major barriers to this systematic approach to reporting for smaller companies.

Figure 10: Types of Document Submitted by Company Type (n=68)



The sectoral profile (by SIC 2003 division) of the reporting sample shows that the lowest level of reporting was among companies engaged primarily in R&D, including research on nanomaterials and nanostructures. This sector sees a heavy representation of micro companies (see Table 14 and Figure 11 below).

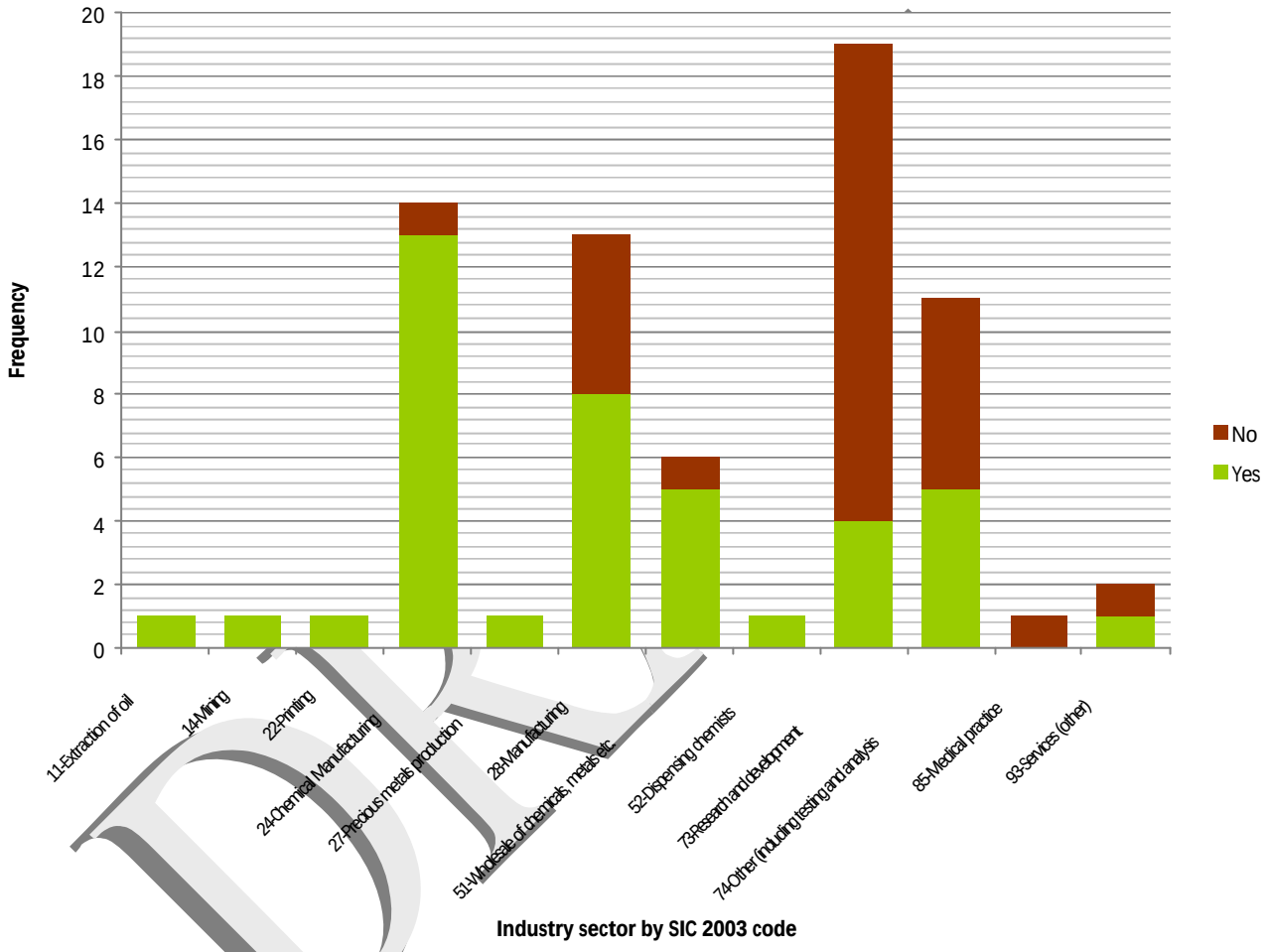
Table 14: Provision of CSR Documents by Industry Sector (n=71)

	CSR Documents Online?		
Sector	**Yes**	**No**	**Total**
11-Extraction of oil	1	0	**1**
14-Mining	1	0	**1**
22-Printing	1	0	**1**
24-Chemical Manufacturing	13	1	**14**
27-Precious metals production	1	0	**1**
28-Manufacturing[4]	8	5	**13**
51-Wholesale of chemicals, metals etc.	5	1	**6**
52-Dispensing chemists	1	0	**1**

[4] "Manufacturing" includes the following SIC code subcategories, all of which involve operations during which nanomaterials or nanostructures may be incorporated into final products: manufacture of metal products, of special purpose machinery/engines, of electronic components, of precision instruments, of auto accessories and other manufacturing..

73-Research and development	4	15	**19**
74-Other (including testing and analysis	5	6	**11**
85-Medical practice	0	1	**1**
93-Services (other)	1	1	**2**
Total	**41**	**30**	**71**

Figure 11: Provision of CSR Documents by Industry Sector (n=71)



There were very few documents that made explicit reference to a company's NST activities, only 12% (8 out of 68 submissions) overall. The majority of these references were only in passing, and did not mention substantive policies. Some companies, however, made explicit reference to balancing potential hazards against benefits. One multinational, for example, commented on the current state of knowledge about dermal penetration as a way of arguing for a balancing of uncertainties against known benefits of products. Another multinational made reference to concerns about NST which had emerged in the course of a stakeholder engagement event. There was, overall, no explicit and detailed discussion in any of the documents we examined of NST-related activities across any of the material CSR criteria on which our survey focused. This should be set against other recent research on CSR and NST. For example, a recent survey of 40 companies in Germany and

Austria manufacturing nanomaterials and/or products containing nanomaterials originating with others indicated a near complete lack of any voluntary risk management framework for nanomaterials (Helland, Scheringer et al. 2008), with 30 of the 40 reporting that they did not actively investigate the possibility of human or environmental exposure of the materials they produced or used (ibid., 642). Similarly, a brief survey of 11 large companies from the chemical and consumer goods sectors conducted as an adjunct to the EU-funded Nanologue project found that only 3 had specific NST-related corporate social responsibility policies, and that both stakeholder dialogue and transparency were broadly lacking (Turk 2007).

External Frameworks and Independent Auditing

A systematic approach to CSR is also correlated with the use of external frameworks to guide and inform the nature of reporting and the selection of performance indicators for inclusion. below indicates this correlation, with documents published by multinational companies, especially annual reports, commonly referring to CSR frameworks (of which the Global Reporting Initiative is the most frequently cited) that include a variety of performance indicators and public reporting standards. It is also notable that the ISO 14000 standard, which provides accreditation for implementing a comprehensive environmental management system, is not widely achieved by SMEs in the survey (2 of 8, or 25%), although the ISO 9001 quality management system standard is more widely awarded to SMEs than to larger and multinational organisations. Those larger companies which have achieved ISO 14001 accreditation are typically being progressively accredited for it on a site-by-site basis.

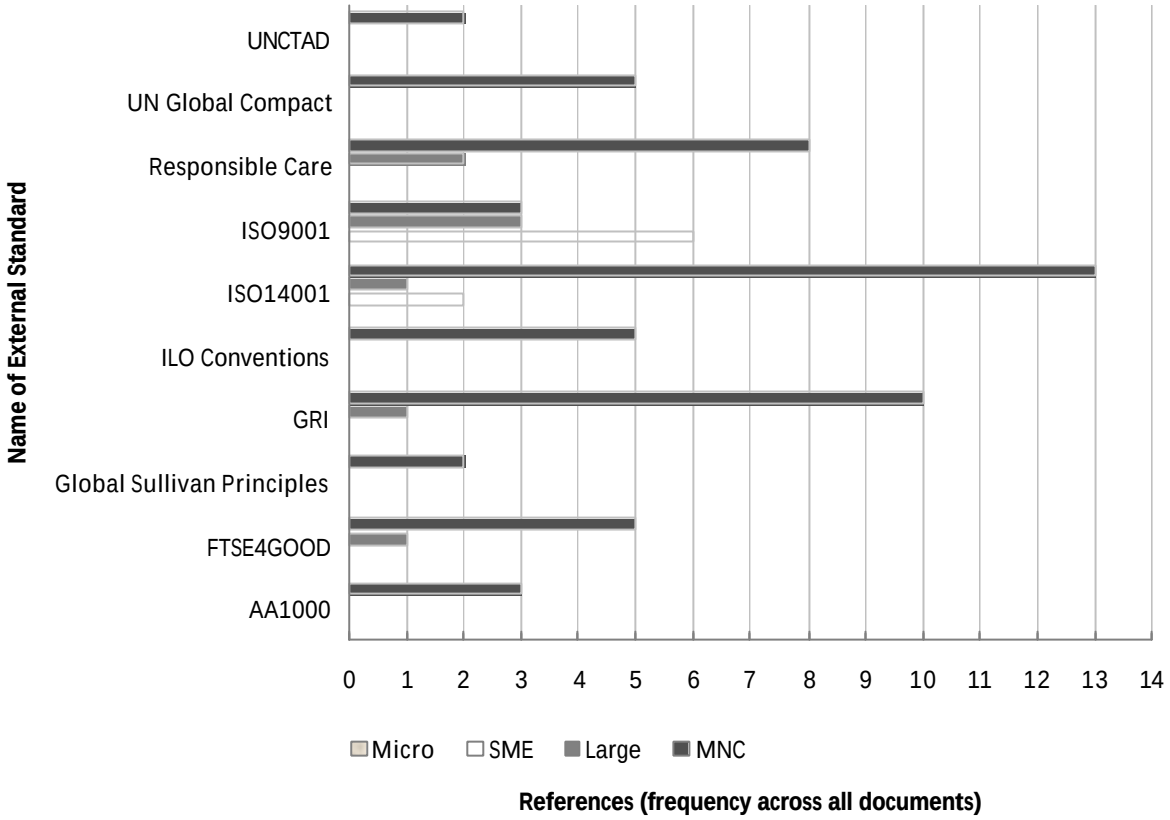
Table 15: Use of External Standards in Reporting by Company Type (includes all documents, n=68)

Name of External Standard

Company Type	AA 1000	FTSE4 GOOD	Global Sullivan Principles	Global Reporting Initiative	ILO Conv.	ISO 14001	ISO 9001	Responsible Care	UN Global Compact	UNCTAD
Micro	0	0	0	0	0	0	0	0	0	0
SME	0	0	0	0	0	2	6	0	0	0
Large	0	1	0	1	0	1	3	2	0	0
MNC	3	5	2	10	5	13	3	8	5	2
Total	**3**	**6**	**2**	**11**	**5**	**16**	**12**	**10**	**5**	**2**

These figures count all cases where companies have used external standards to structure or inform their reporting, have stated their commitment to specific CSR principles, or have cited their achievement of specific accreditation standards (e.g. ISO9001). References could therefore have occurred within documents of any of the three types we have identified for the purposes of this survey.

Figure 12: Use of External Standards in Reporting by Company Type (includes all documents, n=68)



Although some large and many multinational companies refer to and use independent CSR frameworks to provide criteria for the selection of performance indicators and to guide their reporting of CSR performance, another question that has to be asked in order to understand the practice of CSR across the sector concerns how far these companies actually seek third-party auditing of their reporting, as is required under frameworks like GRI and AA1000 for full compliance and accreditation to be possible. 7 companies out of the 43 with online CSR policies have externally audited reporting systems in their annual reports. 1 of these is a large company which uses the GRI framework with some external auditing. 5 of these are multinationals which use the GRI indicators with some external auditing, and 1 is a multinational which uses the UNCTAD eco-efficiency indicators with external auditing, to which it also refers in its general policy statements. It should be noted, however, that none of these are fully externally audited, and all feature some degree of self-assessment under the GRI framework. Compliance is therefore nowhere of the highest order set out by the GRI, with C grade ("beginning to implement CSR systems") being a typical assessment.

Many of the companies in the survey are involved in chemical production or processing, and so it is not surprising to find many of the multinational actors in our survey making reference to the International Council of Chemical Association's Responsible Care code and management systems standard. 2 out of 8 (25%) large companies and 8 out of 21 (38%) of multinationals refer to this.

However, some criticisms of existing voluntary initiatives like Responsible Care in the chemical industry, have often focused on the extent to which external auditing, recommended in the programme itself, is actually sought by participating companies. A recurrent concern with voluntary reporting initiatives that are not externally audited is that the degree of confidence stakeholders can have in interpreting what reported-on indicators mean is necessarily low (King and Lenox 2000) – an issue that will no doubt be important in future assessments of NST-specific CSR initiatives. Gunningham (1995, 70-2) notes that the implementation of Responsible Care has historically been dogged by low levels of external auditing. Following a review of the scheme which finished in 2002, augmented its codes with the Responsible Care Management System (RCMS) (Yosie 2003, 403-4). A key feature of Responsible Care is the implementation of policies which are designed to facilitate continuous improvement in key indicators, but even in 2007, five years after the review, companies are largely left to decide for themselves whether the process of verification meant to be built into the standards is conducted internally or by external auditors (ICCA 2007, 89).

Both the RCMS and its independent third-party certification requirements are designed to be compatible with the ISO 14001 process, an accreditation that measures the rigor of a company's environmental management system (Yosie 2003, 404). This form of accreditation was also sought by a high number of multinationals and some larger companies. The non-environmental management specific ISO 9001 quality management standard was the primary form of external accreditation sought by smaller companies.

Material CSR Issue Profiles

To give a picture of the level of reporting for the different material issues defined in Table 7 above for each of the general, specific and quantified dimensions of reporting defined in Table 8, we calculated the mean number of each kind of statement for each company type. This produced a "profile" of each of these types, based on the frequencies of each category of statement.

<u>Stakeholder Engagement</u>

Given the inevitable uncertainties and ambiguities surrounding the risks which emerging technologies like NST may pose, commentators have noted that traditional risk assessment is not enough in establishing the safety and/or social legitimacy of a technology. The need for early and frequent dialogue with stakeholders has been stressed in an influential attempt to draft a risk management framework for NST published by the International Risk Governance Council (Renn and Roco 2006), in which "concern assessment", a process by which societal concerns about the impact of technologies on institutions and values can be registered and addressed, is recommended as a means of ensuring that technologies are developed in a socially legitimate way. An affirmative stance towards early and regular dialogue is seen by some writers on CSR as advantageous for businesses (Munshia 2007). This is because it can complement effective processes of risk assessment and product stewardship by providing information about how the social reception of a technology or product will affect its marketability. However, there is little evidence in our survey of proactive and regular processes of stakeholder engagement being generally entered into by companies involved in NST activities, although some exceptions are evident. These are typically multinational pharmaceutical companies (see the section on *Qualitative*

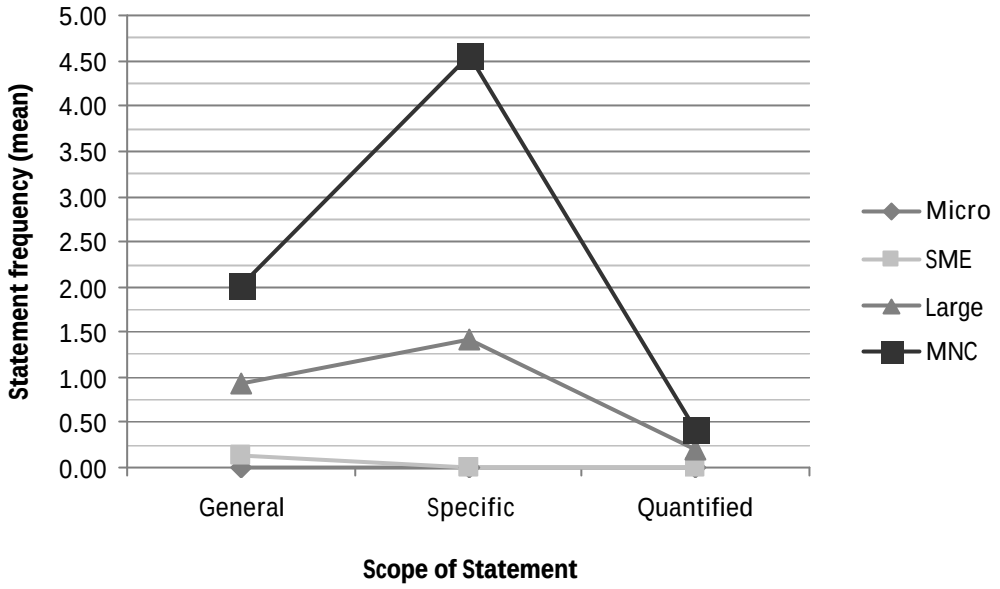
Analysis below for more details) who engage regularly with patient groups on understanding side effects of drug treatments. There are no specific instances of reporting which concern regular and ongoing upstream engagement activities linked specifically to emerging technologies.

As with the implementation of external reporting and management standards and independent auditing, it is evident that there is a significant divide between smaller and larger companies on stakeholder engagement. This is particularly the case in relation to making and reporting on specific measures, as is apparent from Table 16 and Figure 13 below. However, there is much less of a divide when it comes to producing indicators and measuring performance on engagement activities. This may indicate (as is borne out by our qualitative analysis in the relevant section below) that the systematic implementation of engagement systems, including regular contact, mechanisms for feedback and assessment processes, is generally lacking, with one or two exceptions. It is also interesting in this regard that so few companies made explicit reference to the AA1000 independent accountability standards (see Table 15 and Figure 12 above).

Table 16: Stakeholder Engagement Profile by Company Type (n=68)

Company Type	Scope of Public Engagement Statement	Statement Frequency (Mean)
Micro	General	0.00
	Specific	0.00
	Quantified	0.00
SME	General	0.13
	Specific	0.00
	Quantified	0.00
Large	General	0.93
	Specific	1.40
	Quantified	0.20
MNC	General	2.02
	Specific	4.56
	Quantified	0.42

Figure 13: Stakeholder Engagement Profile by Company Type (n=68)



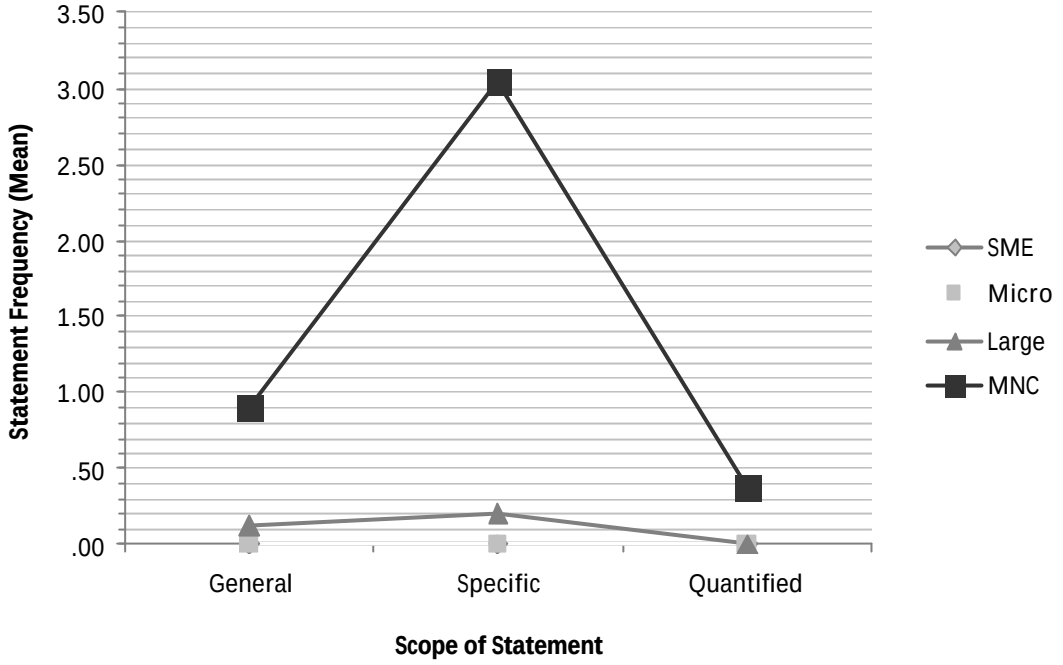
Access

Again, a significant gap was evident between the frequency of policy statements by multinational companies on access and the frequency of such statements produced by other types of organisation. This may be attributed to the fact that multinational pharmaceutical companies often promote detailed policies, largely developed against a backdrop of pressure from stakeholders, on the pricing of drug treatments in the developing world and generic medicines. At the same time, however, there was some evidence of policies being developed by larger companies on intellectual property-sharing agreements (see the section on *Qualitative Analysis* below for discussion).

Table 17: Access/IP Profile by Company Type (n=68)

Company Type	Scope of Access/IP Statement	Mean
Micro	General	.00
	Specific	.00
	Quantified	.00
SME	General	.00
	Specific	.00
	Quantified	.00
Large	General	.13
	Specific	.20
	Quantified	.00
MNC	General	.91
	Specific	3.05
	Quantified	.37

Figure 14: Access/IP Profile by Company Type (n=68)



Risk Management

In the CSR literature, businesses with proactive CSR are commonly held to engage in managerial practices like environmental assessment and stakeholder management (Wood 1991) that tend to anticipate and reduce potential sources of business risk, such as potential governmental regulation, labour unrest, or environmental damage (Orlitzky and Benjamin 2001). The low uptake of such an anticipatory approach to risk management ("beyond compliance") among smaller companies has been noted by researchers (e.g. Gunningham, Thornton et al. 2005). This is reflected in our findings, which show that there is no specific reporting by smaller companies in our survey on risk management (including programmes concerned with product stewardship), Further, the evidence we collected shows large differences between the number of statements made by multinational organisations and the number made by even large companies on specific risk management measures. There are, however, relatively few quantitative statements provided even by multinationals, which suggests that the setting of and reporting on performance targets regarding risk management is an area of CSR which is comparatively undeveloped.

Table 18: Risk Management Profile by Company Type (n=68)

Company Type	Scope of Risk Management Statement	Mean Frequency
Micro	General	0.00
	Specific	0.00
	Quantified	0.00

SME	General	0.14
	Specific	0.57
	Quantified	0.00
Large	General	2.09
	Specific	1.36
	Quantified	0.64
MNC	General	1.31
	Specific	7.14
	Quantified	0.59

Figure 15: Risk Management Profile by Company Type (n=68)

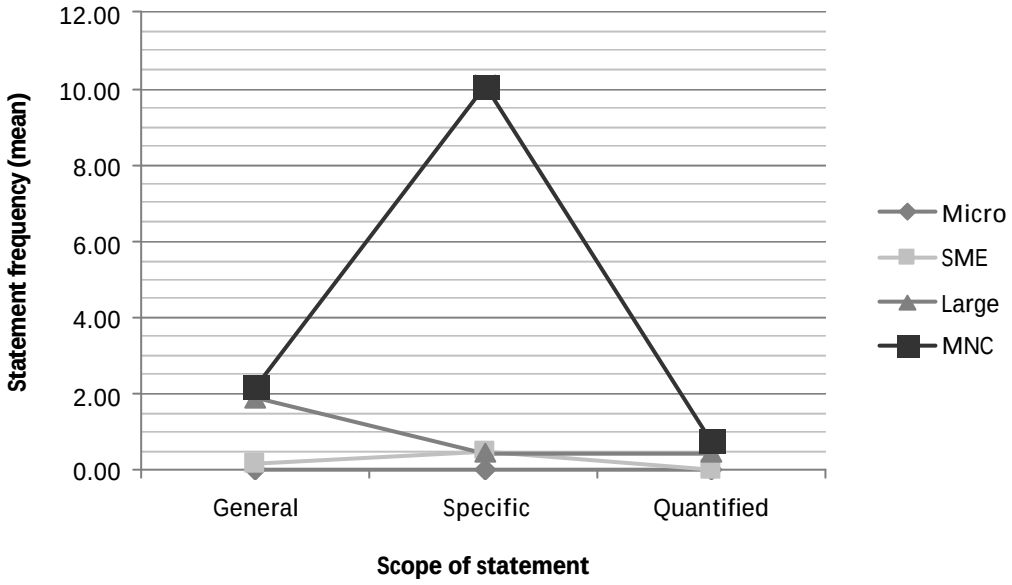


Table 19: Risk Management Profile by Company Type (Annual Report Only, n=23)

Company Type	**Scope of Risk Management Statement**	**Mean Frequency**
Micro	General	No Submission
	Specific	No Submission
	Quantified	No Submission
SME	General	No Submission
	Specific	No Submission
	Quantified	No Submission
Large	General	2.60
	Specific	2.20
	Quantified	0.20
MNC	General	1.68

	Specific	7.37
	Quantified	0.53

Figure 16: Risk Management Profile by Company Type (Annual Report Only, n=23)

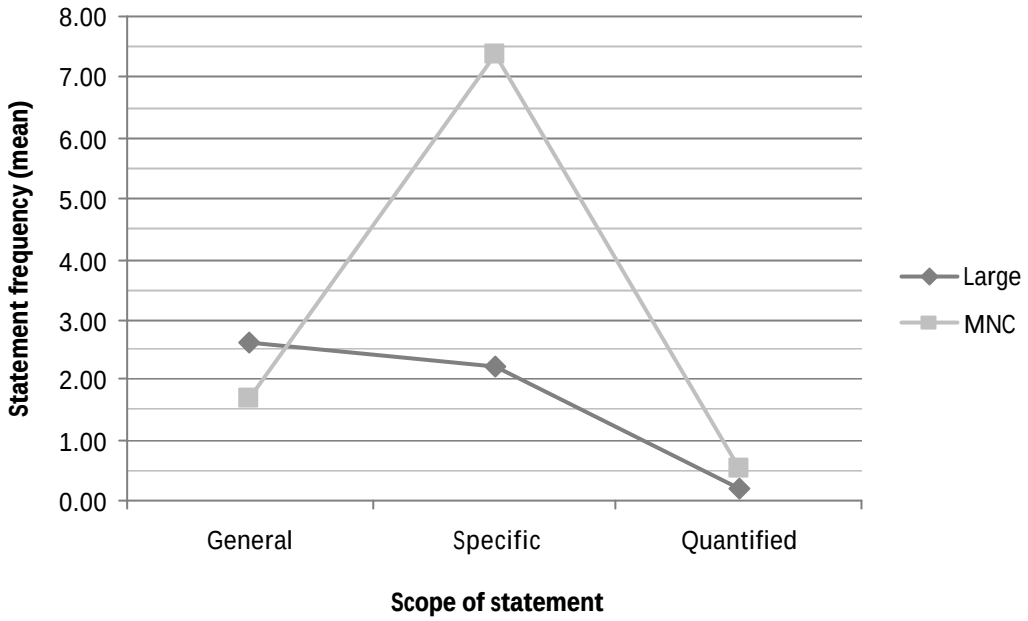
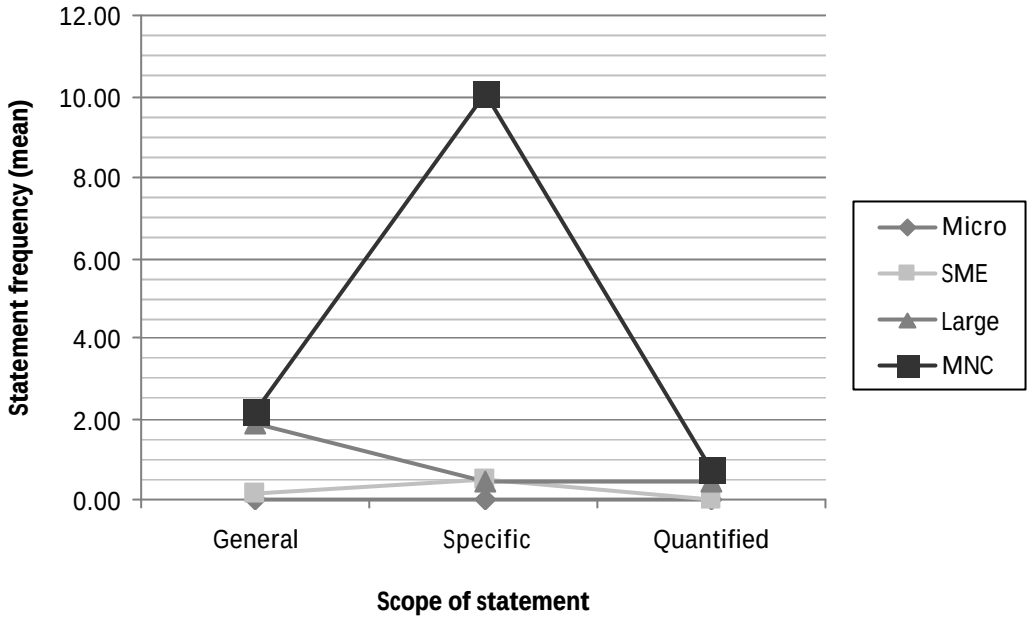


Table 20: Risk Management Profile by Company Type (Policy Statements Only, n=28)

Company Type	Scope of Risk Management Statement	Statement Frequency (Mean)
Micro	General	0.00
	Specific	0.00
	Quantified	0.00
SME	General	0.13
	Specific	0.50
	Quantified	0.00
Large	General	1.86
	Specific	0.43
	Quantified	0.43
MNC	General	2.17
	Specific	10.08
	Quantified	0.75

Figure 17: Risk Management Profile by Company Type (Policy Statements only, n=28)



Qualitative Analysis

Emerging issues

Although, as noted above, very few documents made any reference at all to NST activities, many companies described policies, which despite not being NST-specific, were related to risk management and product stewardship across a product's lifetime and which also stress the promotion of responsibility throughout the value chain of which a company is part. These might offer potential stepping-stones for any CSR strategy that could be responsive to the negative and positive potentials of NST. They perhaps reflect the continuing influence on the CSR policies of the companies in our sample (especially given the number of multinationals from the chemical sector represented in it) of cross-industry initiatives like Responsible Care (see Figure 12 above). These policies tended to present effective risk management as being part of a commitment to implement more general quality management systems, such as those covered by international standards like ISO 14000 and ISO 9001. However, despite this evidence of gradual familiarisation with general principles of product stewardship, it is evident that there are significant problems future efforts must face, which, taken together, make visible gaps in otherwise promising initiatives. Among these are problems which are familiar from the history of Responsible Care. We present here a short summary of these issues, before surveying some notable features of the current CSR environment taken from our data study which future efforts might benefit from considering, and how they relate to these key issues. To assist in outlining the current CSR landscape, we also consider some features of the three major stand-alone NST-specific risk management systems which are currently, or about to become, available to companies (NanoRisk Framework, CENARIOS, AssuredNano), and whether they might assist in developing current CSR approaches to address the problems we identify.

1. *The lack of a clear link between policies on other material CSR criteria like access and public acceptance and understanding*
   There is little evidence of attempts to explicitly link these systems, processes and approaches with measures on access and on stakeholder engagement, under e.g. an umbrella concept of "responsible innovation", This reflects recent findings on the low incidence of CSR policies which centre on shaping innovation (Hockerts and Morsing 2008). It is interesting that the IRGC identified in 2006 two linked dimensions of responsibility in technological innovation. These concerned both the assessment and mitigation of *risks*, understood as the potential for harmful causal impacts on human health and the environment, and the assessment and mitigation of societal *concerns* over wider social effects, persistent uncertainties and the extent of ignorance about the potential of nanomaterials with novel properties for causing unforeseen harm (Renn and Roco 2006). Among the societal concerns which are regularly reported on concerning NST are the potential for the way intellectual property regimes have developed in the industry (Lemley 2005; Vaidhyanathan 2006) to choke off access for developing countries (Correa 2005; ETC Group 2005). These concerns connect up with the material CSR criteria we have used in the content analysis of *social acceptance and understanding* and *access*. There is little evidence of policies on access and policies on stakeholder engagement being linked up with the planning and implementation of systems of risk management to provide a comprehensive approach to responsible innovation. There are no doubt significant practical difficulties which have to be faced by attempts to build such links. For example, the implementation of Responsible Care has, in various national jurisdictions, run into problems due to the Responsible Care Global Charter's requirement on information sharing and stakeholder engagement. Once instance is the idea of a "community right to know" covering the activities of a company in a given locality, which companies have failed to comply with, and even subverted, in Canada and Australia (Gunningham 1995, 77-8).

2. *The degree to which participation among smaller companies may be reduced due to the increased cost of implementing structured risk management systems*
   Proponents of voluntary regulation typically face a collective action problem, given that what might be rational for the industry (and society) as a whole appears to be irrational from the perspective of some smaller actors. There is relatively little incentive for these actors to bear the extra costs associated with proactive and structured risk management systems. The voluntary Responsible Care approach again presents an example of how this problem is already familiar in the context of established CSR policies, and in doing so, suggests that different motivations are behind the differing attitudes of smaller and larger companies to voluntary regulation. Responsible Care has been adopted by larger chemical companies, because it allows them to make improvements to their practices above and beyond what is required by regulation, making it possible to cut future costs of compliance. Smaller companies, on the other hand, often do not sign up to the system, and remain responsive only to mandatory regulations. For them, the short-term costs of non-compliance are great, but the longer-term benefits of Responsible Care implementation are not

perceived as being sufficient to offset these (Gunningham, Thornton et al. 2005, 302).

3. *How far participation and compliance can be ensured throughout the value chain*
   Many large and multinational companies are in the position of manufacturing products which incorporate proprietary materials originating with other organisations. Smaller companies are often also in this position, but many of them (like some larger chemical companies) are also in the position of supplying more basic materials or substances to others. Among smaller companies, micro companies surveyed tended to be engaged in manufacturing basic nanomaterials, particles or structures (57%) as their primary activity, SMEs were almost as likely to focus on manufacture of products incorporating more basic materials or structures (37%) as on nanomaterials (40%). If voluntary regulation is to be a realistic proposition, then companies who manufacture products incorporating materials made by others must have assurance that their suppliers are committed to the same standards they are. For companies which supply materials to others, the same has to be true of their downstream customers. Responsible Care was formulated, in part, to address the concern in the chemical industry that one bad actor could sully the reputation of the whole industry (Gunningham 1995, 64-5). Many of the larger and multinational companies we surveyed reported in their codes of conduct, policy statements and/or annual reporting on thee measures they had in place to audit suppliers and encourage more widespread adoption of the same values and policies that they themselves espoused. For many SMEs, however, the issue of cost may, once again, deter them from pursuing information about their value chains, and from acting upon it. Not only are there costs associated with documenting the compliance of others to a given standard, but the capacity to choose alternative suppliers or customers in response to information about non-compliance is also much reduced for smaller companies.

4. *The need to gather information, both on the potentially hazardous novel properties of some new products, and on the extent of uncertainty and ignorance surrounding the possible outcomes of marketing products which feature ingredients or components with these properties.*
   It is widely recognised that a pressing goal within NST research is to more adequately describe the nature of risks and uncertainties associated with applications which utilise materials whose properties, being novel, have not previously been observed and documented. For example, the authors of the DuPont and Environmental Defence NanoRisk Framework have concentrated largely on the need for the research into and manufacture of products incorporating nanomaterials which may become “free” at some point in the product’s lifecycle to be accompanied by a robust process of documentation of properties and their potential effects. With reference to trials of the NRF carried out at DuPont on three different nanomaterials, they note that the role of the framework could be both to guide systematic risk assessments, and to provide “uncertainty assessments” by indicating where important limitations on current knowledge should influence decision making about product development (EDF - DuPont 2007, 20-1). Both functions would be supported

by the production of information ("base sets") on the properties and toxicological profiles (human and environmental) of nanoscale materials across the lifecycle of a given product, from design through marketing and use to disposal. Although it is not explicitly designed to cover the use of nanomaterials in coatings (which would exclude, for example, some applications in medical devices), the authors of the NRF suggest that their toolkit is flexible enough to be adapted for use in such contexts. They also recognise, however, that one of the chief barriers to implementing such a system is, as with (2) above, the costs that fully documenting the properties and toxicological information for nanomaterials and products incorporating them would have on small businesses. This will particularly be true for some businesses whose activities take place in whole or in part within the EU, thanks to the increase in documentation which will required under the new REACh regulations (Ruden 2004, 336).

Prospects for addressing these issues

1) Promoting integrated responsible innovation

It is significant that, among the current candidates for a fully developed and industry-reviewed risk management standard, neither the NanoRisk Framework nor CENARIOS, nor AssuredNano, fully incorporate measures to address the material CSR dimensions of access and social acceptance within a risk management framework. Each of these standards focuses largely on how to respond to issues of risk and, moreover, uncertainty about causal impacts. Their main concern is therefore with how to construct standards for product stewardship, with emphasis on the responsibility of researchers and manufacturers to give due consideration to the potential health and environmental impacts of their activities in the context of a responsibility which extends throughout the lifecycle of products.

We have already outlined above the essential elements of the NanoRisk Framework approach. For its part, AssuredNano, a private company, has developed, in close contact with industry representatives, a risk management system certification standard. At the time of writing (January 2009) the standard had reached a review stage, before being made commercially available. The central element of the standard is intended to be the promotion of responsibility for practical measures of risk management throughout the value chain to cover all elements of the product lifecycle (Keith Robson, CEO AssuredNano, personal communication, 7 January 2009).

TÜV SÜD's CENARIOS approach (TÜV SÜD GmbH 2008) sets out general requirements for a company's overall risk management system. This includes an adaptation of the typical risk matrix used in risk assessment (classifying risks according to seriousness of consequences and according to probability of risk event occurrence), which, given the lack of knowledge surrounding the probability of particular potential consequences of the introduction of an innovative technology, uses the seriousness of these consequences as the primary classificatory variable. Monitoring of information sources on product risk as the state of knowledge changes is included as a crucial ongoing part of the risk management system, recognising the extended temporal aspects of the risk management process. CENARIOS features annual auditing to support award of accreditation, and established responsibilities of

risk (TÜV SÜD GmbH 2008, 23) and production managers (TÜV SÜD GmbH 2008, 24) to ensure that processes and systems are continuously improved.

Across our survey there are indications that nanotechnology, together with the complex relationships between risk, uncertainty, access and acceptance which surround emerging radical technologies more generally, are beginning to be the focus of concerted efforts to forge a voluntary regulatory agenda on the part of larger companies. There is ample evidence of voluntary collaborations, as well as involvement on the part of multinationals in international programmes on standard setting, metrology, and toxicological research (e.g. the involvement of various companies in NanoCare). Specialist task forces being set up by some companies to tackle emerging issues (including nanotechnology) and to consider how considerations of business risk will increasingly have to take on board not only evolving societal pressures but also new legislative programmes. Efforts to produce voluntary standards for the assessment and management of risk range from high-level and general statements of guiding values and principles, such as Responsible NanoCode to detailed risk assessment protocols such as NanoSafe (Park 2006) and NanoSure (Friedrichs 2007).

Going beyond nano-specific initiatives, it is common to find among the CSR documents produced by larger (especially chemical) companies evidence both of broad commitments to the kind of product stewardship principles which are promoted by programmes such as Responsible Care. These commitments are often translated into policies such as the use of in-house and externally-validated sustainability and/or lifecycle assessment tools as part of general systems of risk management. Ciba, for example, provides a comprehensive set of product stewardship principles which are to govern cradle-to-grave assessments of products and which are intended to be adopted, like a code of conduct, by every employee. The systematic approach it sets out is supposed to involve all business units within the organisation, and to include supply chain relationships. Pharmaceutical companies provided testimony as to their implementation of risk assessment methods based on standardised models of the environmental fate of their products, such as the Pharmaceutical Research and Manufacturers of America (PHRMA)'s PhATE model, which are designed to build evidence and make predictions about the long-term effects of substances on aquatic organisms and human beings (Sammartino, Bellanti et al. 2008, 206). Using the PhATE model, data on predicted sales of a compound and on the calculated removal of substance at various steps (human metabolism, wastewater treatment etc.) are inputted. The model then generates outputs in the form of predicted concentrations of the substance in question in sewage treatment plant effluents, rivers and drinking water under different flow conditions. The development of this model stemmed from the recognition that past models had been undermined by discrepancies between extrapolations of concentrations and actual data.

Some of these tools show signs of being developed to not only comprehensively address lifecycle issues, but social acceptance issues as well. There was one instance in our survey of a risk and uncertainty assessment tool employed by a multinational chemical company which featured not only a broad temporal scope (including lifecycle issues), but also covered potential societal concerns. It bases risk assessment of new products on a comprehensive semi-quantitative profile of the environmental and social impact (taking into account emerging issues and preparedness together

with current and potentially emerging regulatory frameworks) of a product, together with standardised exposure tools intended to be responsive to established and emerging international standards.

Despite the rarity of signs of a fully integrated approach to responsible innovation, it is possible to point to practices elsewhere which provide examples of how the voluntary treatment of access and engagement issues might be improved, on the way to producing more integrated CSR approaches to responsible innovation. The larger pharmaceutical companies in our survey, probably as a result of their sensitivity to campaigns over drug copyrights and also because of their relationships with patient groups, report on a number of initiatives which are of interest. One multinational's latest annual report discussed ongoing issues over drug pricing and the company's responses to them, developed in concert with stakeholders. The issue of cost as a barrier to access for products which are particularly needed in the developing world is treated in depth by the multinational pharmaceutical companies in the survey. Other elements of access sometimes mentioned (again, by the large pharmaceutical companies which are engaged in large scale development of biotechnologies) are the sharing of benefits which arise from the exploitation of genetic resources that are counted among the natural resources of a given state, as detailed under the Convention on Biological Diversity (CBD).[5] Less attention in general, even within the pharmaceutical sector as represented by our sample, is paid to developing new ways of sharing IP and technologies, although pharmaceutical companies once again provided some counter-examples. One annual report mentions technology-sharing initiatives undertaken under TRIPS with companies in India, voluntary licensing initiatives, collaborative patent pooling, and innovation targeted at diseases that particular affect the developing world.

The need to deal with problems of social acceptance for new technologies is also being addressed by some companies, although the quality and effectiveness of stakeholder engagement activities is difficult to judge, based on the relatively low level of provision of information on this material issue. As Figure 13 above indicates, there is little quantitative reporting of goals and performance in this area, and very few documents make reference to international accountability standards such as AA1000 (see Figure 12 above), which require a systematic and iterative approach to engagement, focused on goal setting and continuous improvement. Again, as with reporting on other criteria, it was evident that multinational companies (see Figure 13) were most able to allocate resources to engagement activities, although the most emphasis was given to engagement as "information sharing". However, there were some examples from the submissions of multinational pharmaceutical companies of ongoing stakeholder engagement over issues like access to medicines in the developing world, and on other issues. Two notable examples were provided by two multinationals' annual reports. In one, engagement activities were independently audited by Bureau Veritas[6] against the AA1000 independent accountability standard, while in the other, a self-assessed system of stakeholder engagement was described, which had prepared in accordance with the AA1000 guidelines. The latter presented a systematic approach to engagement, covering the mapping of stakeholder groups, identification of material issues, analysing stakeholder perceptions of these issues and

[5] See the CBD website at http://www.cbd.int/abs/intro.shtml (accessed 18/12/08).
[6] See www.bureauveritas.co.uk

planning engagement activities at a variety of scales, beginning with activities undertaken by management at individual facilities. With respect to early consultation about emerging technologies, there was very little evidence of systematic engagement. The former, Bureau Veritas-assessed report, noted that the company held a stakeholder workshop in the USA in 2007 with representatives of retail customers, regulators, environmental interest groups, health interest groups and academia. Here, nanotechnology was one of the issues identified as a priority for environment, health and safety policy. However, whether this was just a one-off and how exactly input could be used to inform policy is not stated in the company's report. Further, the framework for holding such events is not explicitly detailed here, and it is not made clear how engagement processes relate to research, development and innovation.

It should also be mentioned that criteria for risk communication, both within the company and, in the event of a crisis, outside it, are also part of the CENARIOS standard. Communication must take into account forecasting of possible outcomes of emerging technological and societal developments, including worst case-scenarios. But there is no extensive treatment within the standard's documentation of any systematic approach to public engagement of the kind included within the AA1000 standard.

2) General implementation costs

The problem of implementation costs is one which is largely under-addressed, both by the three stand-alone risk frameworks we have discussed, and by companies in their CSR reporting. Some multinational companies make statements about "assisting" smaller companies with whom they do business with the costs of incorporating particular values or practices into their activities, or about cost and risk sharing in R&D. Within the stand-alone frameworks, there are some acknowledgements of the difficulties smaller companies will face. Under AssuredNano, it is proposed that existing practices undertaken as part of certification for other standards, such as ISO 9001, will be considered as elements counting towards accreditation (Keith Robson, CEO AssuredNano, personal communication, 7 January 2009). This may well be useful in reducing costs to smaller companies, particularly given that, as Table 15 and Figure 12 above indicate, accreditation under ISO 9001 is more strongly represented among SMEs in our survey than any other external accreditation or reporting standard. However, TÜV SÜD and AssuredNano both also acknowledge that their systems are resource intensive for smaller companies to implement (ENDS Report 2008). The NRF recognises the problem of implementation costs, and sets out some recommendations to deal with the problem, such as using appropriate outside experts such as consultants or university researchers to help implement systems, or creating industry consortia to help provide resources (EDF - DuPont 2007, 17-18).

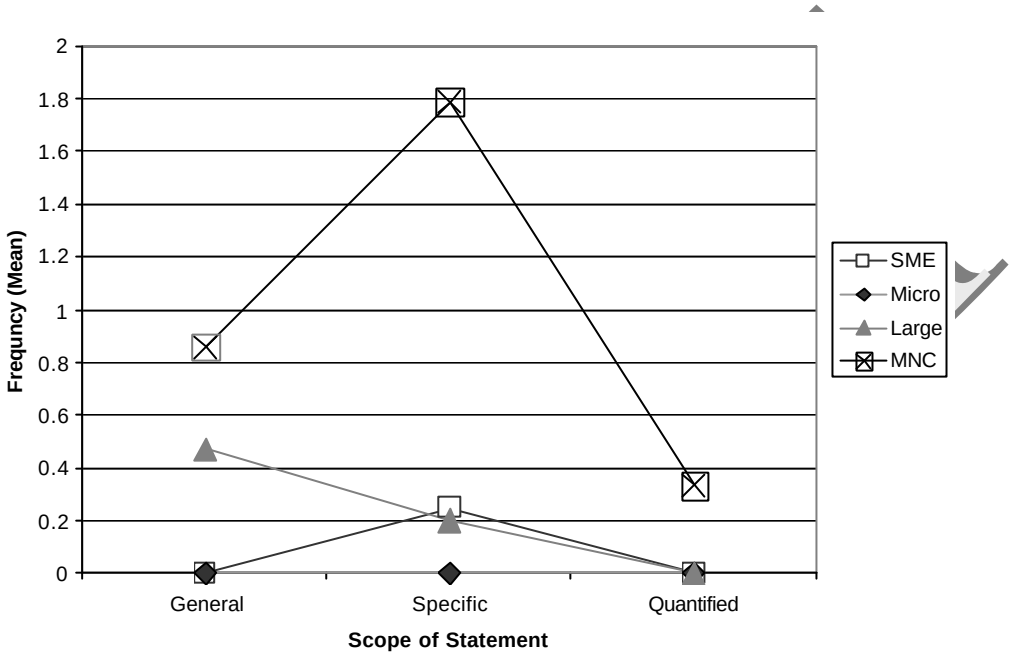
3) Supply chain issues

It is certainly the case that existing efforts to oversee e.g. environmental standards throughout the supply chain are generally much stronger in the larger and multinational companies represented in our survey (see Table 21 and Figure 18 below for profiles of different companies compiled on the basis of the mean frequency values for general, specific and quantified statements companies made about their policies on surveying environmental performance within their value chain).

Table 21: Environmental Impact in Value Chain Profile by Company Type (n=68)

	General	Specific	Quantified
Micro	0	0	0
SME	0	0.25	0
Large	0.47	0.2	0
MNC	0.86	1.79	0.33

Figure 18: Environmental Impact in Value Chain Profile by Company Type (n=68)



This is perhaps inevitable given the multiple relationships multinational companies typically have to other organisations within the value chain, and the relative amount of power they can exert as a result of their market position. The implementation of management systems standards such as ISO 14001 and the use of reporting guidelines like the GRI, together with industry initiatives like Responsible Care, provide motivation and incentives for companies to take a more proactive stance towards suppliers' and customers' stances on the material CSR issues which form the backbone of our content analysis. Again, reference to these standards and initiatives is, as is shown in Figure 12 above, present only in larger and multinational companies' reporting, except for two references by SMEs to their implementation of ISO 14001. All the stand-alone nano-frameworks make reference to the need for suppliers of materials to provide information to customers on the properties of their products (EDF - DuPont 2007, 25; TÜV SÜD GmbH 2008). Again, the cost of undertaking assurance measures in the supply chain will be a problem for smaller companies, which the EDF-DuPont framework recommends should be addressed through cost-sharing arrangements amongst companies (EDF - DuPont 2007, 18)

4) Additional information costs

Smaller companies will also be faced with the costs of more extensive testing and more documentation. As larger companies, in many cases, already require certain

standards from suppliers (see Figure 18 and Table 21 above), there is evidence in our survey for a general awareness among these more powerful actors that smaller companies upstream in the value chain face additional costs arising from material CSR issues and may require assistance in meeting them. The stand-alone frameworks make, for their part, few suggestions as to how this requirement can be dealt with. Under AssuredNano, it is hoped that an emphasis on recognising existing good practice and improving it where necessary can be used as a certifying criterion where possible, in order to keep the need for supplying new information to a minimum. The NRF, with its strong emphasis on testing and information provision, recognises that there are various factors which can affect information costs: for example, costs of implementing the Framework would increase as a product gets nearer to release, or when short-term toxicity tests are required. A number of suggestions are offered by the authors on how to mitigate costs, such as assuming that a material is toxic and requires worker-protection protocols (rather than fully documenting exposure pathways), managing the assessment process so that information costs are spread over time (as there may be a long period from early research to full commercialisation), seeking external funding support from regulatory bodies, and for companies to cooperate with each other to share information through the value chain .

Conclusion

Several major points emerging from the two halves of the study should be stressed. Firstly, there is the very low level of reporting from micro companies or SMEs with NST activities, with 86% of micros and 73% of SMEs failing to provide either a code of conduct, policy statement or annual report that addressed one or more of the areas of CSR materiality identified in the section on *Methodology* above. This is consistent with existing research on the problems facing the implementation of voluntary regulatory measures among smaller companies in general.

Use of third-party auditing for voluntary measures that are based on reporting performance is widely recognised as essential to build trust and credibility. However, there is room for concern at the extent to which the use of external reporting standards, even among multinationals, incorporates a robust audit component. From the data collected, it is evident that the use of external auditing for CSR performance, together with other CSR measures such as the implementation of rigorous, accredited environmental management systems, are not popular with smaller companies active in the NST sector.

Concern with CSR criteria such as access and stakeholder engagement is reserved for larger NST companies in our survey. Again, this is consonant with existing research into the scope of CSR activity in companies. Reporting and evidence of activity among even larger and multinational companies is patchy, however. Evidence of systematic engagement activities is particularly hard to find, with one or two exceptions.

The four problems we discuss in the previous section are ones which are not necessarily unique to NST, but they have features which the current directions taken by regulatory thinking on NST, as well as the current stand-alone risk management frameworks, risk exacerbating. The need to implement new risk assessment and management systems, fully document activities, and properly engage stakeholders to deal with emerging issues of societal concern, as well as to perhaps go beyond the

provisions for product stewardship present within Responsible Care and the NRF to cover longer-term issues such as orphan products, all present the NST industry with cost problems that will require sustained collaborative efforts to address, so that smaller companies are able to reconcile the need to make a profit with the longer term benefits to be had from strategic CSR implementation. Existing evidence of problems with how initiatives such as Responsible Care are implemented should be used as a resource for learning about how these problems can be addressed.

If the twin dimensions of risk and societal concern are to be addressed in order to create both safe development in the near- and long-term, *and* social acceptance going forward, the need to develop CSR policies towards a pro-active and integrated model of responsible innovation is imperative.

Online CSR Survey Coding Sheet

Company Name: DuPont	**TYPE:**	MNC	**Roles:** Nanoproducts incorporating proprietary materials Nanomaterials Manufacturer

Type of Document	
Code of Conduct/ Ethics	
Policy Statement(s)	
Annual Report	

Ref to external standards	Y / N

If Y, which standards?	

Externally	Y / N

CODER:

	General Statements				**Specific Statements**				**Quantified Statements**			
	General CSR		*Nanotech-specific*		*General CSR*		*Nanotech-specific*		*General CSR*		*Nanotech-specific*	
Material Issues	This Company	Supply Chain	This Company	Supply Chain	This Company	Supply Chain	This Company	Supply Chain	This Company	Supply Chain	This Company	Supply Chain
Environmental Impacts (environmental impacts of activities, sustainability/ sustainable development)												
Health and Safety (employees and consumers)												
Privacy/human rights (collection of sensitive data, surveillance and civil liberties etc)												
Access (e.g. sharing of IP, Community projects in developing countries)												
Acceptance/ understanding (Statements on stakeholder engagement)												
Liability (Statements on compliance with liability and other statutes)												
Risk Management (precaution, product stewardship, orphan products)												

Annex 4: Interview Questions

1. Public Sector

The Role of Government and Regulatory Agencies

1. What do you consider to be the role of government bodies in promoting the responsible development, use, and end disposal or recovery of nano-scale materials?

2. In your opinion what components of regulatory frameworks (e.g. mandatory regulations, guidance, information, etc) might make the most important contribution to ensuring that nano-scale materials are formulated, manufactured, supplied, and used safely?

3. "Current existing legislation faces problems of coverage due to the size/scale of nano-scale materials" – do you agree with this statement, and if so, how in your opinion might this issue be resolved?

4. What evidence base is required to enable government agencies/bodies to develop appropriate policies for nanotechnology companies?

5. In particular, what indicators are required in order to measure areas of possible exposure?

6. Should the precautionary principle have a role in policy decisions which are made by government and regulatory agencies concerning the regulation of nanotechnologies?

Industry and CSR

7. Thinking of the dealings you have had/continue to have with industry, what would you say are the chief concerns that companies have in relation to the present and future markets for the nano-scale materials/products they are developing/manufacturing/using?

8. Do you have any views on the benefits of and/or problems with corporate social responsibility in general (i.e. not just with reference to the production and use of nano-scale materials) as a means of encouraging self-regulation?

9. Are you aware of any particularly good or exemplary models of CSR or self regulation being employed within the nanotechnologies industry?

10. Do you believe that important gaps exist in current industry approaches to self-regulation? If yes, what do you think these are? Do you think they exist across different sectors within the industry, or are specific to certain sectors?

11. What drivers do you think might have the most effect on encouraging industry to increase its use of CSR/self regulatory approaches?

12. What is your view on the role of voluntary codes (e.g. Responsible NanoCode) and third sector initiatives (e.g. Institute of Nanotechnology)?

2. Private Sector

General company information/characteristics

1. Please tell me some general information about your company? [Prompt: business activities, age of company, no. of employees, no. of business units, ownership structure, business plan].

2. What are your business goals; are they clearly identified and disseminated to all those concerned?

3. How would you describe your 'way of doing business'? [Prompt: principles, vision].

4. To what extent do your personal beliefs/principles affect your way of doing business?

The Nanotechnology Industry

5. Do you produce, buy, or buy and refine nanoparticulate material? If you produce and sell such material, are your major customers
    a. SMEs
    b. Large and/or multinational companies

6. What do you think the key technological advances in your part of the nanotech sector will be in 5/10 years' time?

7. What changes would you like to see made to the current regulatory situation in an ideal world?

CSR questions

8. How would you define CSR in relation to your company/the nanotech industry?

9. Do you feel under any pressure to become engaged in the CSR agenda? If so, from which sources does this pressure originate [Prompt: government and/or agencies, NGOs, other companies, nanotech industry bodies, general public?]

10. Do you feel that you have enough support to understand and engage in CSR? Which sources of support do you use?

11. Have you heard of/are you involved with any of the following initiatives?

    a. *Responsible NanoCode*
    b. *DuPont/Environmental Defence NanoRisk Framework*
    c. *Responsible Care*
    d. *DEFRA Voluntary Reporting Scheme*
    e. *AssuredNano*

12. Do you think that voluntary CSR measures can be used as an effective form of governance for the nanotech industry?

13. What are the general challenges facing your company/the nanotech industry? [Prompt: gaining financing, identifying market niches, launching innovation strategies, risk identification and management, keeping up with legislation etc].

14. What are the specific challenges your company faces in trying to become more socially and environmentally responsible? [Prompt: Identifying possible activities, promoting activities already carried out, finding resources, receiving support and information].

Specific questions related to CSR type activities

1. Are you aware that the activities you carry out can be categorised as socially responsible?

2. Do you undertake any of the following CSR-related activities?

    a. Use a code of ethics and/or have a set of CSR policies (on environmental management, H&S, stakeholder engagement, etc.)
        - If so, does the company stipulate that it requires certain similar standards/policies from its suppliers/customers?
    b. Reporting- CSR, sustainability, H&S
        - If so, does this conform to external standards? Is it externally audited?
    c. Stakeholder engagement in consultative mode
        - If so, with what stakeholders?
    d. Building links with local communities e.g. sponsorship of local sports teams, support of long-term unemployed, work experience, organising school visits.

3. Do you communicate about CSR internally and externally?

4. What would you say are the benefits to your company of engaging in CSR?

Risk Management

5. Has your company identified sources of risk within the nanotechnology activities in which it is involved?

6. Are there any major areas where scientific uncertainty may affect how your business develops in the future unless more research is forthcoming [Prompt: metrology, knowledge of properties of nanomaterials, toxicological data]

7. Does your company conduct specific risk assessments where nanomaterials are involved?

8. How far do you think life-cycle approaches to risk management are feasible in your part of the sector? (to include LCA, product stewardship, establishing frameworks for orphan products)

9. What factors have been decisive in inclining your company to conduct/not conduct RAs?

10. (if RAs have been performed) Have measures been taken based on these risk assessments?

11. Do you take specific precautionary measures where nanomaterials are produced? [prompt: treating materials as hazardous until proven otherwise, restricting exposure in absence of data]

Stakeholders

12. What does the term stakeholder denote to you; how would you identify your stakeholders and prioritise the importance of different stakeholders?

13. Who would you say are your most important stakeholders?

14. Would you say the contacts you have with stakeholders was

    a. Occasional (e.g.. occasional meetings prompted by a specific issue)
    b. Frequent (e.g. regular meetings to share information and concerns)
    c. Systematic (e.g. regular meetings to review product development and give feedback)

15. Can you give any examples of notably good or bad relationships you may have experienced with a particular stakeholder?

Annex 5: Overview of Interview Participants

1. Public Sector/Government Agencies

Identifier	Organisation/Agency
1	Professor Simon Collinson, Cranfield University
2	Dr Brian Greenwood, Department for Business, Enterprise and Regulatory Reform (BERR)
3	Gill Smith, Health and Safety Executive (HSE)
4	Keith Robson, NanoKTN
5	Christine Northage, Health and Safety Executive (HSE)
6	Kieron Stanley, Environment Agency (EA)
7	Hilary Sutcliffe, Responsible Nanocode

2. *Private Sector*

Company Identifier	Category	Role	Sector	SIC (2003) Code
A	SME	Instrumentation	Process technology	2956
B	MNC	Nanoproducts w. supplied NMs	Pharma/Consumer Health	5146
C	MNC	Nanoproducts w. supplied NMs	Pharma/Consumer Health	2452
D	SME	Nanomaterials manufacturer	Coatings and Composites	7310
E	SME	Nanomaterials manufacturer	Speciality Chemicals	2466
F	SME	Characterisation services	Food	9305
G	SME	Nanoproducts w. supplied NMs	Speciality Chemicals	5151
H	MNC	Nanomaterials manufacturer	Speciality Chemicals	7430
I	MNC	Nanoproducts w. supplied NMs	Food	2466
J	MNC	Nanoproducts w. supplied NMs	Coatings and Composites	2911
K	SME	Nanomaterials manufacturer	Speciality Chemicals	7340
L	Micro	Nanomaterials manufacturer	Speciality Chemicals	2466
M	SME	Nanomaterials manufacturer	Speciality Chemicals	7310
N	Micro	Nanoproducts w. supplied NMs	Medical and Diagnostics	7310
O	SME	Nanoproducts w. supplied NMs	Medical and Diagnostics	3310

Annex 6: Analysis of Interview Data

1. Introduction

Semi-structured interviews were conducted with 7 representatives of government departments, agencies and government/industry supported nanotechnology CSR initiatives, together with 15 companies with substantial involvement in the development of nanotechnologies. Ten companies involved were SMEs or micros, and five were multinationals. The multinationals interviewed represented a cross-section of different key sectors in the UK nanotechnologies industry, with NST involvement in most cases (except for the food packaging and cosmetics companies interviewed) being restricted to R&D:

- food packaging
- speciality chemicals (with customers in e.g. the semiconductor industry)
- cosmetics and consumer health
- pharmaceuticals and consumer health
- coatings and composite materials

The profile of our sample of smaller companies arguably reflects key sectors among the growing number of small players in the industry.

- Providers of specialty chemicals to larger industrial customers, mainly for purposes of industrial R&D (five companies).
- R&D activities in the field of medical diagnostics (two companies).
- Research services to food companies of varying sizes (one company).
- Coatings and composite materials (one company)
- Manufacture of instrumentation for process technology (one company).

Where data relating to “most”, “many” or “some” companies are referred to below, it is this sample of 15 companies that is being referenced.

2. Public Sector/Government Agencies

Analytical Focus	
1. Government role in promoting responsibility in nanotechnologies industry.	*Summary* • Government's role is not just about creating legislation, and nor is it about standing back and promoting CSR; • It should follow a variety of routes to promote responsibility and set a "climate for commercialisation", to take the industry on beyond its current concentration on research and development; • Setting research goals is vital to help create standards and data; • The provision of spaces for debate is vital both for reasons of inclusion and to promote good decision making; and • Government can also act to raise the profile of codes of conduct or accreditation standards One respondent (Public 7) suggested that government should not be involved too closely with simply promoting voluntary regulation, as it can raise suspicions among industry and the public that they are not performing their legislative role properly. Some contrasting views on this issue, particularly in relation to the appropriateness of a "light touch" approach to regulation were evident (e.g. Public 2, 7) Another defined the role of government as primarily being about "setting a climate for commercialisation", which should involve sponsoring themes or pockets of research to address toxicological and occupational hygiene considerations (Public 2, 4). Part of this effort should be to create a broad range of reference materials, allowing toxicological and occupational hygiene requirements to be determined, and moving towards standardisation (Public 3). Government also has a role in promoting the free flow of information, as in debate between scientists, and between scientists and the public (Public 4), and by "inclusively" involving other stakeholders like CSOs and third sector organisations (Public 6). Such a debate is necessary to promote a "reasonable, sensible" debate, in place of immediate, mandatory, nanospecific legislation, which would – without a debate – most likely be too much of a catch-all, and could severely damage the industry (Public 4).

	Finally, the Government could use its position to raise the profile of a given code of conduct or accreditation standard by stating that it will not buy anything from a company which has not been benchmarked under it (Public 4).
2. Contribution of different regulatory approaches.	*Summary* • Given persistent gaps in knowledge, sensible application of precautionary approaches continues to be vital; and • This will largely involve, in the workplace, the extension of existing protocols from the chemical industry. In addition to minding potential regulatory gaps, the promotion of sensible precaution is widely seen as vital (Public 2, 4, 6). For the HSE, precautionary guidance in the form of concrete examples of compliance is vital to ensuring occupational health measures are taken "these are the lines along which we expect people to work" (Public 5). Precaution in nanotechnology workplaces is about applying precautionary protocols already in use in the chemical industry stringently, and providing advice. At the moment, the agency sees occupational health issues in the nanotechnologies industry as adequately covered by existing regulations, including REACh. (Public 3). It should be noted that the 2006 regulatory gaps report for the then DTI by BRASS suggested that there may be some issues affecting REACh coverage, due to (a) tonnage triggers for data requirements (b) questions which remain over the suitability of conventional chemical safety assessment methodologies for nanoscale materials, and (c) assumptions about the substantial equivalence of bulk and nanoscale versions of a substance, particularly given that no nanomaterials have yet been placed on the list of "substances of very high concern" (Frater, Stokes et al. 2006, 59-60).
3. Extent of evidential gaps and application of precaution	*Summary* • Minimisation of risk through minimisation of exposure has formed the keynote of advice offered by agencies to business and academia; • Consultation with industry has been used to fine-tune advice;

	• Gaps include data on human exposure hazards and materials characterisation, but also affect methods of exposure modelling, toxicological methods more widely, and testing protocols. • These issues also affect ecotoxicology, with the added complications of traceability, complex interactions and potential latency effects. With respect to occupational health, an example is precautionary advice on CNTs in the form of a Guidance Note which has been written by the HSE and sent out to industry and academia This has been prepared as a response to potential "early warnings" from academic research, and recommends a precautionary, exposure minimising approach until individual companies can amass enough data to do individual risk assessments (Public 3) and thus prove that no toxicity exists (Public 5). The advice has been the subject of consultation within HSE and within government (e.g. DEFRA, EA) to make sure that its recommendations don't impact adversely on the environment, and was circulated to industry for "fine-tuning" input which made the advice "more practical" (Public 5). Exposure studies at this stage often involve artificial situations which cannot serve as an adequate basis for extrapolating to real world exposure situations (Public 4). Toxicology methods and testing instruments are seen as needing validation, with new ones potentially needing to be developed. *Existing "methods of test" may or may not be suitable for nanoscale devices and nanoscale dimensions. Measurement techniques and instruments need to be developed and/or standardized. New calibration procedures and certified reference materials are needed for validation of test instruments at the nanoscale. (Follow-up email from Christine Northage, HSE)* Concerns over ecotoxicology exist, with how far particles can be traced in water or air a particular issue, together with potential complications further down the line caused by mechanisms such as bioaccumulation – experiences with endocrine-disrupting chemicals, PCBs etc. have sensitized regulators to issues of possible long-term latency (Public 6). Currently, international protocols for ecotoxicity testing are lacking, as they are for human toxicity (Public 3).
4. Drivers within the industry that might encourage the uptake	*Summary* • Reputation and publicity are two key drivers due to effect on company's position in the market; • These might be activated by being benchmarked for a code of conduct or accreditation standard;

of CSR	• A strong profile is needed for any code or accreditation to succeed, which requires involvement of organisations outside business too. • Need for expert advice and information could be used as an additional incentive to be benchmarked. From the HSE's point of view, a development of existing practice (whereby registering with the agency entitles companies to expert advice on compliance) would be seen as a strong incentive (Public 3). Incentives for adopting codes of conduct would be favourable publicity, but this requires that one code be seen as "the only game in town", the "'thing' that companies do", which in turn requires that the code develop a strong profile as a result of pressure applied by NGOs, government, industry peers and so on (Public 7). Responsible behaviour beyond compliance has to be driven by tangible market advantage (Public 3).
5. Companies' concerns regarding present and future markets for their products	*Summary* • The industry remains at an early stage of development, and vulnerable to over-regulation; • Extension of REACh specifically to NMs and NSPs could be the likeliest route to over-regulation; and • Companies still want unambiguous guidance and useful information. Many nanomaterials and other products remain at an early stage of development, and thus vulnerable to over-regulation (Public 3). At this stage, not many companies are probably using large quantities of CNTs, for example, except for R&D (Public 5). But companies still want clear and unambiguous advice and guidance, which is not the same "as being told what to do" as in a command-and-control model of legislation (Public 3). Requirements of REACh are onerous, so nanotechnology companies faces severe economic problems if the full testing regime is required for nanoproducts on the basis of particle size or some other nano-specific criterion (Public 4). Such a move would remove any prospect of a global level playing field and disadvantage the EU.
6. Views on role of codes of conduct	*Summary* • High level codes of conduct are intended to illustrate how compliance with legislation can best be carried out in the nanotechnologies industry, and also to spread responsibility throughout organisations; • Such codes have to operate on the basis of benchmarking, to develop "good intentions" into concrete policies; and

	• Processes of benchmarking are costly, and difficult to implement, but a favourable reception among companies is expected. Codes of conduct or forms of best practice accreditation are seen as giving companies assurance that "they have done the best they can" (Public 4). Responsible Nanocode is largely intended to illustrate and embody examples of compliance with existing legislation (Public 3). It is not intended to be a body of standards, and to operate on a benchmarking of best practice basis rather than on the basis of adoption, given that adoption will tend to catch only those who are already up to scratch. Its uniqueness lies in two features – that it describes required behaviour in a way that can be communicated to non-experts, and, because it is based on principles, it also makes CSR a concern for every company department, rather than defining behaviour in relation to technical legislation which typically concerns only one department (Public 7). Processes of benchmarking are required in order to establish definite processes and procedures to carry through the declaration of intent contained in the code (Public 4). Smaller companies are seen as having less trouble adopting a code of conduct, as with larger companies more internal bureaucracy has to be negotiated (Public 7). Benchmarking process is proving difficult, as getting funding from industry (to be matched by government) is becoming difficult - larger consumer-facing companies are envisaged as the best bet (Public 1). Generally, however, industry appears to be well-disposed to the benchmarking approach (Public 1)
7. Examples of CSR in industry/gaps in practices	*Summary* • Tackling the problem of credibility for voluntary approaches is key, and examples from the chemical and fishing industries have been considered as models; • Multi-stakeholder approaches to formulating best practice may be best, but tend to be slow; • In the meantime, other models such as Responsible Care may be useful; and • Upstream stakeholder engagement processes have had some notable successes in engaging large consumer-facing companies and retailers. It was noted that some in the industry, particularly those in the specialty chemical sector, see Responsible Care as a useful model, but that its usefulness might be questionable, due to the lack of credibility typically accorded to

	measures undertaken by trade associations on their own (Public 7). Multi-stakeholder approaches (like the Marine Stewardship Council, which was an influence on Responsible Nanocode) have been shown to have more credibility. For codes of conduct to work, however, transparency about EHS measures and the like is necessary, and this is not always easy for companies to achieve (Public 7). Nonetheless, Responsible Care was mentioned by another respondent as a useful model to rely on for the time being in providing guidance on how issues like product stewardship could be dealt with in a proactive and precautionary way (Public 4). Larger retailers in the food sector are increasingly engaged with the Responsible Nanocode process (Public 7). Encouraging systematic and repeated participation in upstream stakeholder engagement activities by some larger consumer-facing companies were considered to have been a notable success of recent Government-sponsored engagement efforts (Public 6), although some findings were seen as equivocal (e.g. Gavelin, Wilson et al. 2007).

3. Private Sector

Analytical Focus	
1. Role of foresight/ anticipatory risk management	*Summary* • Smaller companies typically understand the capacity of SMEs in general for foresight as constrained by cost concerns; yet with respect to their own activities, they often show a marked concern with foresight; • Companies often attribute this capacity to values and attitudes held by directors or senior management; • Anticipation of risk is, in isolated cases, seen as an important driver for innovation. • It is more widely seen as a means of being sensitized to regulatory change. A core element of CSR, whether activities are oriented towards minimising risk or towards creating positive social value, is proactive or anticipatory action. Foresight, understood as the systematic use of critical thinking concerning long-term developments, can be understood as necessary to inform and guide such action. All companies surveyed talked about foresight mainly in terms of anticipating new product developments, market needs, and internal industry pressures.

However, there is also some discussion of foresight as a means of anticipating business risk (cf. Wood 1991; Orlitzky & Benjamin 2001) – whether it be from shifts in the regulatory environment, scientific uncertainties, or uncertainties about potential risks or perceptions of risk. In this respect, it is interesting that several of the smaller companies noted that other smaller companies in the industry (not just their sector) tended to see the long-term costs of CSR as a difficult hurdle for companies in their position to get over, with these reported attitudes tending to agree with findings from research on attitudes among SME and micro companies to CSR (Gunningham 1995, 65-7)

> *And I tell you one of the real challenges for CSR is specifically for small companies where to be honest a long term - a long timeframe is six months and I think this is why, whereas for big - for bigger players, the big multinationals they are expecting to be around […] Whereas SMEs they don't have the same - they're not engaged to the same degree as perhaps larger organisations. Yet they tend to be at the cutting edge of technology. (Company G)*

Some remarks from larger companies also bore out this view, with one interviewee noting that making longer-term risk management (such as LCA) mandatory would mean "that nothing in Europe is ever going to be developed by a smaller medium sized company" (Company C). However, this conflict between costs considered over different timescales was not necessarily always evident when discussion turned to a company's own view of longer-term uncertainties and their potential effect on its activities. This concern with anticipation often, small companies report, based on strategic direction coming from the board, who often comprise scientists and directors with backgrounds in larger companies). Here, it was evident in several cases that extensive anticipatory scanning of potential uncertainties was undertaken. Action was taken to direct investment in ways which would help in keeping future opportunities open, rather than threatening the company with less freedom of movement (cf. Husted 2005). In many cases, (e.g. B, D, G) this was associated with technical distinctions between the different kinds of uncertainties associated with different potential products and technologies (see also Analytical Focus 5, below)

Foresight was seen, in several smaller companies, as a capacity which derives from the values and experience of directors and senior management more widely. A comment from Company A concerning their work on novel materials was perhaps typical: "the board members of the company took the view and said, look right assume its deadly and manage it and make sure that, you know we're not harming our customers."

	More unusually, this orientation towards risk minimisation was accompanied in the same interview with an interpretation of business risk as a possible source of further technological innovation: "let's manage the safety side and for us it's making us - it will make us come up with some new technologies to deal with that." (Company A). In general, companies saw foresight as a crucial component of both anticipating regulatory change and of helping to shape it. One smaller company expressed this attitude to regulation by describing it as a kind of "social contract" between business and wider society: "regulation is society's willingness to accept risk." (Company G).
2. Nature and extent of pre-market research/isolation of employee risk factors	*Summary* • Precautionary attitudes, focused on minimisation and monitoring of exposure are claimed across the industry; • Drivers for these attitudes vary, from ingrained values which reflect operators' backgrounds, to e.g. systems of "risk banding" established across a global company's operations; • Companies claim to avoid assumption that NMs are "substantially equivalent" to bulk versions; • Examples exist of specific and extensive pre-market human and environmental toxicology being developed by companies; • Some companies suggest existing toxicology protocols are unsuitable, and better ones would encourage more pre-market research; and • Consumer-facing companies have in place extensive systems of safety testing to meet regulatory requirements, but are either not developing NST-based products at present, or question whether – given regulatory definitions – their products are actually NST-based Various forms of what could be described as precautionary approaches to pre-market testing were described. These varied across sectors: nanomaterials manufacturers spoke of the connection between technical issues, such as improving production processes to the point where reliable production of NSPs or structures with sufficiently similar characteristics became possible (Company E), or upscaling production (Companies A, M), and risk assessment. Without a standardised product of sufficiently reliable and consistent quality to take to market, there would be no point in investing in full toxicology either (Company E). Nonetheless, companies (e.g. E, G, N) stressed that they had not made any assumptions about "substantial equivalence" between their NMs and existing bulk ones, and adapted toxicological approaches accordingly. Company G described how tests on their product

had looked at a number of environmental hazard scenarios (including the effect of their products on the toxicity of other airborne particulates) and had produced risk profiles based on particle size, none of which gave them cause for concern. Where toxicological protocols run by external bodies are relied on, however, some smaller companies (E, K) reported that these did not fit well with the nature of their NM-manufacturing processes (where different production runs might have different toxicological profiles due to variations in product):

> *I can make 10 materials out of one production run by changing the parameters. What I need is someone to tell me, okay, of all of these that one might be 10% less effective but it's 90% less toxic (Company K).*

In fact, they tended to lack flexibility and to be excessively slow to turn around results. Development of a new generation of appropriate toxicological testing protocols was seen by these companies as key to encouraging better pre-market testing.

Precautionary and risk minimisation approaches in the workplace were common among nanomaterials manufacturers, from micro to multinational – companies A, E, K, M stressed the extent of "sensible" (Company K) measures, generally including isolation in suitable fume hoods or other forms of exposure prevention such as encapsulation in matrices (Company M) or growth or manufacture of NSPs in liquid media (Companies H, I, L).

K emphasised how far they minimised exposure by emphasising the difference in orders of magnitude of average numbers of airborne NSPs in different environments:

> *"[…] outside in the big, wide world the average in London it can be 0 to 100,000 - to a million in Oxford Street on a hot Monday morning. Then when your aircraft is out on the runway at calm down and the wind blows in the wrong direction it can peak at half a million. Then at my facility which is the largest manufacturer of nano particles in the UK, dry nano particles it's 8000. So we take it very seriously." (Company K)*

The need to get things "in perspective" to understand exposure risks was a common theme among manufacturers of nanomaterials. The enforcement of a precautionary approach was often in smaller companies attributed to ingrained ways of working, inherited from larger companies or University departments from which they had been spun off: "So you know, we live it. We don't need to be told it, we live it" (Company K). Other small and large

	companies (e.g. Companies H, M) described the mandatory use of material safety data sheets for the new materials and annual health screenings for employees to check exposure levels. For larger companies, such as pharmaceutical multinationals, discussion of the nature of precaution covered detailed systems of hazard definition, including the delineation of uncertainties and consequent minimisation measures based on risk banding: "we take more of a conservative attitude to start with so that we can back off as things would get new data." (Company B). One NM manufacturer, an arm of a chemicals multinational, described how their parent company had assessed their activities under their own risk banding system as low risk, based on the nature of the materials they made (Company H). Further, the consumer-facing activities of pharmaceutical and cosmetics companies give them a specific require specific attitudes to compliance that mandate higher levels of precaution. New pharmaceuticals may take ten years to develop, incorporating e.g. the passage from pre-clinical to clinical trials, and requiring a higher level of data from suppliers of ingredients - to include, in the future, NMs, once NM-based products are developed (Company B). Company C, a cosmetics manufacturer, was careful to point out that the materials they use are not, strictly speaking, nanoparticles, but pigments and emulsions scaled on the micron level, some of which were first introduced to the market over 25 years ago. Researchers at the company continued to update the sizeable body of studies already done on these materials. Acute and extended exposure data for a variety of different scenarios (from dermal exposure to ingestion was available.
3. Sources of influence on company practices from within the industry	*Summary* • Collaboration between smaller and larger companies on product development is vital – in many cases collaborations reach beyond the EU; • This leads to CSR influence from larger companies via the supply chain; • The need to commercialise products that add real value is and will continue to be a significant issue for larger companies and so for the smaller companies that supply them; • These pressures may add to negative perceptions of costs of "beyond compliance" measures; and • Navigating markets and finding customers can impose significant financial and time costs for smaller companies.

With respect to nanomaterials manufacture much UK production (especially with CNTs) is currently for industrial R&D purposes. Smaller companies engaged in NM manufacture seek strong collaborative relationships with large of MNC customers, typically in the USA or in East and Southeast Asia. A common theme was that the hype over the properties of NMs often obscures the real difficulties with using them in actual products. One common problem concerns the conditions under which the manufacturing processes employed by customers operate. A great deal of close technical collaboration is typically required to ensure that supplied NMs do not lose their properties during these processes. This means that exchanges of staff and expertise between companies is common, and that this can include some communication of values and practices from larger companies who often have more established approaches to CSR, along with pressure to conform to particular standards, some of which is aimed at encouraging accreditation under e.g. ISO14000. The experience of e.g. Company M, operating in Japan, is typical:

> *We basically have a range of material that doesn't use any cadmium and that really is a big deciding factor for Japanese companies to work with us because they just don't like any heavy metal in their products.*

We spoke to some larger companies who are in the position of being customers for smaller NM manufacturers. These typically see nanotechnologies as generally being still potential contributions to their product portfolio, whether operating in pharmaceuticals (Company B) or advanced materials (Company J). For companies in this position, a common experience is being approached by "start up companies [with] perhaps single products that they are promoting" (B), but "the technology itself competes against all other kind of things that we look at" and is just "one possible route" (J) to desired improvements, and so considerations like the market value of a product and whether a given technology adds value are of primary concern, not promoting a technology because of some kind of inherent promise.

Smaller companies (E, F, K) were keen also in some cases to stress this point: that the promise of the technology has to be realised in relation to real products to make developing it worthwhile, which as Company F suggested, may be an obstacle to developing nanotechnologies in the food ingredients sector. The need to commercialize rapidly technologies to supply to customers which will "actually improve their efficiency, cut costs, or add extra value", particularly given that nanotech companies outside the EU are seen as "much more advanced in looking at commercialisation issues" (Company N). So far, the UK and EU appear to be lagging behind in this regard, from the point of view of some SMEs. The drive to commercialisation may reinforce negative views of the costs

	associated with CSR, particularly among smaller companies (Companies C, G, H, K, N). In addition, smaller companies often face significant research costs in finding potential customers, as the range of applications for their products is often very large (Company L).
4. External sources of pressure which influence practices (e.g. media, NGOs/CSOs, public perceptions)	*Summary* • Clear differences in attitudes to external pressures were evident among companies based on supply chain position; • Many companies see business risks from negative public perceptions, and relate these to inadequate communication by industry, government and media, with some also citing CSO activities; • Outside larger (particularly consumer-facing) companies, there is little evidence (with one or two exceptions) that these pressures are driving changes in practice; and • Rapid commercialisation of beneficial products is seen as a key route to positive public perceptions. Among small and large companies, there were some evident differences in attitudes to external pressures based on their position in the supply chain. B2B companies differed in their sense of external pressures. Only a couple saw very little business risk coming from public perception of their own area of activity. This was either because of the B2B nature of their business (Company L), or was linked to a perceived low awareness of NST among the public at large (Company D). Others expressed varying degrees of concern about the possibility of localised negative publicity harming all companies involved in NST through a cascading spread of negative perceptions. The impact particularly of even one-off negative stories in either the popular or scientific media was seen as particularly significant by some, with particularly sensitive reactions being seen as possible where food applications were concerned (Company F). One interviewee recalled a recent incident in the US Congress, involving CNTs: *this guy was scaring the bejesus out of a bunch of senators and congressmen saying this was the next devil incarnate in a material and the guy had no real clue or basis for those claims but yet that's what got in the paper (Company M)* Companies across all categories and sectors saw the threat of such pressures as deriving mainly from widespread

"hype" concerning both the negative and positive potential of NST (Companies C, M). A common obstacle which companies saw NST businesses as having to struggle with was the tendency within the media to treat Some saw a negative influence here from CSOs, extending to the "misrepresenting and mis-citing" of scientists (Company C), driven by the need of civil society organisations to attract funding and prestige to big issue oppositional campaigns (Companies G, K), and perhaps by their freedom from processes like peer-review (Company C). Others suggested that CSOs had not, to date, taken a blanket position against NST, having recognised that "could actually have some serious impacts on things like […] global warming" (Company E).

How far such pressures and business risks have driven changes in companies' practices is questionable, at least with respect to smaller companies (see Analytical Focus 7, Stakeholder Engagement). Some small companies (e.g. Companies A, M) expressed a desire to use the absence of regulation as an opportunity to develop models of best practice in communication, and had sent representatives (Company A) on a recent course (March 2009) organised by the RAE, NIA and Nano-Bio-Raise ("Public Communication & Applied Ethics of Nanotechnology"), with a view to developing a published engagement strategy. But other small companies (e.g. E, K) were negative about the benefits of individual companies trying to communicate about their practices in relation to CSR, on the basis that there was little appetite amongst the public for "listening" (Company E: "you must engage publicly, so when you do, no one listens") or that there would inevitably be repetition from companies of the same messages, and people would stop listening (Company K). For one company (E), this attitude was justified in relation to the interviewees' experience in the "GM food industry". Nonetheless, several companies saw the prospect of negative public reactions as a good reason for joining industry groups like the NIA.

Interestingly, commercialisation was in this area once again a major factor which influenced company attitudes and practices. Six companies suggested that the most effective route to public acceptance would be via the development of products which were perceived to be delivering major benefits. Two companies mentioned the example of mobile phones as one where significant uncertainties about risk existed and continued to persist, but where the perception of clear consumer benefits creates acceptance: "most people decide that the benefit to them outweighs that perception." (E); "people discounted that risk because they wanted a mobile phone" (G). By contrast, technologies like GM had failed commercially because people couldn't see such benefits: "people

	couldn't really see the difference between the tomato paste they had in the fridge today versus the one they could buy which was GM modified" (G).[7] Several interviewees foresaw a process of "natural selection" (E) in which various applications of NST would fail to take off, while others would make a huge difference to people's lives and would be accepted. There seemed to be a view amongst these smaller companies (A, D, E, G, M, N) that the market would effectively differentiate between different uses of NST, solving the problems of perception created by hype and sensationalistic reporting. Nonetheless, companies whose products are more "consumer facing" were more concerned to examine the nuances of public opinion and how it might change or be influenced over time. One large pharmaceutical company we spoke to (Company C), having become involved in recent years in "upstream" and "systematic" stakeholder engagement activities, noted that engaging in deliberative assessments of public opinion had for them been a powerful driver in changing business practices in the developing world. Initiatives developed as a result (on access to products, IP and technology sharing) would be most likely also cover future products which incorporate nanotechnologies.
5. Technical questions about manufacture, use and disposal which influence product development	*Summary* • In looking at potential paths of product development, companies tend to distinguish between (i) products with established benefits which are expected to lead to acceptance; (ii) products surrounded with known uncertainties which can be dealt with by established precautionary protocols and (iii) products where scientific uncertainties make them unacceptable business risks; and • Other key technical questions which determine future investments concern the precise extent to which value may be added to products by nanotechnological innovation. Many companies, small and large (B, C, F, H, K, L, M, N) were careful to distinguish between three categories of technical knowledge about products: (i) products whose benefits could be assessed with enough confidence to allow customers and consumers to make assessments based on known risks versus benefits; (ii) products where known uncertainties existed and where precautionary action (based on largely familiar protocols) in manufacture, handling and use downstream in the supply chain would be appropriate (although this may not include recycling

[7] There is some evidence however from research on functional foods which utilise GM to suggest that, with some technological applications, there may be inherent resistance among consumers to them based on the nature of the technology (e.g. Cox, Koster et al. 2004). Whether and how this might also be the case among NST applications (particularly those relating to food ingredients) is unclear.

	or disposal – see Analytical Focus 6 below), and (iii) products or materials whose risk profiles after use in downstream products could not be determined with enough certainty to make them an acceptable business risk (see also Analytical Focus 1 above). Pharmaceutical and medical companies (small and large) pointed out that the particularly strict issues which applied to them meant that the supply of accurate information from suppliers of NMs was critical, and where this was not available or inadequate, they had to engage in often costly characterisation studies of their own (B, N). These same issues applied to a lesser extent to other large companies who bought in nanomaterials, such as one MNC operating in the food sector (Company I). Elsewhere in the food sector, different views were apparent. Company F saw a serious general lack of data and modelling expertise in understanding both exposure pathways and fates of nanomaterials within the human body, which could be expected to have a serious impact on the development of products. More than questions about scientific uncertainty, however, many of the technical issues which concerned companies were about the extent to which nanotechnological innovations could add values to products (the company's own, or a customer's), and what trials, tests and/or stakeholder engagement processes of would be necessary to determine this (Companies B, D, E, F, J, K, N, O).
6. Temporal extent of risk assessment and research and actions resulting from these assessments (including LCA, product stewardship, orphan products)	*Summary* • Various gaps affect the feasibility of LCA, particularly in relation to data and modelling; • Resources and expertise are a problem for smaller companies; • Collaboration and specific funding may assist in making LCA more commercially viable; • Approaches to product stewardship are being widely considered, with development of existing legislation on traceability seen as less onerous for smaller companies; and • Liability for orphan products has not been widely considered, but where it has, the problem is seen as related to IP ownership passed up or down the supply chain. The majority of companies interviewed, large and small (13 out of 15), saw life-cycle approaches as potentially very important for anticipating risks to human health and the environment associated with emerging technologies. However, views as to what such approaches might involve, what impact they would have on companies from different sectors and of different sizes, and whether they should form part of a future regulatory regime differed

enormously.

Producers of basic NMs, for example, are generally not at the stage where products containing their materials are being commercialised, and so have not begun to undertake or commission the kinds of exposure studies that would be needed.

Some smaller companies see LCA as not presenting major difficulties for them, due either to the nature of the products for which their materials are being developed (some may already have an established lifecycle profile, making assessment easier) or special expertise within the company or in one of its subsidiaries or partners (Companies C, G).

Generally, however, there were still seen to be significant problems deriving either from gaps in lifecycle data (Companies A, G), a lack of modelling capability for complex interactions between NMs and the environment or human body (F, K), and/or the relatively early stage of development of a material manufacturing process or a product (A), Larger consumer-facing companies (B, C) had more capacity, as well as (C) access to relevant data, but here the problem was seen as being that "nobody has been able to put all of the pieces together" (C)

Addressing these gaps, it is generally agreed, requires a lot of resources, too much for small companies to undertake such activities on their own in many cases. A lack of access to relevant expertise is also a problem. To enable wider uptake of LCA, collaborations between small companies and larger ones with appropriate expertise were recommended, with the Government assisting, either through providing assistance with coordinating research efforts and collaborative arrangements, or, as one company, already extensively engaged in LCA for its products suggested, actually "put[ting] some seed money in to allow companies to start to do some work" (Company G).

Anticipation of lifecycle and product stewardship issues is, as noted above (see Analytical Focus 1, Foresight), often a key element of strategic decision making on product development. The question of how best to tackle product stewardship for current products produced a range of different responses. One multinational saw the only way to deal with this issue as legislation to bring together companies involved in different stages of a product's life-cycle (Company I). But for smaller companies, such legislation was thought to present significant cost problems, with a full take-back model being particularly damaging. Traceability (rather than full take-back by

	originators) was seen as the best model for product stewardship, and one for which some parts of the industry are already prepared (Company E). Discussions of orphan products and successor liability were marked by little evidence that companies had considered this issue in depth. Some smaller companies dealing with innovations in electronic components or spun out from universities interpreted this issue in relation to IP arrangements (Companies D, N). In the event of the company's dissolution, D saw IP and liabilities returning to the university. N saw them as being on by larger customers who had incorporated N's proprietary technology in their mobile devices, textiles etc.
7. Extent and nature of stakeholder engagement practices	*Summary* • Stakeholders, for most companies (10 out of 15, 66%), are defined first and foremost as peer companies, business customers and employees; • In general, wider engagement tended to be understood in terms of education – not in terms of enabling people to understand the science, but to appreciate the benefits of particular products; • B2B companies, small and large, view stakeholder engagement as difficult, costly, and being best undertaken through intermediaries (media, government, industry bodies). Cosmetics companies are more engaged, though in downstream mode. • Companies involved in the medical/pharmaceutical sectors tend to be most interested in upstream and consultative modes of engagement, often as a result of previous negative publicity. For most companies interviewed (10 out of 15, 66%), stakeholder dialogue means an activity that primarily involves peers, customers, employees and to a lesser extent, regulatory agencies and government. One of the primary aims of engaging with peers and customers is of course to develop the company's products, by attracting investment and collaboration, and by understanding in more depth the nature of the markets in which it operates, including the CSR expectations of downstream customers. In some cases, this has led to changes in a business model, or even to product innovation – a good example being Company M, who remarked on their development of manufacturing processes that do not rely on heavy metals, motivated by the requirements of the Japanese market.

Beyond this level, smaller companies often find the prospect of engaging with the public, media, CSOs and other organisations daunting, particularly in an "upstream" mode, although most believe that such processes may have positive business value. We will explore why they tend to believe this, once we have examined why a minority of companies have a negative view of stakeholder engagement. After covering the attitudes of smaller companies, we offer some comments on the activities of larger companies.

One interviewee professed a "cynical" attitude to engagement activities, both upstream and downstream, noting that

> *At the end of the day it comes to, to you know, people putting their hands in their pockets and pulling out and […] buying the product (Company E)*

This stemmed, according to the interviewee, from experiences in the GM food sector. Whether people saw concrete benefits from individual products would make the difference between e.g. public suspicion and acceptance (see also Analytical Focus 4, above), and while it was important to have industry organisations like the NIA or CIA (for chemical companies) putting data in the public realm and communicating about risk, it was not thought that "it'll make an enormous difference". Engagement exercises, the interviewee noted, tended to happen when something goes wrong, when a company has "hit a brick wall. They don't have a licence to operate."

For another company (K), the value of engagement was undercut if too many people got involved in it on an individual basis, as repetition would quickly render individual efforts increasingly redundant. A company involved in the food industry (F) suggested that companies in that sector find themselves in a double bind over early engagement:

> *The problem is that they can't talk about it. If they are doing it they can't talk about it for commercial sensitivity really. They don't want to talk about it to give their competitors an advantage […]It is very difficult for them to say anything. If they don't say anything then people will think they are doing it anyway, and if they say well, we are not going to involve ourselves in this nanotechnology thing then I don't believe that – with all these benefits of course they are looking at it. So they are on a lose-lose in many ways.*

For these companies, wider engagement was either something which had little value on its own account, marked a failure to secure a "license to operate" by managing risk effectively within the company, or was something which

brought up collective action problems stemming from the logic of the market.

The positive views of other small companies reflected assumptions that wider engagement could be an effective way to demonstrate to people that companies were managing risk effectively, and indeed that the risks of nanotechnologies had to be placed in an appropriate perspective. Public engagement in particular was seen primarily as a form of information management, required because of current inbuilt distortions within public perception, generated primarily not by public irrationality but by media sensationalism and NGO over-concern with technology as a source of risk.

Looking at the present climate, a number of interviewees remarked on the tendency to represent nanotechnology as an over-unified field, which leads to assumptions that e.g. science at the nanoscale as such brings within it certain risks which affect all its applications (Companies A, F, K, M). One company (A) argued that it made excellent business sense, therefore, to undertake to break what sometimes seemed like a mutually reinforcing bond between a lack of public awareness and industry silence, before scare stories damaged the whole industry.

This company felt that both industry bodies like the NIA and individual companies should take responsibility for engaging the public, but also that, in common with other smaller companies who had a more positive view of engagement, this should be primarily via the media, and via the cultivation of contacts with what were seen as a growing number of journalists with a good record on science and technology stories. Models of upstream public engagement which solicit more consultative input from a wide circle of stakeholders (Gavelin, Wilson et al. 2007) were not mentioned by smaller companies as central to the meaning of engagement.

Company E, although taking a more negative view of engagement activities in general, noted that certain intermediaries between companies and the media (such as the Science Media Centre) had proven highly effective at assisting journalists in presenting a discriminating and accurate depiction of science and technology issues. Skill in communicating with the media was a capacity which some (e.g. Company A) acknowledged they found problematic. Success here was seen as depending on being able to discuss issues in terms which spoke to the everyday frame of reference of the listener in order to successfully get across the likely benefits of a product – as opposed to the potential benefits of nanotechnology as such (Company G: “at the end of the day […] people don't buy technology on the whole, they buy products”). This indicates an assumption that it is *individual products* that are the subject of acceptance and rejection, rather than *whole technologies*, unless these technologies are created as an object of specific concern through the advocacy action of CSOs, etc.

When it comes to intermediaries, government and industry associations such as the NIA and CIA were seen as having important, though different roles to play. What links these roles, however, is the way in which they are seen as providing a legitimizing function for the communications activities which individual companies may carry out via the media. The NIA are seen as a coordinating function, through which a consensus industry view of current signature products, realistic future promise, and the current state of knowledge on risks may be produced and promoted. (Companies D, K, L). The government's role with respect to engagement activities was variously interpreted as the provider of opportunities for upstream, multi-stakeholder engagement (Companies F, G) and as coordinating efforts at filtering information, by e.g. setting up review committees who would put forward a balanced view of current research, preventing one-sided "inflammatory" publications and presentations by researchers from getting too much attention (Company A).

Smaller companies we interviewed tended to operate in a business-to-business environment, and this – as well as the question of cost – may well influence views about the difficulties inherent for small companies in activities of this kind (Companies K, M). For larger companies, it is interesting that there was also an evident relation between primarily business-to-business activities and a lack of proactive involvement in wider stakeholder engagement, beyond engaging with the trade and, more occasionally, public media (Companies H, I). Larger consumer-facing companies (B, C) – and also smaller companies involved in medical technologies (N, O) – have more of an active engagement profile, with the most proactive being those involved in the pharmaceutical and medical fields (B, N, O). These companies tend to have regular and ongoing contacts with patient groups and panels of health professionals and representative of public healthcare authorities upstream during the process of product development: small or large, companies speak of ongoing contacts with "patients and the GPs, we already do that and we engage them all the time" (Company N); "engaging with them, getting their opinion of you know the kind of things we're […] possibly interested in developing" (Company B). In addition, Company B mentioned other points of contact, including panels on EHS issues (including CSO involvement) and sustainability. Some of this activity was felt to be a result of past pressures from patients' groups and CSOs, and past "perceived imperfections".

By comparison, the cosmetics company we interviewed tends to engage wider audiences more downstream, taking up opportunities offered to them by other organisations to present information on their activities, and their understanding of the benefits and risks associated with their products: they noted that "very often events that are organised by industry groups are seen as being some sort of front to […] brainwash people" (Company C). Again, as with smaller companies, the intermediary role of government, industry associations and other organisations like consumer groups

	is seen as vital in order to establish the legitimacy of downstream engagement.
8. Extent to which monitoring procedures for products containing nanomaterials differ from those not containing nanomaterials	*Summary* • In the workplace, NMs are treated largely in accordance with existing risk management protocols developed in response to existing regulation; • A generally precautionary approach is evident, which in some cases leads to NMs being treated according to additional protocols and with extra toxicology and risk assessment being done; and • Products incorporating nanomaterials are made to meet the same standards as apply to other comparable products. Precautionary measures adopted by companies A, B E, I, K, ranging from SME to global in size, work on the assumption that hazard types and levels will be similar to existing sometimes very hazardous chemicals and biological agents (including powerful acids, poisons, mutagenic and teratogenic substances), even though their initial data suggests in many cases that nanomaterials they're working with may not be anything like as hazardous. Procedures of regular, systematic and ongoing hazard assessment were also described by companies working on novel materials and other products, which one company (E) described as regularly checking with toxicologists whether the "big red button" should be pressed to stop development. A minority of SMEs noted that they typically monitor exposure levels for staff more stringently where NMs are concerned than with other materials (e.g. Company A). In general, however, NMs were not seen as representing novel forms of hazard that would require unusual or especially innovative measures within the workplace (Company D). However, some smaller companies also reported having run a series of toxicological tests to establish risk profiles for their materials in order to compare them with bulk version of the same chemical, which had led to peer-reviewed publications in toxicology journals (Company G). Beyond the workplace, products are generally assessed according to existing regulations covering specific products, in the absence of nano-specific regulation. One larger company (I) noted that the manufacture of products containing nanomaterials (such as films for use in food packaging) was geared to meet the same standards as other products they made.

	The use of nano-pigments and emulsions in consumer products like sunscreens, one large cosmetics company (C) suggested, did not present any novel problems at all, given nearly 30 years of research into the potential exposure effects of such uses.
9. Influence of modes of governance on attitudes to CSR	*Summary* • Regulatory uncertainty is generally unhelpful, and will not generally of itself drive self-regulation; • Better engagement between regulators and industry might be necessary to educate companies on what regulations apply to them; • Some proposed mandatory regulatory approaches were seen as economically destructive, and a reaction to anticipated public fear; • REACh is seen as sufficient to capture NMs as it stands, and is welcomed by some as a positive regulatory model, though costs are high; • Mandatory regulations to deal with uncertainties surrounding NST (e.g. lifecycle risks) are seen as economically destructive rather than a positive driver for CSR uptake; and • Codes of conduct, for guidance and for accreditation, are seen as a useful step forward, on the other hand. 6 out of 14 companies interviewed emphasised that the current regulatory environment in the UK and EU was, as they saw it, characterised by significant uncertainties. Of these, two multinationals (C, I) and one micro (L) saw this situation as negative, while two SMEs (A, G) saw it as a mix of positive and negative, and one SME saw the situation as a positive opportunity for the industry to develop its own models of best practice (Company M). Nonetheless, to resolve this uncertainty (by consolidating at the very least authoritative forms of guidance for self-regulation) is seen as an urgent need. As one company pointed out, *the absence of clear regulations, especially at an early stage of a technology, raises concerns around the controlled environment to levels that don't actually reflect necessarily the risk (Company G)* However, this was seen as not a task which should be carried out, in the first place, by resort to hard law. One obstacle to further mandatory regulations might be, as two companies (M, N) suggested, a persistent lack of sufficient knowledge among companies of the regulatory environment in which they operate now.

Companies small and large were generally keen to stress that they strive to comply with all relevant regulations of which they are aware, but that further regulations designed to capture some of the risks and uncertainties that have been associated with nanotechnology (such as lifecycle risks) might have serious negative consequences. For example, the costs implied by imposing full liability for disposal on manufacturers of NMs used in other products would mean such measures would be unworkable (Company E), and similar measures designed to make full life-cycle analysis of materials mandatory would be equally ruinous for the nanotechnology industry in the EU (Company C).

In this regard, companies' evaluations of REACh are interesting. One small NM manufacturer, who had been involved both with the DEFRA VRS and its counterpart in the USA run by the EPA, noted that the EPA version featured a phased approach to declaration and risk assessment that corresponded to the different technical problems associated with low-volume manufacturing for R&D on the one hand and high-volume manufacturing for commercialisation on the other:

> *"We've got a consent order against manufacturing for export, from the E.P.A. in the States and within that they give us guidelines, that if we hit a certain value or quantity we then have to do full toxicological assessment […] Now to me that's sensible regulation.[…] It allows development and allows us to get to the point where it, it justify the costs of doing this, and until you get to the point, you have to use a precautionary approach."(Company E)*

For E, it was felt that REACh is moving in the same direction, and would therefore encourage good practice in the industry, even though its costs are high. Others (e.g. Company H) affirmed that the general approach of REACh was useful to the industry, but that further mandatory regulation requiring additional data and reporting efforts would impose onerous costs.

Further, companies see serious difficulties with targeting regulations appropriately. For example, various surveys of public opinion have suggested that labelling of nanoproducts is often called for by consumers (e.g. Which? 2008). This form of governance was very unpopular with consumer-facing companies. Cosmetics companies (C) and companies engaged in exploring how NST could be applied to food ingredients and packaging (F) noted that proposed EU measures on labelling could be very counterproductive and should not be used as a "one-shot" form

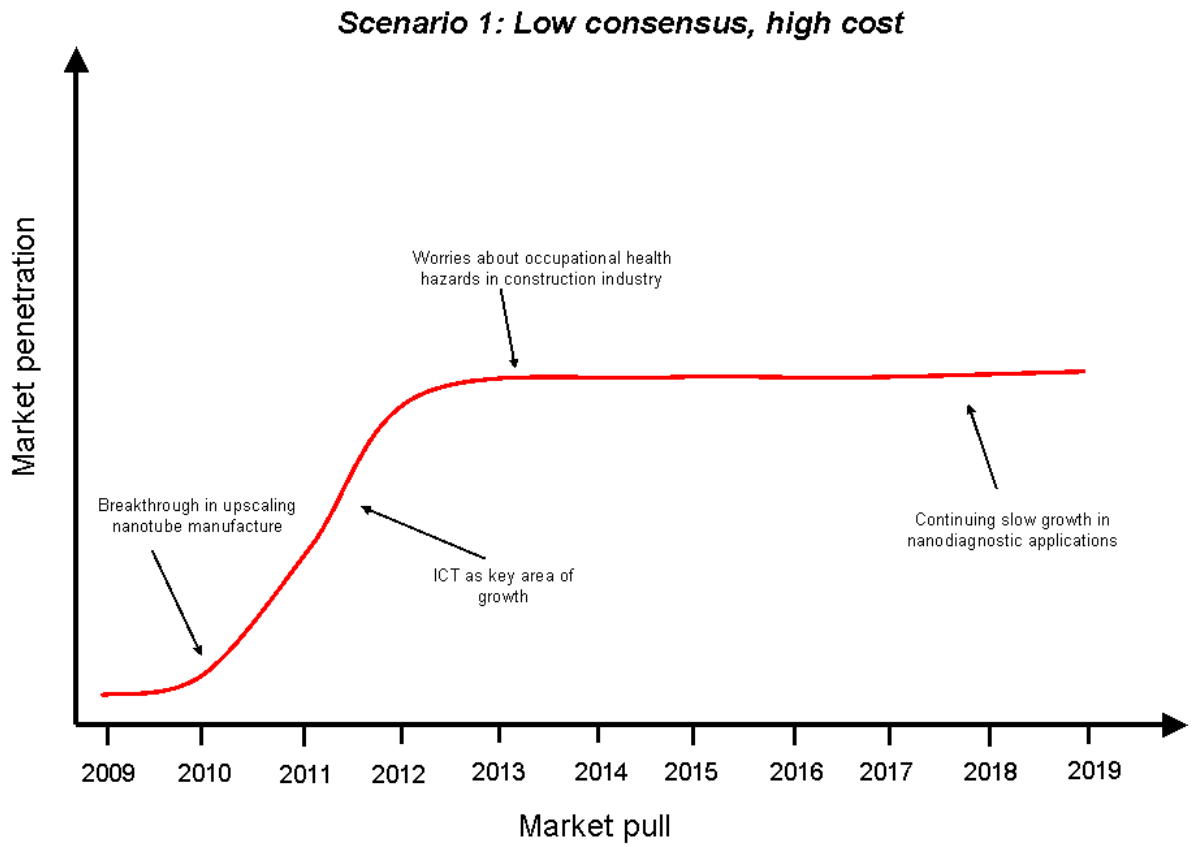
	of regulation for the industry. Company C noted that, in conjunction with a general lack of public awareness about NST, labels would be interpreted primarily as warnings, especially on sunscreens, despite the company being assured that no evidence exists of health risks through dermal exposure. Company F made a similar point, noting also that a labelling regime based on "nanotechnology" risked positing too much of an identity between different applications based on factors such as particle size. C addressed this point too, arguing that the current EU definition of nanotechnology, as applied to cosmetics, meant that "any cosmetic product that contains an ingredient that has one or more dimensions of the order of 100 nanometres or less" would be covered by labelling. This was, C argued, a "hopeless" definition, and potentially one that could lead to WTO-driven conflicts on the international stage. In the current industry environment, some companies characterised the most useful forms of regulation as CSR "guidance", perhaps provided through codes of conduct developed by multi-stakeholder groups including CSOs (Company F). Another, related form of governance which was strongly supported (by smaller NM manufacturers in particular) was accreditation for implementing codes of conduct (E, G), which could drive the adoption of CSR by having clear commercial benefits in terms of providing a "license to operate". The uptake by several companies of ISO9001 and ISO14000 indicate that accreditation as a form of governance is something which companies already take seriously, particularly where they collaborate with large companies from overseas (see Analytical Focus 3 above). However, Company E noted that accreditation standards, when connected to codes of practice, need to have "bite" – something, it was suggested, that some other attempts at such standards (such as those stemming from Responsible Care) have not possessed, and which industry bodies such as the NIA may help to promote.

Annex 7: Scenarios Exercise – Overview of Scenarios[8]

Scenario 1: Low consensus, high cost

Summary

- Public institutions have been slow to plan for the possibility of health or environmental risks related to nanotechnology and self-regulation on the part of industry has been hesitant.
- This regulatory environment, together with a global recession at the end of the first decade of the 21st century, has been widely linked with a slower than expected spread of nanotechnologies.
- Some occupational health concerns have emerged, and as a result public worries about nanotechnologies escalated.
- Although nanoscale science is still being widely applied in commercial applications, the term nanotechnologies is used less, and the prefix nano has all-but disappeared.



[8] These scenarios were developed on the basis of ones employed in the engagement activities undertaken by the EU-funded *Nanologue* project (see www.nanologue.net).

Timeline

2009	A public opinion poll of European citizens showed that, among the minority that had heard of nanotechnology, most had positive associations with the term, though didn't necessarily trust either public institutions or private businesses to govern the application of the science effectively. Relatively slow R&D in key areas meant that nanotechnology products were still peripheral in the marketplace. Much heralded applications in healthcare and pharmaceuticals were still to emerge, with some companies projecting up to 10 years for these to reach market.
2010	A major venture capital firm announced that it had embargoed all investment in nanotechnology-related products, citing a failure of the technology to deliver in the market as expected. This decision was ridiculed by most in mainstream science. An editorial in 'Nature' magazine said the decision was "not only foolish, but dangerous." A number of different accreditation schemes for nanotech production companies have been launched in the last year, based on a mixture of CSR-type approaches: ranging from high-level codes of conduct to detailed lifecycle risk management policies with auditing. Takeup has to date been slow: companies appear to be waiting to see which one becomes the "industry standard".
2010	Attempts to set up a global approach to regulating nanotechnology have begun, following a series of international meetings. The Framework on Nanoscale Technologies aims to be in place by 2012. Breakthrough advances in high volume manufacture of carbon nanotubes thought by industry insiders highly likely to make commercialisation of a growing number of applications an option, due to greater predictability of product and lower costs.
2011	The UK Government criticises the slow development of the Framework, and moves to publicly back one of the available accreditation standards. Adoption of the guidelines it provides is voluntary. Takeup remains slow among SMEs – some complain about compliance costs. Advances in processor computing speeds based on extensive use of nanotubes and other nano-based advances in semiconductor technology are the business story of the year.
2012	ICT continues to be a major area of application, with monitoring and anti-counterfeiting technologies showing particularly strong growth.
2013	It is reported that some construction workers involved with cutting concrete have begun developing difficult to treat respiratory complaints. They are discovered to have unusual complications. A UK newspaper publishes story about the constructions workers' illnesses, suggesting a connection between their condition and the recent emergence of nanotube-reinforced concretes in the industry. The story surveys the growing use of nanotubes across a number of sectors. It also

	compares the workers' condition to "World Trade Center syndrome" (whose cause remains unknown), and recalls the studies published from 2006 onward concerning the potential toxicity of the materials.
2014	A coherent EU regulatory framework for nanoscience and technology was finalised, based loosely on the UK guidelines.
2015	A consortium of European businesses published a report criticising the EU framework and committed to developing its own, stricter guidelines.
2018	Nanodiagnostics continue to develop, and with them, concerns over privacy Applications are now no longer marketed explicitly as "nano". The widespread nature of certain uses of nanoscale science is rarely brought up in debate.

In depth

Risk management and regulation

Despite early attempts, it has proven impossible to establish a level playing field globally for regulating the development of new technologies. Instead, we have a piecemeal approach. In Europe, we have a legal framework, finalised in 2014 and based on voluntary guidelines established by a joint private-public working group in the UK.

The USA has a different set of laws, as do the other main producers of nanoproducts. Recently, concerns have been raised that the framework isn't tight enough. It is difficult to see how one company's code of conduct aligns with another and to hold companies to account for their voluntary initiatives.

Public debate

Today, the dominant public discourse draws on a few high profile "scandals". Many in science and industry feel that this is holding back progress. The media has adopted a sensationalist and adversarial approach, and is perceived by science as ill-informed and as continually returning to a series of iconic failures. The substantial number of lower-impact successes has largely been ignored and level-headed debate informed by scientific method is hard to come by. Likewise, in attempting to draw attention to risks, the NGO sector has missed the opportunity of separating out socially or environmentally beneficial applications of the technology from more worrisome ones.

Access and inequality

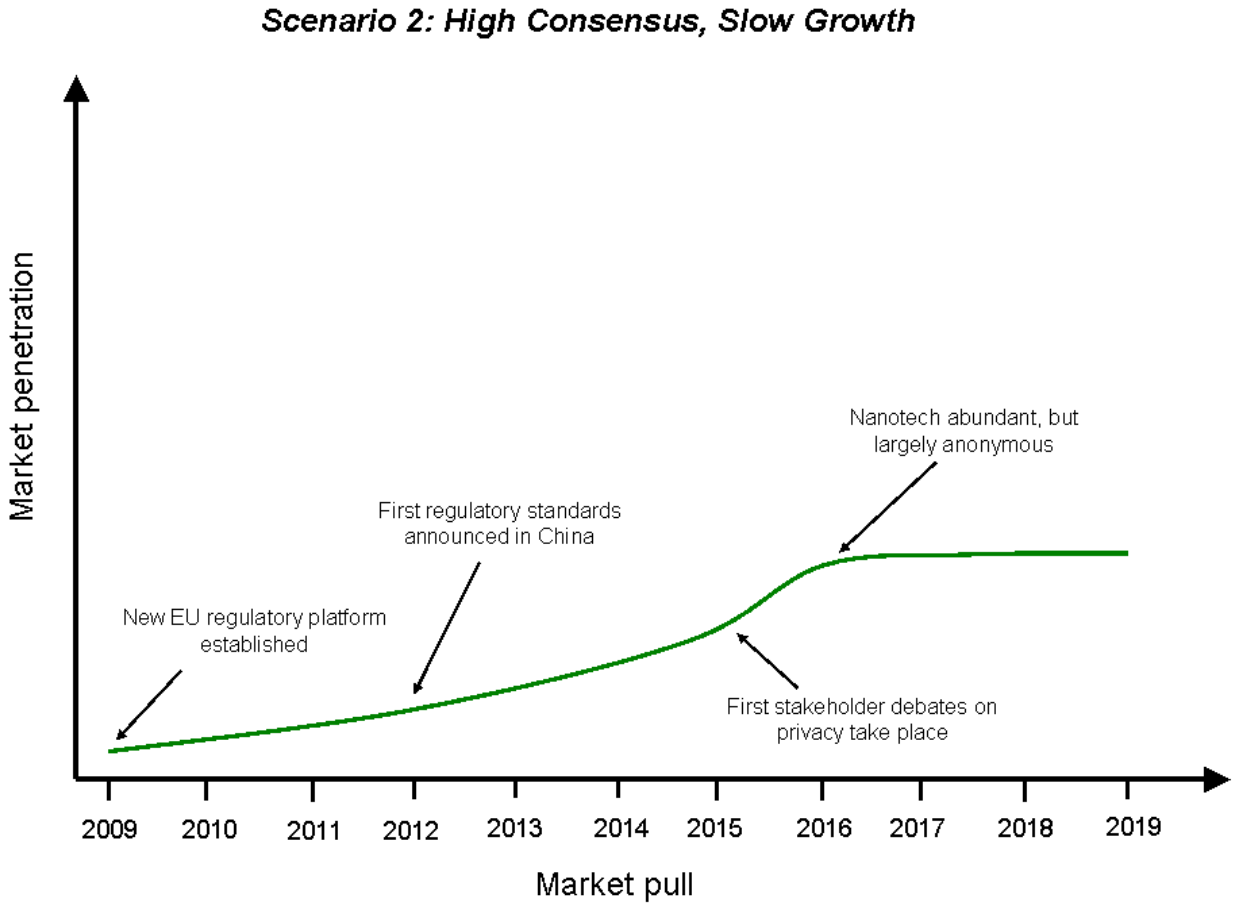
Due in part to the slow speed of commercialisation, and because the anticipated economies of scale have not taken place, nanotechnology-enabled products tend to be more expensive. It is thought this is likely to change in the near future, however, as the geographical centre of production continues to shift eastward, and countries formerly thought of as developing begin to determine the sort of products that are released onto global markets. The untapped markets in these countries present innovative companies with a major opportunity.

Once this opportunity is exploited, nanotechnology-enabled products will probably become available to a larger audience. At present there are few organisations clamouring for private or public sector action to open up access to nanotechnology. If anything, despite the benefits that nanotechnologies could deliver, prominent NGOs are arguing that it is the poor who have less freedom to avoid potentially dangerous nanoparticles.

Scenario 2: High Consensus, Slow Growth

Summary

- Regulation of new technologies has been standardised internationally and strong accountability systems are in place.
- Public sector incentives, supported by multi-stakeholder participation forums, have directed research towards products that explicitly benefit society.
- Local stakeholder forums debate issues that arise from the use of technology (such as privacy) and make decisions for their local area.
- The strong regulatory regime, especially around issues of toxicity, has meant that health and safety risks are spotted early on and are well-managed.



Timeline

2009	Several new developments in the EU mark a potential shift in the regulatory environment. Following new recommendations on labelling for cosmetics containing nanomaterials and calls from MEPs for an extension of the "no data, no market" principle, a review of the EU nanotechnologies action plan for 2005-2009 has taken place. As a result, a new platform was developed for dialogue between scientists, product developers, NGOs, consumer groups and others on the social and environmental aspects of nanotechnology. Early progress was made with some quick wins including: • Funding allocated for The European Centre for Environment, Health, Safety and Toxicology (ECEHST) • Moves to include training on the ethical, legal and social aspects of nanotechnology into all relevant higher education courses • Development of a protocol for the assessment of risk and implementation of moratoriums, if necessary • A requirement for all funding applications to be accompanied with a completed ethical, legal and social aspects (ELSA) assessment • Education programmes and funding to support development of skills and mitigate anticipated skills shortage in Europe Companies complain that there is no longer a level playing field, either within countries or internationally, as larger companies can absorb additional costs.
2010	An OECD process for developing standards on nanoparticles is underway. The ECEHST was opened. The centre identified potentially harmful particles, provided guidance for regulation (e.g. where moratoriums were necessary) and advised on safety issues for workers and users. The development of life-cycle analysis for nanomaterials was a particular focus.
2011	It is evident that growth in nanotechnology has slowed considerably. Many smaller companies have left the sector, with economic difficulties due to the global recession being exacerbated by increased regulatory costs. The food sector is particularly affected by the extension of modified labelling requirements to the emerging sector of nanofoods. The use of nanotech in electronics continues to grow, with a slow but significant increase in its diagnostic applications.
2012	The first publication of standards for nanoparticles was announced in China. The OECD standards on nanoparticles were launched quickly in response, informed by data from the ECEHST. This is proclaimed by some as heralding a major step forward in providing a level international regulatory field, but others argue that the damage to nanotech has already been done.

	International discussions begin on overhauling intellectual property/patenting systems, with a view to ensuring access to important enabling technologies.
2013	The first moratoriums were announced and a number of products were recalled, based on research from the ECEHST. Little progress has been made on issues of intellectual property.
2014	Privacy came to the forefront of the debate over. Nanosensors tracked what people bought, where they went and even what they said. The media and civil rights groups began to talk about this as an infringement on civil liberty and increasingly the public took notice.
2015	Stakeholder debates took place across Europe to discuss what was off limits with respect to the use of nanotech to collect and transmit information. Clear signposts were required where the technology was in use, and products that used this type of surveillance technology were labelled accordingly.
2016	By now, it was clear that the word "nanotechnology" was no longer a marketing tool. Nonetheless, nanoscale science was in abundant use, without attention being drawn to its employment.
2017	Larger companies are examining the possibility of developing technology-sharing programmes with developing countries, drawing on long-established models from the pharmaceuticals industry.
2019	BBC documentary 'Whatever happened to nanotechnology?' is broadcast. The programme revisits 2009, the fears of the time and looks at developments of the past ten years. The programme takes viewers back to some of the more radical predictions that were made, as well as some of the more serious forecasts about risk, such as those concerning the possibility of human and ecological toxicity.

In depth

Risk Management and Regulation

A strict regulatory environment has evolved. International regulatory standards, promoted by the OECD, have been in place since 2012. Environmental and social impact assessments are now required for every new application that uses nanotechnology. Life cycle analysis is standard, analysing the impacts of each product from production, through use, to disposal.

Based on findings from the ECEHST, set up in 2010, there have been a number of moratoriums put in place on certain applications of nanotechnology.

There is a central website resource from the ECEHST updated with all the information on the vast number of safety standards related to nanoparticles. This is mainly used by scientists and product developers but is free to access. EU and government funded multi-disciplinary teams that include representatives from NGOs,

companies, regional governments and delegates from local stakeholder forums, advise on regulation and the direction of research funding.

Public debate

Early mapping of key stakeholders enabled the European Commission to engage those with an interest in, those who might be affected by, or those who had a strong influence over, the development of nanotechnology – including scientists, product developers and other representatives from industry, NGOs, consumer groups, the media and academia. Effective dialogue at EU, national and regional levels has been key in directing nanotechnology towards more societal needs and building consensus. Educated through a series of high profile media workshops early on, the media has played a vital role in providing informed and balanced information on nanotechnology and galvanising effective public debate.

Although nanotechnology itself does not have a high enough profile to warrant specific debate, issues related to the impact of nanotechnology, such as privacy, do. NGOs have also become much more targeted in their campaigning around specific issues – to great effect.

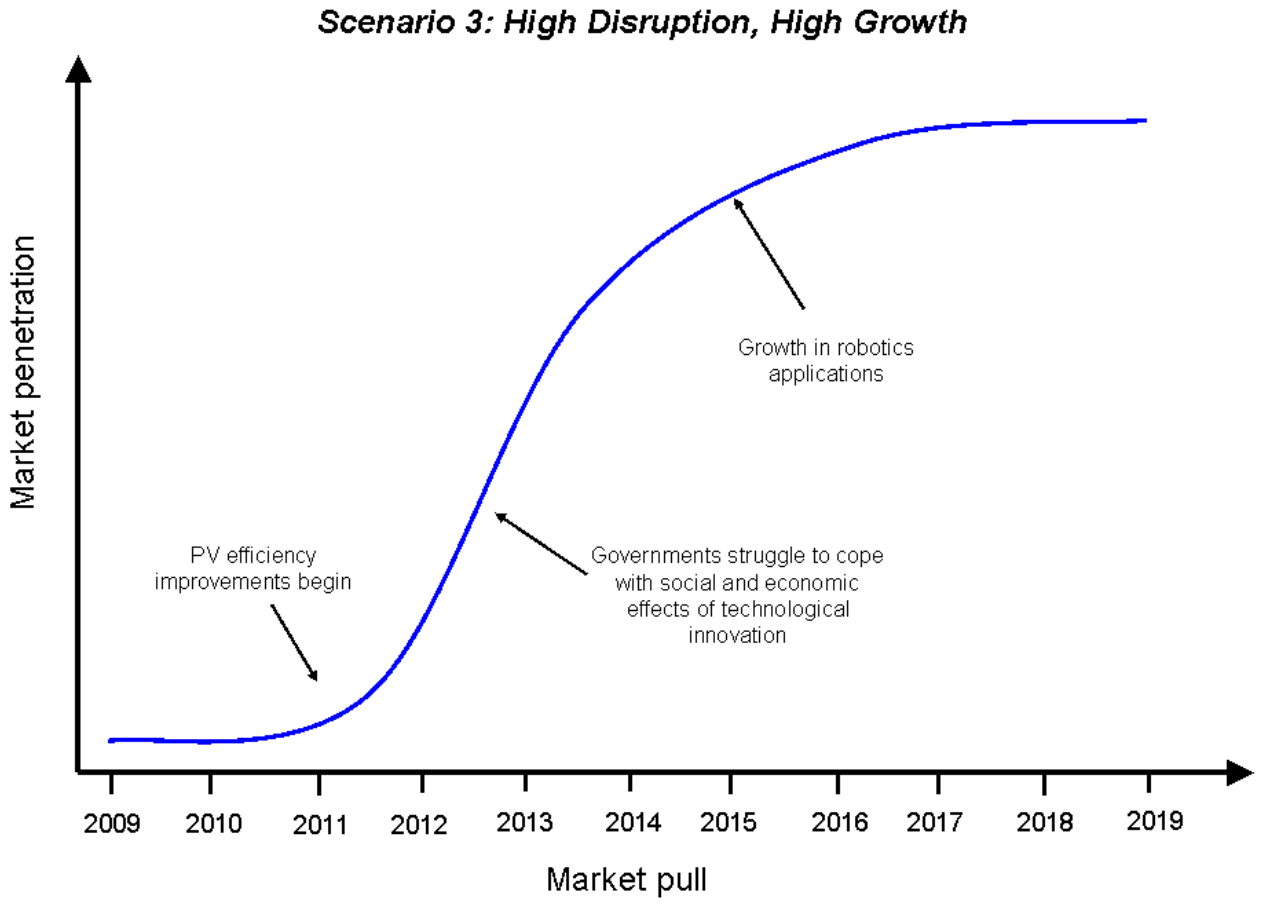
Access and Inequality

An unintended consequence of the careful approach in taking new technologies to market has been to add a premium to nanotechnology-related products. Consultation and dialogue cost money, and it is eventually the consumer that pays the price for this. Although this hasn't affected the success of products in the market, it has contributed to an emerging "nanodivide" in Europe and the developing world. Therefore, rather belatedly, significant effort is going into developing new mechanisms to broaden access, although this poses many difficulties. For example, some NGOs are entering into partnership with companies to deliver crucial products to "bottom of the pyramid" markets, often bringing in third-party companies based in the developing world. The continuing suggestion of public sector subsidy for the most important products, such as water purifiers and air filters, is hotly debated. In 2012, international patent law came under sustained scrutiny in an attempt to prevent individual companies from wielding excessive market power and raising barriers to entry for new or smaller players, but little progress was made. Today, some are placing great hopes in efforts by large companies to open up access based on some established IP and technology sharing models from other sectors.

Scenario 3: High Disruption, High Growth

Summary

- Scientific progress has been faster than expected and nanotechnology-related products are making a real impact on society and the economy.
- Dramatic improvements have taken place in the efficiency of solar photovoltaic (PV) cells.
- Long-term investments in fossil fuel resources are progressively losing value and new market entrants are growing quickly.
- The speed of change has left regulation behind. Nonetheless, public debates seem to indicate that people feel the benefits so far outweigh the risks.



Timeline

2009	UK nanotech companies take the lead in backing a new code of conduct-based model of voluntary regulation, overseen by a trade association. Some commentators note the resemblances between this approach and Responsible Care in the chemical industry. Many smaller companies are concerned at the potential costs of demonstrating they are compliant with the code.
2010	After a short recession, business confidence is buoyed up by the emergence of small, efficient fuel cells, which are beginning to replace batteries in smaller electronic devices such as mobile phones and laptops. Progress in this area drove research in other areas of fuel cell research and led to advances in larger fuel cell technology for transport use.
2011	There were dramatic improvements in PV – experimental solar cells were operating at 30 per cent efficiency. Prices began to drop.
2012	Rapid developments occurred with the first commercially available printable PV. Governments across Europe struggled to keep up with the rapid pace of technological change. There was a lack of defined regulation. However, products were seen to have widely applicable benefits, so there were few objections. European governments offered large subsidies to home-owners who invest in microgeneration.
2013	NGOs criticized the industry's system of voluntary regulation, arguing that it lacks adequate oversight. They pointed to the emerging long-term problems of resource over-use and waste management. There was an increasing shortage in engineers and researchers resulting in an increase in salaries. There was a dramatic increase in the use of fuel cells in cars, at least ten years earlier than had been expected. Storage problems were solved by use of new composite materials and some houses were fitted with fuel cells as power sources.
2014	Many of the old energy giants lobbied hard against the decentralisation of energy production. Greenpeace produced a report on resource use, which highlighted the limits of platinum availability and concerns about the lack of recycling of nanomaterials.
2015	A Nobel prize was awarded to the team responsible for developing cheap, efficient spray-on solar cells. Robotics started to kick off due to small, cheap and highly efficient batteries.

2016	Concerns over resource use and pollution continued to increase. The recycling issue had still not been resolved. The first major nanotechnology-related incident at a manufacturing plant highlighted the risks involved and forced a rethink from governments on regulation. There was a worrying skills shortage in Europe.
2017	The rapid spread of spray-on solar cells led to a worldwide rise in renewable energy production. For the first time there were signs that major reductions in CO2 emissions might be achievable. The importance and timing of these developments cannot be overstated as atmospheric concentrations of CO2 had reached 400ppm. The religious right in the US scaled up its opposition to nanotechnology with a publication called 'The End of God's Children', which questioned the religious implications of the advancing science of human modification.
2019	In 2019 the disruptive nature of the developments has become apparent as centralised energy production begins to fall dramatically. There is increasing unrest in countries that have no access to the technology and representatives are calling on governments and corporations to ensure wider distribution.

In depth

Risk Management and Regulation

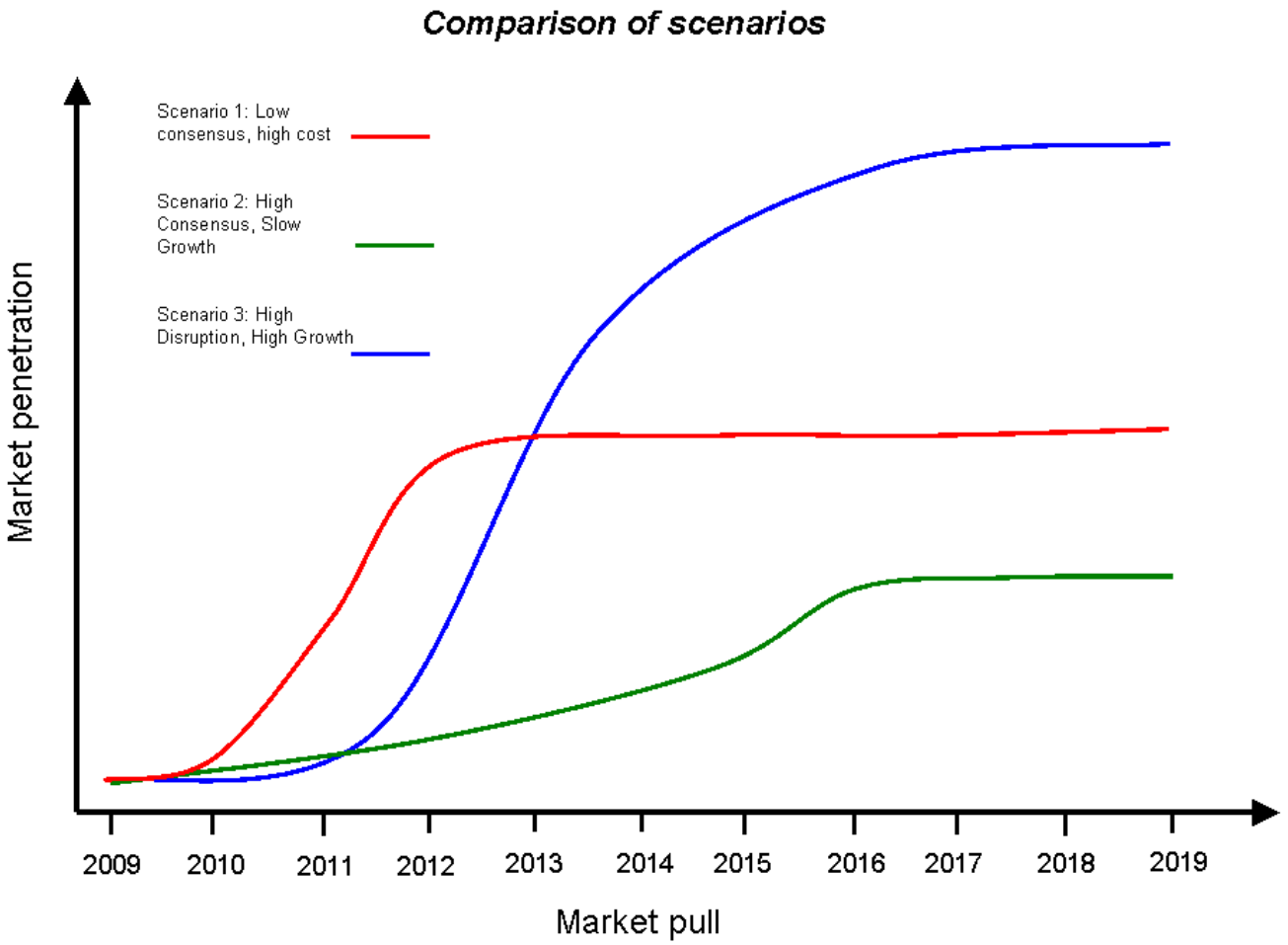
The regulatory environment has struggled to keep up with the pace of technological change. Health and safety at the workplace and concerns over life-cycle impacts have recently made regulation a higher priority. Because of the increasing complexity of nano-enabled devices, and the fact that they are often embedded in other materials (as with solar clothing), recycling them effectively is extremely difficult. As the technology has a high profile in society and a huge market value there is resistance from business interests to any additional red tape. Regardless of this pressure, governments are finally starting to react to the rapid development of technology and new legislation has been introduced in the last two years concentrating on health and safety and long-term producer responsibility, including disposal.

Public Debate

In the years leading up to 2019, most public opinion polls showed an overwhelmingly positive response to nanotechnology. Nanotechnologies are seen by most to be delivering an obvious societal benefit. However, debate has intensified about the trade-off between rapid progress and the potential down-sides. Spray-on solar has raised awareness of the potential issues around how waste is dealt with when the product has reached the end of its useful life. There is increasing pressure for biodegradable alternatives to be developed. There is also increasing unease in religious circles about the path that the advances in technology are taking us, particularly with respect to advances in the science of human modification.

Access and Inequality

There are still a number of developing countries that have not been able to take advantage of the rapid development of technology due to lack of infrastructure and investment. There is growing demand for energy technology to be made more universally available.


Comparison of scenarios
Scenario 1: Low consensus, high cost
Scenario 2: High Consensus, Slow Growth
Scenario 3: High Disruption, High Growth
Market penetration
2009
2010
2011
2012
2013
2014
2015
2016
2017
2018
2019
Market pull

Annex 8: Analysis of Scenarios Exercise

Summary

- In general, effective anticipatory action on the part of industry and regulators requires that both stakeholders engage better with each other in more formal and systematic ways.
- Effective communication with regulators and with the public is one of industry's chief obligations, which may require institutional innovations within the industry.
- The role of voluntary standards or forms of accreditation was seen as important, but as not providing anything like a panacea. Government needs to provided guidance on what such standards should cover.
- Foresight is not just about anticipating negatives, but also about anticipating benefits, and enabling these to be spread as widely as possible without engendering negative socio-economic impacts
- Upstream and consultative modes of wider engagement are very problematic, but in the face of insuperable uncertainties about latent effects, the question of how far such initiatives are possible and necessary will probably not go away.

Introduction

The scenarios exercise was run as part of a roundtable event for representatives from companies who had participated in the interviews in Phase 3, academia, and regulatory agencies. Three scenarios were provided, to serve as the basis of discussion of what were considered to be less and more desirable future outcomes for the development of nanotechnologies within society over the next decade. Each scenario was constructed around "outlier" or wild card events which were of low probability, but which could have a high impact. Each consisted of a summary, a ten-year timeline of developments from 2009, and a more in-depth look at issues surrounding risk management and regulation, public debates about the technology, and economic impacts (see Annex 7 for full description of each). The development of these scenarios, using a set developed by the EU-funded Nanologue project as a template, was designed to reflect initial findings from Phase 2 and Phase 3 of the research.

Methodology

Participants were divided into two groups, including a chair and scribe, and asked to consider how voluntary regulation may play a role, in each scenario, in bringing about negative and positive impacts.

Specifically, they were asked to consider the following questions:

1. What could business and regulators have done to prevent or avoid negative outcomes?
2. What might be the barriers here in 2009 to dealing successfully with the issues that arise within your scenario?

In thinking about these questions, they were asked to consider in each case drivers which might be important within the three areas that are addressed "in depth" in each scenario: public debate, risk management and regulation, and technology access.

They were requested to formulate 3-4 measures which should be undertaken (a) by regulators and (b) by business in order to address the barriers they had identified as existing in the present.

Participants

Identifier	Organisation
Group 1 (Scenarios 1 & 2)	
A	**Academic**
B	**HSE**
C	**MNC – Food**
D	**SME – Medical and Diagnostics**
Group 2 (Scenarios 1 & 3)	
E	**NanoKTN**
F	**SME – Food**
G	**SME - Instrumentation**
H	**Academic**

Discussion

Overall, Scenario 1 was interpreted as the scenario that industry fears most, in which regulatory gaps and/or poor practices lead to a situation which threatens to blight the nanotechnologies industry. Tackling such a situation was seen to require several different measures.

First, clear and early communication about risk and benefit was seen as vital, both within and outside the industry, in order to counteract potential negative consequences of media reporting. Trade organisations were seen as playing a key role here, with the goal being to help a wider circle of stakeholders understand the technologies, why they are being developed, and what benefits they might bring: "if they understand it more they may be prepared to adopt it." Companies and trade organisations must avoid "talking down" and also have to make the message "credible and believable" (Participant F). But legitimacy and trust would be undermined by having the government take a lead on communication efforts, as they would be seen to have compromised their position as regulators in doing so (E). One suggestion for how trade bodies could organise was that, instead of umbrella organisations striving to represent the whole of the nanotechnologies industry, sectoral bodies could be constituted, helping define clear positions on risks and benefits for specific applications, and helping "quarantine" issues as they arose.

Secondly, a lack of data and toxicological knowledge was seen as a contributing factor in the emergence of the CNT-related health scare. Participants suggested that more action should be taken at EU level to coordinate toxicology efforts, and that, at the national level, more targeted regulation based on exposure, risk and potential harm should be looked at in order to better capture the differences between potential applications of nanotechnology in different sectors. There was also some discussion of how well technology graduates are being trained to examine their activities in light of ethical and duty-of-care considerations. It was also possible, participants noted, that the latency of an exposure problem might make it impossible to predict its emergence, no matter how much toxicological research was done. Nevertheless, regulation had to be proportionate and react to risk and uncertainties as they were discovered.

Although Scenario 1 was felt to be highly negative, Scenario 2 was felt to represent another source of danger – over-regulation. Indeed, this scenario was interpreted as demonstrating

some of the difficulties inherent in attempting to put in place the kind of measures that were seen as necessary to avoid Scenario 1.

Early and heavy regulation in this scenario (particularly around the need to engage with the public in upstream mode) was interpreted as having added to economic difficulties caused by the recession (in the present. Compliance with regulation was seen as having imposed heavy costs on smaller players, with the result that many small companies had been driven out of the industry. The main response participants saw as appropriate to this scenario was much more engagement between regulators and industry to decide early on what level of regulation would be necessary in order to ensure acceptance of technologies, along with safety.

Perhaps the key interaction here was seen as between public consultation and a lack of profitability across the industry. The possibility of public opinions actually vetoing specific applications was seen as potentially having a direct impact on the survival of a broad range of nanotechnologies.

The role of accreditation standards in driving responsible activity was also discussed in relation to both Scenarios 1 and 2, with some concern evident over how best these could be developed without engendering a collective action problem. Unless companies were given a clear view of which of several standards would be the best overall option, then they would be likely top wait to see which one survived a process of VHS versus Betamax-style natural selection (Participant E). One way forward might be for the Government to specify what kinds of criteria a code of conduct or accreditation standard might need to meet, and then allowing different standards to be developed.

Scenario 3 was much seen in a much more ambivalent light. The benefits of the rapid technological advances detailed in the scenario were seen as leading directly to public acceptance, but that a demonstrable lack of foresight from industry and from regulators was evident, given the problems which emerged around the recycling, reuse and disposal of sophisticated and complex nano-devices and materials.

A need for early investment in large-scale recycling and disposal infrastructure suited to potential future uses of nanotechnologies was seen as a key need, in order to avoid the creation in future of an excess of material. Investment in such infrastructure could come from both government and industry, but this would be a global problem, as increasing access to complex consumer products in developing countries would probably not be matched by a corresponding increase in availability of "lifecycle technologies" or end-of-life infrastructure. A combined effort of increasing technology access in these areas to compensate, together with (as most signature products here are consumer products) a concerted programme of public education about the best ways to recycle products would be necessary. This scenario was seen as being one which most obviously required a great deal of complex coordination of efforts at a global level.

Conclusions

It was evident that participants from both public bodies and private companies saw in the three scenarios evidence that led them to call for better engagement between regulators and industry, both to avoid situations like the exposure problems detailed in Scenario 1, the issues of overregulation which participants saw as central to Scenario 2, and the lack of foresight apparent in Scenario 3. The need to differentiate between different uses of nanotechnology, both in terms of assessments of risk and of benefit, recalls various observations recorded during Phase 3 of the research (see pp. 104 and 114 above). The need to build in such considerations to processes of communication was seen as particularly important, both in terms of the forms of

information being promulgated, and in terms of the institutional innovations which might be necessary to communicate effectively (such as sectoral industry bodies representing food, speciality chemicals, and so on).

As some participants noted, however, the possibility of latent and unpredictable problems (perhaps both in terms of health and environmental risks, and socio-economic issues, as in the technology access problems within Scenario 3) remains something which is extremely difficult to address, if not impossible. It is interesting here that the processes of wider engagement and consultation described in Scenario 2 were viewed negatively. As one company we interviewed suggested, regulation could be thought of as representative of "society's willingness to accept risk" (see p. 98 above). If these kinds uncertainty are unavoidable, then questions of how regulation extends to encompass them (which some have suggested may extend to formal processes).

References

AccountAbility (2005). *Stakeholder engagement standard*, London, AccountAbility.

Aitken, R. J., M. Q. Chaudhry, et al. (2006). "Manufacture and use of nanomaterials: current status in the UK and global trends." *Occupational Medicine-Oxford* **56**(5): 300-306.

Allianz (2007). *Small sizes that matter*. Munich, Allianz AG. Online at: http://www.allianz.com/migration/images/pdf/saobj_796424_allianz_study_nanotechnology_engl.pdf.

Bainbridge, W. S. (2007). "Converging technologies and human destiny." *Journal of Medicine and Philosophy* **32**: 197-216.

Anton, P., R. Silberglitt, et al. (2001). *The global technology revolution: bio/nano/materials trends and their synergies with information technology by 2015*. Santa Monica, CA, RAND.

Baker, M. (2003) "Doing it small". *Ethical Corporation Magazine*, August 20th, 2003.

Barnett, J., A. Carr, et al. (2006). Going public: risk, trust and public understandings of nanotechnology. In *Nanotechnology: risk, ethics and law*. G. Hunt and M. D. Mehta. London, Earthscan.

Bauer, C., J. Buchgeister, et al. (2008). "Towards a framework for life cycle thinking in the assessment of nanotechnology " *Journal of Cleaner Production* **16**(8-9): 910-26.

Bellobono, I. R., F. Morazzoni, et al. (2005). "Photosynthetic membranes, Part 74: Solar energy driven photocatalytic membrane modules for water reuse in agricultural and food industries." *International Journal of Photoenergy* **7**: 87-94.

Besley, J. C., V. L. Kramer, et al. (2008). "Expert opinion on nanotechnology: risks, benefits, and regulation." *Journal of Nanoparticle Research* **10**: 549-558.

Bettis, R. A. 1983. Modern Financial Theory, Corporate Strategy, and Public Policy: Three Conundrums. *Academy of Management Review* **8**, 405–414.

Bijker, W. E., I. D. de Beaufort, et al. (2007). "A response to 'Nanotechnology and the need for risk governance' O. Renn & M. C. Roco, 2006. J. Nanoparticle Research 8(2): 153-191." *Journal of Nanoparticle Research* **9**(6): 1217-1220.

Blaise, C., F. Gagne, et al. (2008). "Ecotoxicity of selected nano-materials to aquatic organisms." *Environ Toxicol* **23**(5): 591-8.

Blum-Kusterer, M., & Hussain, S. S. *(2001). Innovation and Corporate Sustainability: An Investigation into the Process of Change in the Pharmaceuticals Industry.* Business Strategy and the Environment, *10: 300-316.*

Brumfiel, G. (2006). "Consumer products leap aboard the nano bandwagon." *Nature* **440**(7082): 262-262.

Carpenter, G. and White, P. *(2004), "Sustainable Development: Finding the real business case,"* Corporate Environmental Strategy: International Journal for Sustainable Business *11(2). pp. 2-51*.

Carroll, A. B. (1991). "The Pyramid of Corporate Social Responsibility: Toward the Moral Management of Organizational Stakeholders." *Business Horizons* **34**(4): 39-48.

Chan, V. S. W. (2006). "Nanomedicine: An unresolved regulatory issue." *Regulatory Toxicology and Pharmacology* **46**(3): 218-224.

Chatterjee, R. (2008). "The challenge of regulating nanomaterials." *Environmental Science and Technology* **42**(2): 339-343.

Chau, C. F., S. H. Wu, et al. (2007). "The development of regulations for food nanotechnology." *Trends in Food Science & Technology* **18**(5): 269-280.

Chaudhry, Q., M. Scotter, et al. (2008). "Applications and implications of nanotechnologies for the food sector." *Food Additives and Contaminants* **25**(3): 241-258.

Chen, X. and H. J. Schluesener (2008). "Nanosilver: A nanoproduct in medical application." *Toxicology Letters* **176**: 1-12.

Cheng, J. and S. H. Cheng (2005). "Carbon nanotubes delay slightly the hatching time of zebrafish embryos". 229th American Chemical Society Meeting, San Diego, CA, March 2005.

Cobb, M.D. & Macoubrie, J. 2004. Public perceptions about nanotechnology: risks, benefits and trust. *Journal of Nanoparticle Research* **6**, 395–405.

Committee on Industry, Research and Energy (EU). 2006. Report on Nanosciences and nanotechnologies: An action plan for Europe 2005-2009

Cordes, C. (2004). Shifting the agenda of science and technology. *Conservation Biology* 18(4): 867-68.

Correa, C. M. (2005). *How intellectual property rights can obstruct progress*. SciDev.Net [accessed: 13/05/08]. http://www.scidev.net/en/opinions/how-intellectual-property-rights-can-obstruct-prog.html.

Cox, D. N., A. Koster, et al. (2004). "Predicting intentions to consume functional foods and supplements to offset memory loss using an adaptation of protection motivation theory." *Appetite* **43**(1): 55-64.

Davey, C. L., Wootton, A.B., Thomas, A., Cooper, R., and Press, M. *(2005), "Design for the Surreal World?: A New Model of Socially Responsible Design," in* European Academy of Design Conference Proceedings, *March 29-31, Bremen, Germany.*

de S. Cameron, N. M. (2006). "Nanotechnology and the Human Future: Policy, Ethics, and Risk." *Annals of the New York Academy of Sciences* **1093**: 280-300.

Donaldson, K., R. Aitken, et al. (2006). "Carbon nanotubes: A review of their properties in relation to pulmonary toxicology and workplace safety." *Toxicological Sciences* **92**: 5-22.

Donaldson, K., C. A. Poland, et al. (2008). "Carbon nanotubes introduced into the abdominal cavity of mice show asbestos-like pathogenicity in a pilot study." *Nature Nanotechnology*, **3**, 423-28.

Donaldson, K., V. Stone, et al. (2004). "Nanotoxicology." *Occupational Environmental Medicine* **61**: 727-28.

Donaldson, T. and L. Preston (1995). "The stakeholder theory of the corporation: concepts, evidence and implications." *Academy of Management Review* **20**(1): 65-91.

Dorbeck-Jung, B. R. (2007). "What can prudent public regulators learn from the United Kingdom Government's regulatory activities?" *Nanoethics* **1**: 257-70.

Dunkley, R.W.S. 2004. Nanotechnology: social consequences and future implications. *Futures* **36**, 1129–1132.

Dyllick, T. (1994). Umweltverträgliches Wachstum durch Innovation. *Politische Studien*, 45: 60-69.

EDF-DuPont (2007). *Nano risk framework*, EDF/Dupont.

Einsiedel, E. F. and L. Goldenberg (2006). Dwarfing the social? Nanotechnology lessons from the biotechnology front. In *Nanotechnology: Risk, Ethics and Law*. G. Hunt and M. D. Mehta, London: Earthscan**:** 213-221.

ENDS Report. (2008). Private sector steps in to address nano concerns. Retrieved 8 January, 2009, from http://www.endsreport.com/index.cfm?action=report.article&articleID=19495&q=nanotechnology&boolean_mode=all.

Englert, B. C. (2007). "Nanomaterials and the environment:uses, methods and measurement." *Journal of Environmental Monitoring* **9**: 1154-61.

Environmental Defense Fund - DuPont Nano Partnership (2007). *Nano risk framework*, EDF/DuPont.

Environmental Protection Agency (2008). *Nanoscale Materials Stewardship Program*. [accessed: 04/10/08]. http://www.epa.gov/oppt/nano/stewardship.htm.

ETC Group (2003). *The Big Down: from Genomes to Atoms*, online at http://www.etcgroup.org/documents/TheBigDown.pdf.

---- (2005). Nanotech's "Second Nature" patents: implications for the Global South. Online at: http://www.etcgroup.org/upload/publication/pdf_file/54.

European Commission (2002). *Corporate social responsibility: a business contribution to sustainable development*. Luxembourg: Office for Official Publications of the European Communities.

---- (2004). *Nanotechnologies: a preliminary risk analysis on the basis of a workshop organized in Brussels on 1–2 March 2004 by the Health and Consumer Protection Directorate General of the European Commission*. Brussels.

---- (2005). *Nanosciences and nanotechnologies: an action plan for Europe 2005-2009*. EC: Brussels: European Commission.

---- (2008a). Recommendation on a code of conduct for responsible nanosciences and nanotechnologies research. Brussels: European Commission.

---- (2008b). *Regulatory aspects of nanomaterials: summary of legislation in relation to health, safety and environment aspects of nanomaterials, regulatory research needs and related measures*, Brussels; European Commission.

European Commission (SCENHIR) (2006). *Modified opinion (after public consultation) on the appropriateness of existing methodologies to assess the potential risks associated with engineered and adventitious products of nanotechnologies*. Brussels: European Commission.

Franco, A., S. F. Hansen, et al. (2007). "Limits and prospects of the "incremental approach" and the European legislation on the management of risks related to nanomaterials." *Regulatory Toxicology and Pharmacology* **48**(2): 171-183.

Frater, L., E. Stokes, et al. (2006). *An overview of the framework of current regulation affecting the development and marketing of nanomaterials*, Cardiff, BRASS. Online at: http://www.berr.gov.uk/files/file36167.pdf

Freeman, R. E. (1984). *Strategic management: a stakeholder approach*, Boston, Pitman.

Friedrichs, S. (2007). Risk classification made easy: the NanoSURE™ control banding scheme. Nano-EXPO, East Midlands Conference Centre, Nottingham, UK, 16-17 May 2007. Online at: http://www.nanotechia.org/lib/tmp/cmsfiles/File/NIA_NanoSURE_May2007.pdf.

Friends of the Earth (2008). *Out of the laboratory and onto our plates: nanotechnology in food and agriculture*, Friends of the Earth Australia, Europe and USA.

Gatti, A. M. and S. Montanari (2008). "Nanopollution: the invisible fog of future wars." *The Futurist* **42**(3): 32-4.

Gavelin, K., R. Wilson, et al. (2007). *Democratic technologies? The final report of the Nanotechnology Engagement Group (NEG)*. London, Involve.

Global Reporting International (2006). *Sustainability reporting guidelines*. Amsterdam, GRI.

Gordon, B. (2007). *The state of responsible business: Global corporate response to environmental, social and governance (ESG) challenges*. London, Ethical Investment Reseach Services (EIRIS).

Groves, C. (2009). "Future ethics: risk, care and non-reciprocal responsibility." *Journal of Global Ethics* **5**(1): 17-31.

Gunningham, N. (1995). "Environment, self-regulation and the chemical industry: assessing Responsible Care." *Law and Policy* 17(1): 57-109.

Gunningham, N. A., D. Thornton, et al. (2005). "Motivating management: corporate compliance in environmental protection." *Law and Policy* 27(2): 289-316.

Guston, D. H. (2006). "Responsible knowledge-based innovation." *Society* 43(4): 19-21.

Hagens, W. I., A. G. Oomen, et al. (2007). "What do we (need to) know about the kinetic properties of nanoparticles in the body?" *Regulatory Toxicology and Pharmacology* **49**: 217-29.

Hamel, G. (2006), "The Why, What, and How of Management Innovation," Harvard Business Review, *84(6), pp. 72-84.*

Hannah, W. and P. B. Thompson (2008). "Nanotechnology, risk and the environment: review." *Journal of Environmental Monitoring* **10**(3): 291-300.

Hansen, S. F. and J. Tickner (2007). "The challenges of adopting voluntary health, safety and environment measures for manufactured nanomaterials: lessons from the past for more effective adoption in the future." *Nanotechnology, Law and Business* **4**(3): 341-59.

Hansson, S. O. (2004). "Great uncertainty about small things." *Techne* **8**(2): 26-35.

Helland, A., M. Scheringer, et al. (2008). "Risk assessment of engineered nanomaterials: A survey of industrial approaches." *Environmental Science and Technology* **42**(2): 640-646.

Hockerts, K. (2008*).* Managerial Perceptions of the Business case for Corporate Social Responsibility. *CBSCSR Working Paper Series: Copenhagen Business School.*

Hockerts, K. & Morsing, M. (2008). A Literature Review on Corporate Social Responsibility in the Innovation Process. *Copenhagen Business School (CBS), Center for Corporate Social Responsibility. Online at: http://www.csrinnovation.dk/web/wp-content/2008/09/literaturereviewsep08full.pdf*

Hoet, P. H. M., I. Bruske-Hohfeld, et al. (2004). "Nanoparticles: known and unknown health risks." *Journal of Nanobiotechnology* **2**: 12-26.

Hunt, G. (2006). The global ethics of nanotechnology. In *Nanotechnology: risk, ethics and law*. G. Hunt and M. D. Mehta. London, Earthscan**:** 183-95.

Husted, B.W. 2005. Risk Management, Real Options and Corporate Social Responsibility. *Journal of Business Ethics* **60**(2), 175-183.

ICCA (2007). *Responsible Care Status Report*. Arlington, VA, International Council of Chemical Associations.

International Council of Chemical Associations (2007). *Product Stewardship Guidelines.* Online at: http://www.icca-chem.org/pdf/Guidelines.pdf.

International Labour Office (2001). *Tripartite Declaration of Principles Concerning Multinational Enterprises and Social Policy*, Geneva, ILO Publications.

International Risk Governance Council (IRGC) (2006). *White paper on nanotechnology risk governance*. Geneva, International Risk Governance Council. Online at: http://www.irgc.org/IMG/pdf/IRGC_white_paper_2_PDF_final_version-2.pdf.

Jamali, D. (2008). "A stakeholder approach to corporate social responsibility: a fresh perspective into theory and practice." *Journal of Business Ethics* **82**: 213-231.

Jamieson, D. (1992). "Ethics, public policy and global warming." *Science, Technology and Human Values* **17**(2): 139-53.

Joy, B. (2000). "Why the future doesn't need us." *Wired* (April 2000).

Kanter R. M. 1999. From Spare Change to Real Change, *Harvard Business Review* **77**(3), 122–132.

Kearnes, M., R. Grove-White, et al. (2006). "From Bio to Nano: Learning Lessons from the UK Agricultural Biotechnology Controversy." *Science as Culture* **15**(4): 291-307.

Kearnes, M., P. Macnaghten, et al. (2006). *Governing at the nanoscale: people, policies and emerging technologies*, London: Demos.

Kearns, M. P. and Wynne, B.). 'On nanotechnology and ambivalence: the politics of enthusiasm.' *Nanoethics* 1: 131-142.

Keiper, A. (2007). "Nanoethics as a Discipline?" *The New Atlantis* **16**: 55-67.

Keulartz, J., M. Schermer, et al. (2004). "Ethics in technological culture: a programmatic proposal for a pragmatist approach." *Science, Technology and Human Values* **29**(3): 3-29.

King, A. A. and M. J. Lenox (2000). "Industry self-regulation without sanctions: the chemical industry's Responsible Care programme." *Academy of Management Journal* 43(4): 698-716.

Klaine, S. J., P. J. J. Alvarez, et al. (2008). "Nanomaterials in the environment: Behavior, fate, bioavailability, and effects." *Environmental Toxicology and Chemistry* **27**(9): 1825-1851.

Köhler, A. R., C. Som, et al. (2008). "Studying the potential release of carbon nanotubes throughout the application life cycle." *Journal of Cleaner Production* **16**(8-9): 927-37.

Krug, H. F. (2005). "Auswirkungen nanotechnologischer Entwicklungen auf die Umwelt." *Umweltswissenschaften und Schadstoff-Forschung* **17**(4): 223-30.

Kuzma, J. (2007). "Moving forward responsibly: Oversight for the nanotechnology-biology interface." *Journal of Nanoparticle Research* **9**(1): 165-182.

Lee, R. and D. Jose (2008). "Self-interest, self-restraint and corporate responsibility for nanotechnologies: Emerging dilemmas for modern managers." *Technology Analysis & Strategic Management* **20**: 113-125.

Lemley, M. A. (2005). "Patenting nanotechnology." *Stanford Law Review* 58(2): 601-630.

Lovern, S. B. and R. Klaper (2006). "Daphnia magna mortality when exposed to titanium dioxide and fullerene (C60) nanoparticles." *Environmental Toxicology and Chemistry* **25**(4): 1132-37.

Lubick, N. (2008). "Risks of nanotechnology remain uncertain." *Environmental. Science and Technology*. **42**(6): 1821-1824.

Ludlow, K., D. M. Bowman, et al. (2007). *A review of possible impacts of nanotechnology on Australia's regulatory framework*, Melbourne, Monash University.

Luoma, S. N. (2008). *Silver nanotechnologies and the environment: old problems or new challenges?*, Washington, DC, Project on Emerging Nanotechnologies.

MacGregor, S.P. & Fontrodona, J. (2008). Exploring the Fit Between CSR and Innovation. *IESE Business School – University of Navarra Working Paper, WP-759, July, 2008.*

McWilliams, A. and Siegel D. 2001. *Corporate Social Responsibility: A Theory of the Firm Perspective*, Academy of Management Review ***26(1), 117–127.***

Marchant, G. E. (2003). "From general policy to legal rule: Aspirations and limitations of the precautionary principle." *Environmental Health Perspectives* **111**(14): 1799-1803.

Marchant, G. E. and D. J. Sylvester (2006). "Transnational models for regulation of nanotechnology." *Journal of Law Medicine & Ethics* **34**(4): 714-725.

Maynard, A., R. J. Aitken, et al. (2006). "Safe handling of nanotechnology." *Nature* **444**: 267-9.

Midttun, Atle (2007), *"C(S)R and innovation, compatibility or contradiction? Towards a dynamic reinterpretation of C(S)R," paper for a special issue of the* Corporate Governance Journal *on "Corporate Sustainability, Strategic Management and the Stakeholder View of the Firm."*

Mills, K. and C. Fledderman (2005). "Getting the best from nanotechnology: approaching social and ethical implications openly and proactively." *IEEE Technology and Society Magazine* **24**(4): 18-26.

Montague, P. 2004. Welcome to NanoWorld: nanotechnology and the precautionary principle imperative. *Multinational Monitor* **25**(9), 16–19.

Munshi, D., Kurian, P., Bartlett, R.V., and Lakhtakia, A. 2007. A map of the nanoworld: Sizing up the science, politics, and business of the infinitesimal. *Futures* **39**(4), 432-452.

National Science and Technology Council (NSTC) (2006). *Environmental, health and safety research needs for engineered nanoscale materials*. Arlington, VA, National Nanotechnology Coordination Office.

Nel, A., T. Xia, et al. (2006). "Toxic potential of materials at the nanolevel." *Science* **311**: 622-27.

Nohynek, G. J., E. K. Dufour, et al. (2008). "Nanotechnology, cosmetics and the skin: is there a health risk?" *Skin Pharmacology and Physiology* **21**: 136-49.

Oberdorster, G. (2004). "Manufactured nanomaterial (fullerenes, C60) induce oxidative stress in the brain of juvenile largemouth bass." *Environmental Health Perspectives* **12**(10): 1058-62.

Oberdorster, G., A. Maynard, et al. (2005). "Principles for characterizing the potential human health effects from exposure to nanomaterials: elements of a screening strategy." *Particle and Fibre Toxicology* **2**(8).

Orlitzky, M. and Benjamin, J. D. 2001 Corporate Social Responsibility and Firm Risk: A Meta-analytic Review, *Business and Society* **40**(4), 369–396.

O'Sullivan, M. A. (2000). The Innovative Enterprise and Corporate Governance, *Cambridge Journal of Economics*, 24: 393-416.

Park, B. (2006). *Proposed ideal regulatory system*. Kidlington, Oxonica. Online at: http://www.nanotechia.org/lib/tmp/cmsfiles/File/OXONICA_NanosafebasedriskassessmentBarryParkJune2006.pdf

Pedersen, E. R. (2009). "Modelling CSR: how managers understand the responsibilities of business towards society." *Journal of Business Ethics*, DOI: 10.1007/s10551-009-0078-0.

Pidgeon, N. and T. Rodgers-Hayden (2007). *"Opening up nanotechnology dialogue with the publics: risk communication or 'upstream engagement'?"* Health, Risk and Society ***9****(2): 191 – 210.*

Powell, M. C., M. P. A. Griffin, et al. (2008). "Bottom-up risk regulation? How nanotechnology risk knowledge gaps challenge federal and state environmental agencies." *Environmental Management* **42**(3): 426-443.

Put, J. (2004). Mapping out nano risks. In *Nanotechnologies: a preliminary risk analysis on the basis of a workshop organized in Brussels on 1–2 March 2004 by the Health and Consumer Protection Directorate General of the European Commission.* Brussels, European Commission**:** 119-24.

Renn, O. and M. C. Roco (2006). "Nanotechnology and the need for risk governance." *Journal of Nanoparticle Research* **8**(2): 153-91.

RESPONSE (2007). *Understanding and responding to societal demands on corporate responsibility*, Fontainebleu, INSEAD. Online at: http://www.insead.edu/v1/ibis/response_project/documents/Response_FinalReport.pdf

Responsible NanoCode (2008). *Information on the Responsible NanoCode Initiative.* Online at: http://www.responsiblenanocode.org/documents/InformationonTheResponsibleNanoCode.pdf.

Robichaud, C. O., D. Tanzil, et al. (2005). "Relative risk analysis of several manufactured nanomaterials: an insurance industry context." *Environmental Science and Technology* **39**(22): 8985-8994.

Roco, M. C. (2004). "Nanoscale Science and Engineering: Unifying and Transforming Tools." *AIChE Journal* **50**(5): 890-897.

Royal Society and Royal Academy of Engineering (2004). Nanoscience and nanotechnologies: opportunities and uncertainties. London, Royal Society.

Ruden, C. (2004). "Acrylamide and cancer risk - expert risk assessments and the public debate." *Food and Chemical Toxicology* 42(3): 335-349.

Sammartino, M. P., F. Bellanti, et al. (2008). "Ecopharmacology: Deliberated or casual dispersion of pharmaceutical principles, phytosanitary, personal health care and

veterinary products in environment needs a multivariate analysis or expert systems for the control, the measure and the remediation." *Microchemical Journal* 88(2): 201-209.

Savage, N. and M. S. Diallo (2006). "Nanomaterials and water purification: opportunities and challenges." *Journal of Nanoparticle Research* **7**: 331-42.

Sawhney, M., Wolcott, R.C., and Arroniz, I. (2006*), "The 12 Different Ways for Companies to Innovate,"* MIT Sloan Management Review*, 47(3), pp. 74-81.*

Schaller, S. 2008. Corporate social responsibility: A guiding concept for dialogue on nanotechnology. http://www.smalltimes.com/display_article/318882/109/ARTCL/none/none/1/Corporate-social-responsibility:-A-guiding-concept-for-dialogue-on-nanotechnology/ [date accessed 17/09/2008].

Schulz, J., H. Hohenberg, et al. (2002). "Distribution of sunscreens on skin." *Advanced Drug Delivery Review* **54**: 157-63.

Service, R. F. (2004). "Nanotoxicology: Nanotechnology grows up." *Science* **304**(5678): 1732-1734.

Siegrist, M., C. Keller, et al. (2007). "Laypeople's and experts' perception of nanotechnology hazards." *Risk Analysis* **27**(1): 59-69.

Social Accountability International (2008). *Social Accountability 8000*. New York, SAI.

Stern, S. T. and S. E. McNeil (2008). "Nanotechnology safety concerns revisited." *Toxicological Sciences* **101**: 4-21.

Sutherland, W. J., M. J. Bailey, et al. (2008). "Future novel threats and opportunities facing UK biodiversity identified by horizon scanning." *Journal of Applied Ecology* **45**(3): 821-833.

Swierstra, T. and A. Rip (2007). "Nano-ethics as NEST-ethics: patterns of moral argumentation about new and emerging science and technology of advanced materials." *Nanoethics* **1**: 3-20.

Swiss Re (2004). *Nanotechnology: small matter, many unknowns*. Zurich, SwissRe. Online at: http://www.swissre.com/resources/31598080455c7a3fb154bb80a45d76a0-Publ04_Nano_en.pdf.

Theodore, L. and R. G. Kunz (2005). *Nanotechnology: Environmental Implications and Solutions*, New Jersey, Wiley-Interscience.

Thomas, K. and P. Sayre (2005). "Research strategies for safety evaluation of nanomaterials, Part I: Evaluating the human health implications of exposure to nanoscale materials." *Toxicological Sciences* **87**: 316-21.

Throback, I., M. Johansson, et al. (2007). "Silver (Ag(+)) reduces denitrification and induces enrichment of novel nirK genotypes in soil." *FEMS Microbiological Letters* **270**(2): 189–194.

Tilt, C. A. (2001). "The content and disclosure of Australian corporate environmental policies." *Accounting, Auditing and Accountability Journal* 14(2): 190-212.

Turk, V. (2007). *Corporate social responsibility and nanotech: assessing and communicating environmental, ethical and social aspects of nanotech*. Corporate Social Responsibility and Nanotech, European Nanotechnology Trades Alliances Meeting, 14 March 2007.

Turk et al. (2007). *Nanologue:* Scenarios: The future of nanotechnology. We need to talk. Online at: http://www.nanologue.net/

TÜV SÜD GmbH (2008). *Cenarios Certification Standard*. Munich, TÜV SÜD Industrie Service GmbH.

UK Government (2005a). *The Government's outline programme for public engagement on nanotechnologies (OPPEN),* London, UK Government.

---- (2005b). *Response to the Royal Society and Royal Academy of Engineering report: 'Nanoscience and nanotechnologies: opportunities and uncertainties'*. London, Department of Trade and Industry.

---- (2005c). *The Government's Outline Programme for Public Engagement on Nanotechnologies.* London: Department of Trade and Industry.

---- (2006). *Characterising the potential risks posed by engineered nanoparticles*. London, Department of Environment, Food and Rural Affairs. Online at: http://www.defra.gov.uk/environment/nanotech/research/reports/progress-report061019.pdf.

---- (2007). *Characterising the potential risks posed by engineered nanoparticles*, Department of Environment, Food and Rural Affairs. Online at: www.defra.gov.uk/environment/nanotech/research/pdf/nanoparticles-riskreport07.pdf.

---- (2008a). *Statement by the UK Government about nanotechnologies*. Department for Innovation Universities and Skills. Online at: http://www.dius.gov.uk/policy/documents/statement-nanotechnologies.pdf.

---- (2008b). *UK Voluntary Reporting Scheme for engineered nanoscale materials*, London, Department of Environment, Food and Rural Affairs.

Uskokovic, V. (2007). "Nanotechnologies: what we do not know." *Technology in Society* **29**(1): 43-61.

Vaidhyanathan, S. (2006). Nanotechnologies and the law of patents: a collision course. *Nanotechnology: risk, ethics and law*. G. Hunt and M. D. Mehta. London, Earthscan: 225-36.

Verband der Chemischen Industrie (VCI) (2008). *Responsible production and use of nanomaterials*. Frankfurt a.M., VCI.

Vila, J. and MacGregor, S.P. (2007), "Business Innovation: What it brings, what it takes," IESE Alumni Magazine.

Webb, T. (2007). Strategy & Management: Unilever's CEO: Social innovation and Sustainability the only game in town. *Ethical Corporation*, **5** (2007).

Which? (2008). *Small Wonder? Nanotechnology and cosmetics*, London, Which?

Wilsdon, J. and R. Willis (2004). *See-through science: why public engagement needs to move upstream*, London, Demos.

Wolfson, J. R. (2003). "Social and ethical issues in nanotechnology: lessons from biotechnology and other high technologies." *Biotechnology Law Report* **22**(4): 376-96.

Wood, D. J. 1991.Corporate social responsibility revisited. *Academy of Management Review* **16**, 691–718.

Yosie, T. F. (2003). "Responsible Care at 15 Years." *Environmental Science and Technology* 37(21): 400A-406A.

Zhang, W. X. (2003). "Nanoscale iron particles for environmental remediation: An overview." *Journal of Nanoparticle Research* **5**(3-4): 323-332.