Responsible Innovation Lab Report & Roadmaps

D2.3 Report 2: Nanotechnology (BE)

RESPONSIBLE INNOVATION COMPASS

Grant agreement number	710543
Project acronym	COMPASS
Project website	www.innovation-compass.eu
Deliverable number	2.3
Version/last editor	1.1 (Marcelline Bonneau, SDS)
Work package number	2
Lead	Catherine Flick
Nature	Report
Dissemination level	Public
Author(s)	Malcolm Fisk, Catherine Flick, Marcelline Bonneau, Francois Jegou, Christophe Gouache, George Ogoh
Tel	+44 116 207 8487
Fax	
Email	cflick@dmu.ac.uk
Project Coordinator	a.Prof Dr. André Martinuzzi Institute for Managing Sustainability Vienna University of Economics and Business (WU Vienna) Welthandelsplatz 1, A-1020 Vienna/Austria http://www.sustainability.eu/

This project has received funding from the European Union's Horizon 2020 research and innovation programme under grant agreement No 710543

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1. Lab Report

The labs (hereafter called "workshops") undertaken as part of the COMPASS (710543) project helped in pointing to the variation in the nanotechnology 'sector' and elicited useful and often insightful comments about the potential for and the risks relating to nanotechnologies. Most of the companies were relatively small and, it must be stated, did not seem prone to hype. Their concerns were more prosaically on getting to market with a safe product (or products) and making a profit. The reference to 'safely' here indicates that there was a clear ethical dimension, albeit perhaps relating to just one ethical 'element', to their activities. This section describes the application of the methodology and an analysis of the findings used throughout the roadmap creation process.

1.1. Methodology

The workshops were presaged by extensive work to recruit participants. This was not helped by what appears to be a rapid turnover of companies (indicated, for many, by the obsolescence of the contact details on the various listings that were used).[1] There was also a high level of non-responses from companies approached which we believe was, in the main, due to sensitivities about commercial confidentiality. Added to this may be time considerations and a reluctance of companies to subject themselves to what they may have seen as over-intrusive enquiry. We must surmise, furthermore, that those companies (or in a few cases organisations) that did engage were more likely than others to be aware of the ethical concerns. A lack of participation of companies meant that other organisations (European funded projects, civil society organisations) were also recruited to provide input to the process and challenge the companies involved to further reflect on the process. Inputs in this report are anonymised in accordance with our ethical requirements, and are supplemented by interview data collected as part of Work Package 1 to further illustrate and understand the interests and requirements of nanotechnology companies.

The methodology (described in D2.1, Lab Methods Report) was followed most thoroughly by the Nanotechnology workshops – recruitment and engagement via a sustained set of co-creation exercises such as a Nanotechnology breakfast held in Brussels, followed by a series of online and offline webinars and workshops to a) orient the participants; b) develop the foresight exercise, c) reflect on this exercise, and d) conduct the backcasting/roadmapping exercise. In total, two companies were recruited, alongside several European project consortium members in nanotechnology and members of the Enterprise Europe Network subgroup on micro- and nanotechnologies[2]. Throughout this process feedback was gained via input from experts such as Arie Rip. A full discussion of the effectiveness of the methods and comparative uses of the methods in different sections will be provided in D2.6 Comparative Assessment Report.

[1] The identification of companies for interview or inclusion in workshops was undertaken, in the main, through Internet searches, listings of participants at European events, and, more especially, the use of listings or registers such as www.nanoorbit.com and www.nanowerk.com. Approaches were made through websites, via telephone and email.

[2] https://een.ec.europa.eu/about/sector-groups/nano-microtechnologies

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1.2. Analysis

The workshops guided participants in relation to key ethical issues that relate to 'responsible innovation' but then, through raising non-leading questions, responses were invited and further probing (not prompting) was undertaken that gathered a richness of information that helped inform the content of the roadmap (see later).

With regard to the outcomes, the extent to which environmental issues (noted earlier as missing from the European Commission framework) were raised is very striking. Asked about the matter, one interviewee opined that 'the Hippocratic Oath is a good place to start. Do no harm'! A range of more specific comments illustrate the point. All the companies had undertaken, at least in general terms, impact assessments that had guided the thinking that underpinned their strategies for research, manufacturing and engaging with (and obtaining feedback from) customers.

> ***These materials could be produced in ways that are not careful about their being introduced into the environment and could create a bigger problem downstream. We have to have safeguards to prevent unintended consequences of the usage of these materials in ways that were not meant. (Participant)***

> ***Our core principles are caring for health, caring for buildings and caring for the environment. [We need to] look at the wider picture … the cradle to grave of products in terms of their carbon when they're produced, their lifespan and then how you dispose of them at the end of their useful life. (Participant)***

> ***The product comes with comprehensive safety sheets explaining what it is and the potential hazards. We're aware that the technology has to be used very responsibly – to protect the employees of the company, to protect the public and the environment. (Participant)***

The evident environmental concerns were, however, sometimes seen as in tension with the need to get to market in order to obtain a return on initial investment. The workshop facilitators noted in their report 'high competitiveness between companies makes it very difficult to involve them into cooperative and contributive process'. Linked with such matters was the worry that less ethical competitors might get to market first – this signalling, in the minds of some, a need for the adoption of at least a common code of practice (though arguably not easy - given the variation within the 'sector' that is discussed in section 4). It was suggested, however, that the development and enforcement of standards might assist. The ongoing work around the 'Safe by Design' initiative and wider risk governance matters being addressed in the NanoReg2 and caLIBRAte projects will help with this.

> ***Short term thinking is often a bit of a barrier to responsibility, whereas if the capital that you raised was a little more patient, then you could really take the time to have a major impact. (Participant)***

The environmental issue (and the risks relating to the same was), therefore, axial for the nanotechnology companies. Any potential over-excitement (hype) about the innovative potential in their development or use of materials and products was, accordingly, tempered by this ethical concern to 'do no harm'. There was recognition, too, of the importance of customer and user feedback.

Could 'responsible innovation' become a new normal in the nanotechnology sector? Not, according to one workshop participant (a RRI expert). That expert also reflected that if RRI did not avail of a 'concrete description' (which, we surmise, is acceptable to nanotechnology

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companies and enables them to further their steps towards responsible innovation) it would, he suggested, be unlikely to share the duration of corporate social responsibility (CSR), the relevance of which (and the overlap with RRI) was noted earlier.

> ***As long as we present RRI as an obligation, it's not really going to fly. We have to define something that actually presents tangible benefit If we want to broaden the movement, how can we define the benefits? (Participant)***

Such comments are helpful as we move to set out a roadmap for the sector. This roadmap had, it became clear, to embrace the 'responsible' in 'responsible innovation'; provide at least a nudge in that direction; and, crucially, signal the strategies (including codes of practice and standards) that could make it happen in a way that adequately removes (e.g. through alternative approaches), minimises or controls potential damage to people, animals and the environment.

2. Roadmap Introduction

This roadmap helps to shape ethical approaches to innovation within the nanotechnology sector. The work draws on relevant published information and follows consultations undertaken through interviews (from WP1) and workshops with nanotechnology companies. It also notes the positions and views of related researchers and representative bodies for the sector.

The context for the roadmap is set through an introductory section that focuses, most notably, on Corporate Social Responsibility (CSR) and the way that this relatively well known aspect of commercial conduct links to Responsible Research and Innovation (RRI). What follows are then pointers to three 'features' that most strongly characterise the sector. First is the 'variation in the sector', a feature so marked that aspects of nanotechnology might, it is observed, be regarded as sectors in themselves. Second is the 'hype' that has been associated with the imagined benefits that will arise from nanotechnology innovations. Third is the 'preoccupation with risk' that reflects a widespread (and welcome) understanding among innovators about the potential damage to people, animals and the environment that can arise from the manufacture or use of nanoparticles.

The exploration of these three features draws from both the published information and the consultations. The feature concerned with risk was particularly highlighted in the consultations. It was seen as in tension with the need to get to market. Relating to such matters, significant work addressing risk and safety are noted as having been (or as being) undertaken within European Commission funded projects - perhaps the most important of these being reflected in the setting out of 'safe by design' approaches. This, in turn, is linked to the matter of standards – seen as essential in order to guide innovation and commercial conduct in the sector.

Finally a roadmap for the nanotechnology sector is set out. This emphatically points to some 'fundamentals' considered as 'vital' for companies (or, indeed, any enterprise) involved in innovation within the nanotechnology sector. Unsurprisingly a major aspect of those

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fundamentals is concerned with risk and safety. This is pointed to as applying at *all* stages - from initial research; through design and preparation; production; marketing and sales; *and* (importantly) to product purchase and usage. A clear responsibility is signalled, therefore, not in a vague way to people, animals and the environment; but to company employees, contractors, customers and those who transport, deliver and apply nanotechnology products.

It follows that the roadmap demands that companies should have and implement codes of practice (understood and practiced by all staff) that help to embed the 'safe by design' ethos. Associated with this is the necessity of a heightened readiness among companies to (a) respond to new knowledge about nanotechnologies; (b) work closely with relevant industry bodies; and (c) maintain links over a 'sustained' period with customers and users. 'Responsible innovation' and sustainability are, therefore, key facets – both of which can be linked to the elements of RRI.

3. Roadmap Contextualisation

The COMPASS (710543) project commenced in mid 2016. It is funded by the European Commission under the GARRI programme on Responsible Research and Innovation (RRI). The European Commission definition of RRI is as 'an approach that anticipates and assesses potential implications and societal expectations with regard to research and innovation, with the aim to foster the design of inclusive and sustainable research and innovation'.[3]

The COMPASS (710543) project objectives were concerned to provide evidence of and promote 'better uptake' of RRI in three key sectors of innovation, each of which was seen as linking to particular societal challenges (or threats, see Table 1 'Sectors in Focus'). These areas are healthcare technologies and services, nanotechnology and cybersecurity.

Sector	Challenges
Healthcare technologies and services (biomedicine)	Maintaining health and wellbeing in a context of demographic change; empowering service users through technologies and service design; promoting greater health literacy and facilitating self-management of health.
Nanotechnology	Avoiding damage to the environment; promoting better air and water quality; ensuring safety when seeking to realise the potential of new products (e.g. for coatings and precision medicine); avoiding the danger to people of ingesting nano-particles.

[3] See https://ec.europa.eu/programmes/horizon2020/en/h2020-section/responsible-research-innovation

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Cybersecurity	Protecting individuals, businesses and services against cyber-threats and their consequences in terms of service breakdowns, disruption to manufacturing and distribution systems, financial and reputational loss, identity theft, fake news, etc.

Table 1: Sectors in Focus

In this roadmap we concentrate on **Nanotechnologies**. There are, however, some common aspects of RRI that apply in each sector.

The work of the COMPASS (710543) project has been informed by both primary and secondary research. It draws on multiple sources (some of which are noted in this report); the undertaking overall, in total, of nearly 30 personal interviews with senior staff in the three sectors; and the holding of successive workshops (to identify issues and inform the roadmap) with staff at different levels. The latter have involved some 15 organisations.[4]

In the course of identifying both individuals and companies to engage with the project, it became clear, at that initial point, that their awareness of 'Responsible Research and Innovation' was low.[5] The simpler term 'responsible innovation' was, therefore, quickly adopted by the project and is used throughout this report (except where a specific facet of RRI is being discussed or quoted).

The project will, in 2019, complete its work by testing and revising roadmaps for the three sectors. Educational and training materials, together with a self-test tool will be provided. These materials will help organisations in those sectors (whether in public ownership, for profit or not for profit), to consider in depth some specific ethical and governance issues that impact (or will impact) on them as they pursue sustainable commercial goals.

What is 'Responsible Innovation'?

The idea of responsible innovation is not new. One researcher references the invention of a flying machine, known as the Passarola ('ugly bird'), designed by a Portuguese priest (Bartolomeu Lourenço de Gusmão) around 1700 (see illustration below). A 'rudimentary' version was launched in 1708.[6] The inventor, surely an innovator (albeit that written accounts are scant),[7] reported its potential benefits in terms of transport and also its use in war.[8]

[4] Detail of the methodology is posted on the project website at www.innovation-compass.eu .
[5] That levels of awareness are low is unsurprising. This does not detract, however, from a significant level of public interest in scientific matters as is evidenced in a Eurobarometer survey undertaken in 2013. Eight out of ten respondents agreed that the 'EU should actively promote worldwide respect for European ethical principles for conducting scientific research'. See European Commission (2013) 'Eurobarometer Responsible Research and Innovation, Science and Technology', Memo 13,987 Brussels.
[6] See translator's note in Saramago J (1982) 'Baltasar and Blimunda', Random House, London.
[7] Videira Louro F and De Sousa JM (2014) 'Father Bartholomeu Lourenço de Gusmão: a Charlatan or the First Practical Pioneer of Aeronautics in History', Paper to the 52nd Aerospace Sciences Meeting, National Harbour, Maryland.
[8] Von Schomberg R (2013) 'A Vision of Responsible Innovation' in: Owen R, Heintz M and Bessant J (Eds.) 'Responsible Innovation' London: John Wiley pp51-74.

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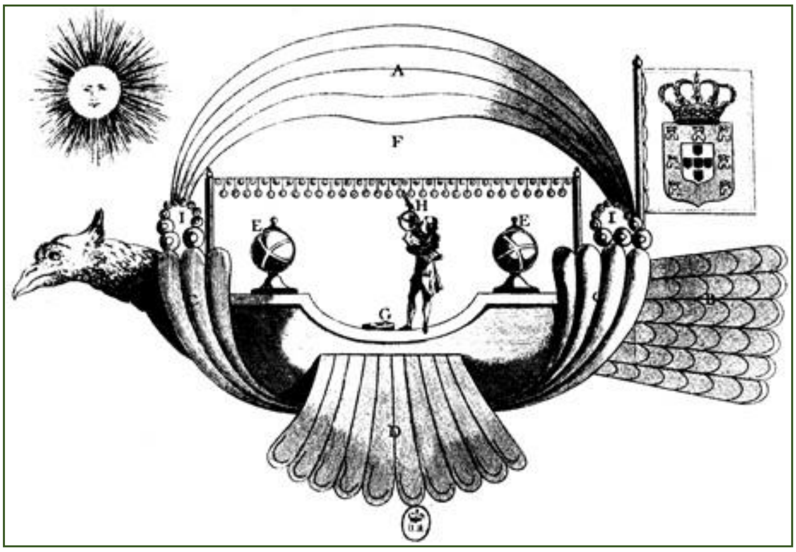

Figure 1: The Passarola (Ugly Bird)

The important point here is that there was a consciousness at that time that, whilst technologies are in some senses neutral, they might be used for good or ill. It was a matter of 'responsibility', therefore, to consider the uses to which they might be put – and if necessary to place restrictions on their availability.

It is highly unlikely that the European Commission had the dilemmas associated with the 'ugly bird' in mind when conceiving of RRI. The Commission would, however, have been influenced by debates and discussions that addressed (in modern parlance and in relation to contemporary innovation) the tension between the benefits and any negative potential effects of emerging technologies.

In the 300 years since the 'innovative' idea of the 'ugly bird' was put forward, the debates and discussions have continued as technological developments take place and their positive and negative effects have been evident – from industrial reform (characterised by increased productivity and the loss of jobs through mechanisation) to warfare (characterised by increased suffering and loss of life). And it is in the context of war that we can note two major contributions to the debate, those of Robert K. Merton, a sociologist, and Karl Popper, a philosopher (see Fig 2).[9]

Merton, in 1942, affirmed that 'scientists have been jarred into a state of acute self-consciousness: consciousness of self as an integral element of society with corresponding obligations and interests'.[10] He railed against a 'sanguine isolationism' whereby 'he' [sic, the scientist] might have come to 'regard himself as independent of society'. Merton offered five methodological canons which have (and retain) relevance to 'responsible innovation'. These included an 'ethos of science' that demands improved knowledge and the maintaining of a moral COMPASS (710543); 'disinterestedness' in order to remove judgements that may be

[9] Work by other theorists is noteworthy - see, for instance, Polanyi K (2001) 'The Great Transformation: the Political and Economic Origins of Our Time', Beacon Press, Boston. Polanyi's book was originally published in 1944.
[10] Merton RK (1942) 'Science and Technology in a Democratic Order', Journal of Legal and Political Sociology 1 pp115-126.

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biased; and 'organised skepticism' so that questions of fact' may be asked about the 'potentialities concerning every aspect of nature and society'.

Karl Popper's work can be seen as complementing that of Robert K Merton. Popper held that 'scientific practice is characterized by its continual effort to test theories against experience and make revisions based on the outcomes of these tests'.[11] *Within that practice Popper recognised two kinds of scientific 'boldness' – first, relating to scientists making testable claims with a 'willingness to take a risk of being wrong'; second, having* the 'readiness to look for tests and refutations'.

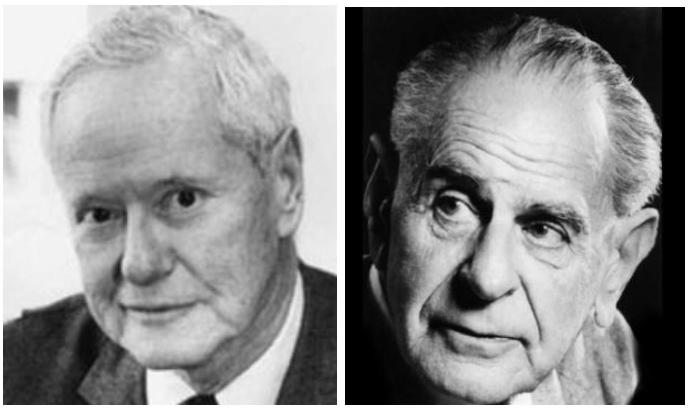

Figure 2: Robert K Merton (1910-2003) and Karl Popper (1902-1994)

The asking of questions (Popper) and the testing of theories (Merton) both resonate with the notion of 'reflexivity' – a key element of RRI. Such reflexivity has been defined as 'the process by which experience and knowledge continually influences attitudes, behaviours and actions and *vice versa*. This may be 'first order' relating to particular knowledge for a time or event; or 'second order' relating to new knowledge and understanding'.[12] It is illustrated in Fig 3.[13]

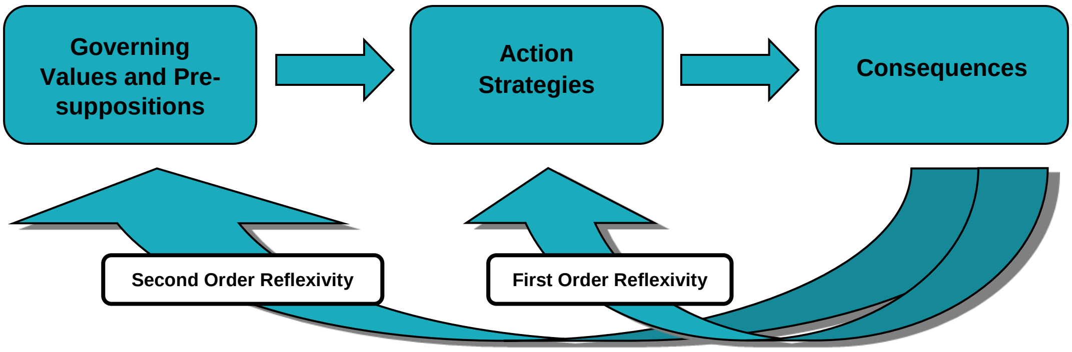

Figure 3: Reflexivity (per Gianni and Goujon)

Themes and Issues

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[11] Shea B (2016) 'Karl Popper, Philosophy of Science' in Fieser J and Dowden B (Eds) Internet Encyclopedia of Philosophy. http://www.iep.utm.edu/pop-sci/
[12] Wilford S, Fisk M and Stahl B (2016) 'Guidelines for Responsible Research and Innovation', Centre for Computing and Social Responsibility, De Montfort University, Leicester.
[13] Gianni R and Goujon P (2013) 'Analytical Grid: Current Theory and Practice (in RRI)' GREAT Project.

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The introductory discussion points to the emergence of some key aspects of responsible innovation. These relate to matters such as risk, openness and the importance of scepticism. Responsible innovation, it follows, is doing things in ethically appropriate ways in order to ensure that 'social as well as commercial benefits are harnessed; and that any harm to the social and physical environment is obviated or minimised'.[14] Reflexivity can be noted as one of the key mechanisms by which 'responsibility' can be exercised. For the purpose of this roadmap the definition of 'innovation' is set aside in deference to those who have particular expertise in the specific sectors where it is deemed to take place.

The backdrop to this roadmap is, therefore, at least partly in place. The task now is to consider such matters in relation to contemporary thinking and, crucially, to set out, in a 'roadmap', what this means for companies (corporately) and researchers (individually) in pursuit of 'responsible' innovation.

The context is one where the intense pace of technological developments must be recognised. These relate, almost needless to say, to innovation around (amongst other things) communications technologies (with the advent of the Internet) and to developments that are evident in all three areas that are the focus of the COMPASS (710543) Project (healthcare technologies and services, nanotechnology and cybersecurity). None of these developments will have been in the minds of Merton or Popper (and certainly not de Gusmão). But there are two contemporary perspectives that are familiar to many industrialists, researchers and entrepreneurs. Both have ethical dimensions that can be seen as responding to the ongoing imperative concerned with harnessing benefits (doing good) and avoiding harm. These perspectives are those of Corporate Social Responsibility (CSR) and Constructive Technology Assessment (CTA).

The notion of Corporate Social Responsibility (CSR), of course, relates to centuries old debates about responsibility in industry. The specific 'label' of CSR, as noted by Madrakhimova (2013), is one of many that relate to corporate citizenship, responsible investment' etc., and is generally attributed to Howard Bowen who published a seminal work 'Social Responsibility of a Businessman' in 1953.[15,16] Crowther and Martinez noted CSR as being 'in vogue' in 2004 but opined that 'as a concept it [CSR] is vague and means different things to different people'.[17] That 'vagueness' extends, according to Pellé and Reber (2015) to the 'very definition of responsibility'.[18] The European Commission definition (though dating from 2001) of CSR is as 'a concept whereby companies integrate social and environmental concerns in their business operations and in their interaction with their stakeholders on a

[14] This draws from the definition of RRI provided in the GREAT project. See Wilford S, Fisk M and Stahl B (2016) 'Guidelines for Responsible Research and Innovation', Centre for Computing and Social Responsibility, De Montfort University, Leicester.
[15] Madrakhimova FS (2013) 'Evolution of the Concept and Definition of Corporate Social Responsibility', Global Conference on Business and Finance: Proceedings 8,2 pp113-118.
[16] Pellé S and Reber B (2015) 'Responsible Innovation in the Light of Moral Responsibility', Journal on Chain and Network Science 15,2 pp107-117.
[17] Crowther D and Martinez EO (2004) 'Corporate Social responsibility: History and Principles' in Crowther D and Caliyurt KT (Eds) 'Social Responsibility World', Ansted University Press, Penang.
[18] Pellé S and Reber B (2015) op cit.

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voluntary basis'.[19] The Commission also developed the schema of RRI but with it being 'unexpected' (according to Pellé and Reber) that its relationship with CSR had 'rarely' been addressed.

But CSR, according to Schroeder and Iatridis (2016), was the 'biggest and possibly most powerful concept' with a close link to RRI (and, by extension, to responsible innovation).[20] They affirmed the importance of three corporate responsibilities that relate to social, economic and environmental concerns – with CSR seeking to address the whole 'cycle of business life'. Of significance is that they noted were three issues that carry a healthy dose of reflexivity, viz.[21]

- the identification (and understanding of the significance) of social and environmental impact of business practices;
- exploring the efficacy of tools and policies to mitigate negative impacts (and the adoption of practices that 'look ahead' in order to effect their avoidance); and
- understanding, prioritising and addressing the concerns of the 'most important stakeholders', including customers.

Martinuzzi et al (2018) pointed to RRI 'building on and going beyond CSR' - expanding 'on concepts and theoretical approaches previously used'.[22] RRI, they argued (unlike CSR), seeks to embed 'responsibility' at 'very early stages of research and innovation' and carry the potential (albeit half a century after Merton and Popper posited their arguments) that 'RRI offers the potential to bring CSR from the margins into core strategic decision processes'.[23] Pellé and Reber (2015), meanwhile, had asserted that the 'CSR framework already provides a basis to develop the conception of responsibility in innovation'.[24] The question arises (albeit not asked in this way) as to why RRI, with its particular construction, was needed when CSR is already in place and widely recognised?

Constructive Technology Assessment (CTA) is a concept that relates to socio-technical scenarios. It is supportive of and pre-dates RRI in its advocacy of stakeholder involvement. A strong advocate of CTA is Arie Rip who pointed, with Robinson (2013), to the provenance of CTA in the late 1980s in The Netherlands.[25] Two key components of CTA activity were noted as, first, 'the building of socio-technical scenarios of possible developments'; and, second, 'organizing the orchestration of workshops with a broad variety of stakeholders'. Both of these

[19] European Commission (2011) 'A Renewed EU Strategy 2011-14 for Corporate Social Responsibility', Communication from the Commission to the European Parliament, the Council, the European Economic and Social Committee and the Committee of the Regions COM/2011/0681 final.
[20] Schroeder D., Iatridis K. (2016) The Basics of Responsible Research and Innovation. In: Responsible Research and Innovation in Industry. Springer Briefs in Research and Innovation Governance. Springer, Cham
[21] Schroeder and Iatridis (2016) op cit.
[22] Martinuzzi A, Blok V, Brem A, Stahl B and Schönheer N (2018) 'Responsible Research and Innovation in Industry – Challenges, Insights and Perspectives', Sustainability 10, 702 DOI 10.3390/su10030702.
[23] Martinuzzi et al (2018) op cit.
[24] Pellé and Reber (2015) op cit.
[25] Rip A and Robinson DKR (2013) 'Constructive Technology Assessment and the Methodology of Insertion' in Doorn N, Schuurbiers D, van de Poel I and Gorman ME (Eds) 'Early Engagement and New Technologies: Opening Up the Laboratory', Philosophy of Engineering and Technology 16 DOI 10.1007/978-94-007-7844-3 3. Springer Science and Business, Dordrecht. Note that Arie Rip has been consulted during the work of the COMPASS (710543) project.

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help the development of insights and knowledge by which better (or, rather, aware) and more reflexive decisions regarding technological developments can be made. Konrad et al (2017) explained that such stakeholder workshops 'typically start with the analysis of current and recent developments and then expand into the future, exploring different directions [and] how the observed dynamics may further unfold … also, how strategic and governance actions may play out and interrelate, or how different actor groups may react'.[26]

Rip and Robinson placed CTA within the broader context of technology assessments (TA) with an aim that was concerned to 'reduce the (human) costs of learning by trial and error … by anticipating future developments and their impacts, and by accommodating these insights in decision making and implementation'.[27] The adoption of CTA in any case was seen by them as increasing 'reflexivity' with a contribution to this being made through the involvement of a wider range of stakeholders.

Both CSR and CTA are therefore of some significance in helping to set a background within which we can consider 'responsible innovation'. A reference is necessary, however, to the thematic elements of RRI framework set out by the European Commission. It is arguable that, whilst of certain relevance, the framework is undermined by the remarkable exclusion of environmental concerns. Various studies have noted this, with Wilford et al (2016) simply adding 'Environmental Stewardship' (Taking Care of our Planet) to the European Commission list - set out in Table 2.[28] Ethics and Governance can, of course, be seen as something of a 'catch all' within which other ethical considerations (elements) are also brought into play.

European Commission Thematic Elements of RRI

Public Engagement	Choose Together
Gender Equality	Unlock the Full Potential
Science Education	Creative Learning, Fresh Ideas
Open Access	Share Results to Advance
Ethics	Doing the Right 'Think' and do it Right
Governance	Design Science with and For Society
AND ADDED (BELOW) IN THE GUIDELINES PRODUCED BY THE GREAT PROJECT	
Environmental Stewardship	Taking Care of our Planet

Table 2: RRI Elements (per the European Commission)

[26] Konrad K, Rip A and Greiving VS (2017) 'Constructive Technology Assessment – STS for and with Technology Actors' European Association for the Study of Science and Technology (EASST) Review 36,3 November.
[27] Rip and Robinson (2013) op cit.
[28] Wilford et al (2016) op cit. See www.great-project.eu . For other studies see Martinuzzi et al (2018) op cit.; and Jirotka M, Grimpe B, Stahl B, Eden G and Hartswood M (2017) 'Responsible Research and Information in the Digital Age' Communications of the ACM DOI 10.1145/3064940.

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The above provides us with the context for this roadmap. It provides a number of reference points – with a background provided by Merton and Popper (and de Gusmão); and a more contemporary perspectives by Corporate Social Responsibility, Constructive Technology Assessment and the framework provided by the European Commission.

4. Specific challenges for Nanotechnology

This exploration of 'dilemmas and challenges' draws on secondary sources as well as the outcomes of interviews and workshops with senior staff of a variety of nanotechnology companies.

In setting the context for those dilemmas and challenges it is important to recognise three major features of the nanotechnology 'sector'. The first relates to its breadth and variation; the second to a certain 'hype' associated with the benefits that might result from nanotechnology innovations; and the third to a preoccupation with risk.

Feature 1: Variation in the Sector

The question for Nano really is how long is a piece of string? It is in all sectors *[our emphasis]* ***- an infinite number. (Claire Skentelbery, Director General, Nanotechnology Industries Association)*** [29]

The variety in the nanotechnology sector means there are also some particular issues that relate to certain areas that could be considered as sectors in themselves. Some of that variation is indicated by the listing offered by Malsch and Andersen (2011) of the ObservatoryNano project that was completed in 2012 (see Table 3).[30]

Nanotechnology Sectors	
Nanoelectrics	Construction
ICT	Energy
Aerospace	Environment
Automotive and Transport	Health
Chemistry and Materials	Medicine and Biotechnology

Table 3: Nanotechnology Sectors

But as evidenced in the searches undertaken in the COMPASS (710543) project, the nanotechnology 'landscape' is wider and more complex that this simple categorisation would suggest. As affirmed by one workshop participant 'Nanotechnology is such a

[29] Correspondence with Claire Skentelbery 11th May 2018.
[30] Malsch I and Andersen AMF (2011) 'Ethical and Social Aspects of Nanotechnology ICT and Security Technologies' ObservatoryNano WP4 Annual Report 3.

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broad church … there is very little in common with what we do!' One thing that they do have in common, however, is a preoccupation with risk (the third 'feature' noted below).

Feature 2: Hype

The second major feature of the sector is the hype associated with the imagined benefits that will arise from some of the innovations. Madhwani (2013) opined that 'Nanotechnology is a novel, emerging, exponential, cutting edge technology with fascinating applications that promise scientific advancement for medicine, *amazing* [our emphasis] cosmetics, state of the art compact electronic devices, food shelf life enhancers, superior packaging, durable quality clothing, fuel and energy saving devices (to list a few) … making our world a better place to live in'.[31] To be fair to Madhwani, his eulogy is accompanied with a clear note about some of the risks that relate to such technological innovation (see below). Indeed, both the hype and the risks were pointed to a decade ago Bennett-Woods (2008) when she affirmed that 'unlike other scientific disciplines, nanotechnology has the capacity to rapidly change the sciences and other industries which necessitates greater oversight and protection against abuses'.[32]

Parandian et al (2012), in a paper co-authored by Arie Rip (noted earlier as an expert in CTA within the context of RRI), provided a more sober reckoning.[33] They pointed to what they term a 'halo' effect where 'new technologies like nanotechnology are surrounded by big promises, envisioning a third industrial revolution, environmental remediation and human enhancement'. Of course, all these things *may* happen but, as Parandian and Rip explain, 'these promises can be an obstacle to the realisation of these envisaged benefits because of their diffuse and open-ended nature'. This, they add, 'makes actors uncertain about directions to go and creates reluctance to invest in concrete developments' - noting the potential for what they call a 'hype-disappointment cycle'.

Feature 3: Preoccupation with Risk

A preoccupation with risk is absolutely necessary and welcome in view of some of the unknowns associated with nanotechnology innovations. That risk starts with the employees or contractors of the companies that are seeking to realise the 'promise' of nanotechnology – wherever they are within the 'sector'. The risk ends with any potential damage to people, animals and the environment. In relation to this Hjorth et al (2017) observe the need for companies to move from a paradigm of risk 'control' to 'a more nuanced and realistic navigation of complexity and uncertainty'.[34]

[31] Madhwani KP (2013) 'Safe Development of Nanotechnology: A Global Challenge', Indian Journal of Occupational and Environmental Medicine 17,3 pp87-88. To be fair, Madhwani also is very clear about some of the risks that relate to such technological innovation.
[32] Bennett-Woods D (2008) 'Nanotechnology, Ethics and Society' CRC Press, Boca Raton.
[33] Parandian A, Rip A and te Kulve H (2012) 'Dual Dynamics of Promises and Waiting Games around Emerging Nanotechnologies' Technology Analysis and Strategic Management 24,6 pp565-582.
[34] Hjorth R, van Hove L and Wickson F (2017) 'What can Nanosafety Learn from Drug Development? The Feasibility of Safety by Design', Nanotoxicology DOI 10.1080/17435390.2017.1299891

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The central problem for nanotechnology is that only some of the risks are known. The miniscule size of nano-particles (that is, as observed by Morose, with at least one dimension in the range of 1-100nm viz. no larger than one eight hundredth of the diameter of a human hair)[35] means that they behave differently to larger particles. A key risk is that they can be readily inhaled or absorbed into the body and its organs. The consequence of such absorption can be seriously detrimental to health in view of the nano-structures or products being able to carry toxins.

Madhwani (2013) and the final report of the Nanomile Project noted evidence of adverse effects from various studies of nanotechnologies, and in the latter case from their own work.[36] Nanomile concluded that 'an increasing body of scientific evidence would suggest that some materials in their nano-form may induce harmful biological or environmental effects through a variety of potential mechanisms, not all of which are fully understood or quantified as yet'. They opined that 'sustainable commercialisation of nanotechnology' could not, as yet be possible.[37]

This report and roadmap does not need to go into detail regarding the risks around nanotechnologies, but it is an ethical 'given' that appropriate action must be taken to mitigate those risks at all stages – from design, through manufacture, marketing and usage. Morose (2009) offered five principles (listed below) that point to how some of the risks may be reduced in the context of 'product stewardship'.[38] Also to be noted as an outcome from the European Commission funded LICARA project, is a 'first-version' to guide SMEs about new nanotechnology products.[39]

Echoing Morose's work, the European Commission has championed the concept of 'safe by design', this underpinning the approach of several Horizon 2020 funded projects such as CaLIBRAte (concerned with the assessment and management of human and environmental risks);[40] NanoMILE (concerned to understand the way that nanomaterials interact with the environment);[41]; and NanoReg2 (concerned with regulatory frameworks for nano-technologies).[42] Both CaLIBRAte and NanoReg2 are ongoing with NanoReg2 being in the process of defining 'a system of tools, guidance and checklists' for a 'safe innovation approach'.

Five Principles of 'Design for Safer Nanotechnology'[43]

1. Size, Surface and Structure	Adopting size, surface or structure so that 'functionality is preserved but hazard and/or exposure potential … is diminished'.

[35] Morose G (2009) 'The 5 Principles of Design for Safer Nanotechnology', Journal of Cleaner Production 18,3 pp285-289.
[36] Madhwani (2013) op cit.
[37] See https://cordis.europa.eu/result/rcn/204304_en.html
[38] Morose (2009) op cit.
[39] https://www.nanopartikel.info/en/news/1891-licara-guideline-through-the-labyrinth-of-nanomaterials
[40] www.nanocalibrate.eu
[41] http://nanomile.eu-vri.eu
[42] http://www.nanoreg2.eu/safe-design
[43] Ibid.

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2. Alternative Materials	Identifying materials 'that can be used to replace the hazardous nanoparticle'.
3. Functionalization	'Bonding of atoms or molecules to nanoparticles to change the properties'.
4. Encapsulation	Ensuring complete enclosure of the nanoparticle 'within another material'.
5. Reduce the Quantity	'Using smaller quantities of the hazardous nanoparticle while maintaining functionality'.

Table 4: Five Principles of 'Design for Safer Nanotechnology'

NanoReg2 is perhaps of particular importance in offering three 'pillars' for Safe by Design (see Table 5).[44] These relate to the design, production and usage of nanomaterials. Both the potential risks and some of the remedies are indicated in the Figure. The model is not, however, without its critics. Hjorth et al (2017), as noted above, sought to increase the level of awareness of uncertainty, noting that there is 'no reliable and complete body of knowledge on the risks of ENMs [Engineered Nanomaterials] that can be incorporated into the design processes'.[45]

Further work is being undertaken on Safe by Design to move its 'status as a concept into a more well-defined framework, with attention being paid at standards level'.[46] It can be noted in this context that Rip and Robinson pointed to a danger of too much responsibility being placed on 'technology developers' rather than the regulators.[47] Some of the themes and issues indicated are 'picked up' later in this report.

[44] Ibid.
[45] Hjorth et al (2017) op cit.
[46] Correspondence with Claire Skentelbery 11th May 2018
[47] Rip and Robinson (2013) op cit.

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Safe Products by Design

- Seeking less hazardous nanoforms (based on chemical or other properties)
- Enhancing the safety of MNMs (manufactured nanomaterials)
- Adopting appropriate testing strategies
- Evaluating of hazard evolution during lifecycle of MNMs (including aged materials)

Safe Use of Products

- Evaluating exposure risks to humans and the environment
- Defining risk reduction and mitigating actions; and identifying acceptable uses of MNMs
- Identifying where restrictions on usage are necessary
- Optimising and defining acceptable use

Safe Industrial Production

- Ensuring safety principles applied for workers and industrial environments
- Controlling of conditions of production, industrial processes, storage and transport
- Ensuring appropriate training and certification schemes in place (including for workers)

Table 5: The Three Pillars for Nanomaterial 'Safe by Design'

It follows from our work within the COMPASS (710543) project that meanings around 'responsibility' in relation to innovation in the nanotechnology sector are dominated by a particular ethical concern relating to risk and safety. The addition of 'Environmental Stewardship' (Wilford et al, 2016) to the list of original elements in the European Commission framework is, therefore, justified.[48] This element, in terms of the priorities and ethical thinking of the companies engaged in the study, stands head and shoulders above the other elements and must, therefore, be a primary concern within the roadmap.

The clear priority attributed to risk and safety in the environmental context is not, however, to diminish the importance of the other elements of RRI and what might be seen as key components of 'responsible innovation'. A brief note on these 'other' elements is warranted.

With regard to 'Open Access' there was evidence in the interviews and workshops of a willingness to be reasonably open, especially to ensure that clients and customers of nanotechnologies were well informed (albeit with limitations attached because of concerns about commercial confidentiality).

In respect of 'Public Engagement' there was a willingness to consider and act on feedback from those clients and customers, albeit that deeper involvement had not generally been

[48] See Wilford et al (2016) op cit.

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countenanced. The need for 'more engaged outreach and public communication on nanotechnologies' was, it can be noted, a central theme within the European Commission funded Nanodiode project. Within this the need was expressed to 'transcend the perspective of benefits versus risk' and include what they termed 'soft impacts' of nanotechnologies.[49] This positive view of the need for public engagement links closely to the notion of reflexivity that was noted earlier as a key matter for both CSR and RRI.

'Science Education' was clearly a concern because of the urgent need for (and difficulty in recruiting) knowledgeable staff in to enable exploitation of the 'innovation' opportunities around nanotechnologies. 'Gender Equality' appeared not, however, to be a consideration. There was, however, no indication of any gender discrimination – rather it was a question of finding the key people (in all positions within the companies) regardless of gender. In this context it can be noted (not just for nanotechnologies) that, whilst the gender gap is narrowing, in 2015 women represented 'less than half of tertiary educated professionals employed as scientists and engineers (out of the total for both sexes)'.[50]

With regard to 'governance' it can be noted that the European Commission funded caLIBRAte project is developing a 'state of the art governance framework for assessment and management of human and environmental risks on manufactured nanomaterials'.[51] The goal is to build trust in nanotechnology companies who follow 'different nano-specific models and methods … for risk assessment, prioritisation and management of occupational, consumer and environmental risks'.

A Note on Standards

One aspect of the necessary commitment for organisations involved in responsible innovation (and, for nanotechnology, in large part emerging out of the concerns about risk and safety) is the need to adhere to codes of practice and applicable standards. A backdrop is provided by the International Organization for Standardization in their standard ISO26000 that gives guidance on social responsibility.[52] It can be noted that this standard has been pointed to as a key reference point for CSR by Pellé and Reber (2015).

The standard argues that 'an organization's commitment to the welfare of society and the environment has become a central criterion in measuring its overall performance and its ability to continue operating effectively'. It adds that 'this, in part, is a reflection of the growing recognition that we need to ensure healthy ecosystems, social equity and good organizational governance'. Seven 'core subjects' are defined within the ISO standard – each contributing to what is considered good governance (see Fig 5).[53]

[49] Schuurbiers D (2014) 'Identifying Needs for Outreach and Dialogue on Nanotechnologies in Europe' WP1, Deliverable D1.1 of the Nanodiode project. See www.nanodiode.eu
[50] European Commission (2016) 'SHE Figures 2015' DG Research and Innovation, Brussels.
[51] See www.nanocalibrate.eu
[52] International Organization for Standardization (2014) 'ISO 26000: Guidance on Social Responsibility', Geneva.
[53] See https://www.iso.org/publication/PUB100259.html

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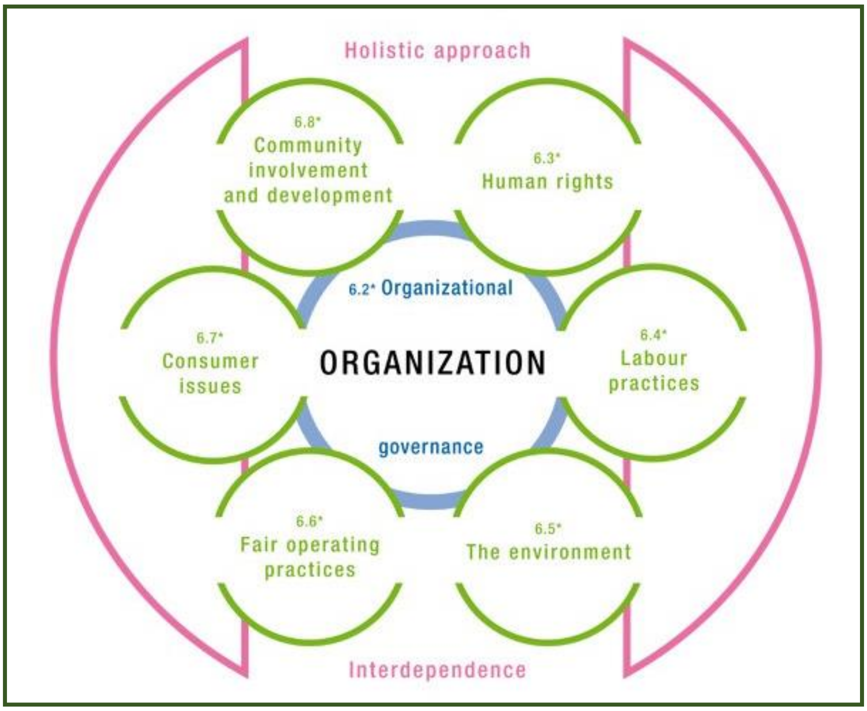

Figure 5: Social Responsibility: Seven Core Subjects (ISO)

All of these, from human rights to community involvement and development have been touched on in this report. Clause 4 of the standard, it can be noted, sets out principles of social responsibility (see Table 6). Especially significant for this report is the inclusion within the standard of 'the Environment' as a 'core subject' including (per Clause 6.5.6) 'protection of the environment, biodiversity and restoration of natural habitats'.[54]

Principles of Social Responsibility[55]
Accountability
Transparency
Ethical Behaviour
Respect for Stakeholder Interests
Respect for International Norms of Behaviour
Respect for Human Rights

Table 6: Principles of Social Responsibility

More specific to the technical matters relating to nanotechnologies, it can be noted that the American National Standards Institute (ANSI) lists numerous standards that are relevant and signals the related work (to produce new standards) within different Technical Committees.

54 Ibid
55 Ibid

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Most of the extant standards have been issued by the ISO or the International Electrotechnical Commission (IEC).[56]

Within the European Union, following a Mandate in 2010 (i.e. a request to the three European standards bodies) called for standards around nanotechnologies. Specific European standards are, therefore, beginning to emerge.[57] For instance, the work of CEN (Comité Européen de Normalisation) has now produced a 'provisional' technical specification (TS16937) entitled 'Guidance for Responsible Development of Nanotechnologies'. This covers 'incidental' manufactured nanomaterials (MNMs).[58] It takes into account the seven principles set out in the 'Responsible Nano Code' - an initiative that involved the Nanotechnology Industries Association (NIA) (Mantovani et al, 2010).[59] The seven principles are

- Board Accountability
- Stakeholder Involvement
- Worker Health and Safety
- Public Health, Safety and Environmental Risks
- Wider Social, Ethical, Environmental and Health Impacts
- Engaging with Business Partners
- Transparency and Disclosure

The 'Responsible Nano Code' was developed to provide 'strategic guidance on the governance of nanotechnology' and 'offer potential indicators of good practice to guide their responsible behaviour … during the transitional period while the appropriate … regulatory frameworks are being evaluated and, if necessary, developed'. It, and the Technical Specification, are important in helping shape the roadmap. We can note, in addition, the development of a series of papers from the OECD (Organisation for Economic Cooperation and Development) dating from 2005 on the 'Safety of Manufactured Nanomaterials'.[60]

5. Nanotechnology Roadmap

5.1. How to use the Roadmap

To use the roadmap, it is worthwhile investigating whether the initial fundamental aspects required are already embedded within the company's structure and practices. It is important

[56] See https://www.nano.gov/you/standards
[57] See Mandate 461 on 'Standardization Activities Regarding Nanotechnologies and Nanomaterials' at http://ec.europa.eu/growth/tools-databases/mandates/index.cfm?fuseaction=search.detail&id=443
[58] Incidental (or unintentional) nanomaterials are 'naturally naturally occurring (e.g., volcanic ash, soot from forest fires) or generated as incidental (unintentional) by-products of combustion processes (e.g., welding, diesel engines)'. See www.safenano.org
[59] Mantovani E, Porcari A and Azzolini A (2010) 'Synthesis Report on Codes of Conduct, Voluntary Measures and Practices towards a Responsible Development of Nanosciences and Nanotechnologies', AIRI/Nanotec. See See http://www.nanotec.it/public/wp-content/uploads/2014/04/NanocodeProject_SynthesisReport_Codes_of_Conduct.pdf
[60] See www.oecd.org and, more particularly (accessible through the website) OECD Environment Directorate (2017) 'Consumer and Environmental Exposure to Manufactured Nanomaterials: Information Used to Characterize Exposures: Analysis of a Survey Series on the Safety of Manufactured Nanomaterials, No. 84.

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to note that these, although called fundamental, may require some time and expertise to put into place. They are also often ongoing activities, or may be activities that require specific expertise or assistance in implementation. However, they are considered here as fundamental as they should be considered for part of the fundamental practices of the business.

The specifics of the roadmap in the implementation phase show how aspects of the roadmap need to link together throughout the entire research, design, production, marketing, and after-sales stages of development. Dotted lines represent feedback; solid lines represent the transitions between stages. It is important to note the role external engagement plays throughout this process – without external feedback into all stages (and not just testing or market research) the process cannot be considered responsible.

5.2. The Roadmap

The nanotechnology roadmap that follows extends the NanoReg2 ‘pillars’ (that are illustrated in Table 5) but it draws on some of their content.[61] Further material that, in particular, relates to the environmental context is added in order to do justice to the ethical imperative for nanotechnology companies (whether innovators involved in the manufacture of nanomaterials or as suppliers) to take related risk and safety issues into account when dealing with clients and customers. There are some company management overall fundamental aspects indicated for the roadmap that are detached from the pillars. In other words there are certain understandings and precautionary actions that need to be in place at the time the research (and innovation) process begins. An immediate commitment to such fundamentals is considered here as an essential aspect of ‘responsible innovation’ with an accompanying commitment to make progress in other areas where such an expectation is reasonable.

The emphasis is on responsibility. The roadmap, therefore, only lightly touches on more general issues of governance. But by reference to the content of mission statements and protocols, the users of this roadmap, will recognise the ethical imperatives that apply. The backdrop provided in this report, furthermore, demonstrates that many of the issues are not new. It is suggested, however, that the risks associated with the rapid pace of technological developments (of which nanotechnology is a clear example) means that ethical issues must come to the fore.

Aside from the company management aspects, there are four stages. These comprise (a) idea generation and research; (b) development; (c) testing & production; and (d) market and impact. They, therefore, add to the three pillars noted earlier from the NanoReg2 project (giving, therefore, greater credence to the initial research process and customer and user perspectives). This in keeping with the responsible innovation (and RRI) approach and one of its core features that relates to the engagement of and usage of views of and feedback from a wide range of stakeholders.

The tenor of the roadmap is one where it is assumed that the companies that may find it useful will, in any case, have beliefs about good governance. Many (if not most) aspects of the roadmap will be in place. The roadmap calls, therefore, for companies to remedy any omissions and strengthen their approaches *wherever necessary* in relation to the particular risks associated with nanotechnologies. The interviews and workshops undertaken as part of

[61] http://www.nanoreg2.eu/

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the project have been noted as demonstrating clear concerns among participants about risk. This reflected company understandings about their duty to take social and environmental issues into account at the same time as pursuing their wholly legitimate goals of maintaining profitable and sustainable businesses.

Finally it is important to note that the roadmap lacks efficacy if the commitment to and understandings around responsible innovation are incomplete. This means that, when the individual issues within the roadmap are considered, their applicability must be recognised as relevant and understood by the widest range of people. This includes employees, contractors, investors, customers and users. Indeed it is the obligation of the company or organisation concerned to ensure that contractors and partners act in accordance with the framework that is set out.

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COMPANY MANAGEMENT

Vital

- Developing, reviewing or re-affirming mission statement in order to set context for responsible innovation. Demonstrating therein a commitment to the care and protection of employees, customers and other stakeholders.
- Ensuring commitment at all levels to ethical and safe modes of operation for products and services at stages of (a) idea generation and research; (b) development; (c) testing & production; and (d) market and impact.
- Ensuring that the ethos around safety and ethical working practices is clear within employment contracts, recruitment procedures, etc. and will, where breached, lead to disciplinary action.
- Ensuring impact assessments are undertaken at all stages (taking account of the range of stakeholders and wider environmental issues). Linking these to procedures (with clear lines of responsibility) that facilitate the making of key decisions to move forward or halt the innovation process.
- Having emergency and contingency plans in place for the accidental release of nanoparticles.
- Demonstrating readiness to engage with and respond to feedback from clients, customers, end users and ensuring protocols are in place for dealing with feedback (openness to information sharing) and involving them in decision-making process where appropriate.
- Adhering to codes of practice and applicable standards. Obtaining certification after compliance established via an accredited external agency, where appropriate.
- Working and collaborating with a relevant industry association body with a shared ethos and, with or independently of it, to contribute to standards development in the field.
- Developing and/or maintaining a code of conduct that is transparent and publicly available.

Desirable

- Being forward in raising public awareness of nanotechnology; and providing support for science education (with a gender-balanced approach).
- Leaving room for fundamental research (where appropriate in collaboration with centres of expertise) applicable to the sector.

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IDEA GENERATION & RESEARCH

- Base research on the best evidence available and be ready to consider implications of new knowledge arising from ongoing research.
- Give specific attention to research that relates to risk, ways for risk avoidance and minimisation, and consider necessary responses to 'worst case' scenarios.
- Be sure about market need for the product and that nanotechnology is appropriate way to meet that need (are there non-nanotechnology alternatives?).
- Reach out to and use feedback from stakeholders to inform the research.
- Be very aware of emerging standards and be ready to conform with requirements that may relate to these.

External Engagement
…ensuring regular feedback from clients, customers and users - impacting on design and production.

DEVELOPMENT

- Ensure 'Safe by Design' approach embedded in all stages, taking account of the life-cycle of the nanomaterials used (and related issues for recovery and disposal).
- At a minimum, ensure that the five principles of design for safer nanotechnology are followed (see Table 4).
- Recognise the need for product 'fit' in relation to specific standards.

Internal Feedback
Regular feedback within the organisation

TESTING & PRODUCTION

- Implement guidelines for workplace safety (not just production areas) and provide training regularly to promote conformity.
- Ensure regular feedback and discussion with designers and researchers regarding matters arising during the production. process (or preparation for the same).
- Ensure safe procedures for packing and storage before despatch.

MARKET & IMPACT

- Provide clear and comprehensive information in all marketing and sales materials and activities (including risks).
- Ensure that the information addresses the matter of risk with the extent of risk never understated.
- Guide, with absolute clarity, customers and users (and those involved in collection, storage, transporting and delivery) regarding the risks and reporting arrangements in the event of damage or accident.
- Maintain contact with customers and users (i.e. wherever the nanomaterials are located) over a sustained period in order to provide reminders about the importance of following safe practices, establish usage the nature of usage (and any changes to the same) and gather relevant feedback.

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