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Theme 3: how to manage novel materials in society: governance and regulation

16. Is REACH the right framework for regulating novel materials and nanotechnologies?

In Europe REACH is the right framework to start with, and could provide a model for the rest of the world. Nanomaterials should first be recognised as new materials, even if in this context of scale-difference-only, 'new material' *also* has a different sense from the ordinary. Exactly how the precautionary principle is to be taken seriously by corporations in the context of global competition needs to be negotiated through stakeholder dialogue. Given the urgency of the situation, decades of bartering will hinder global environmental readjustments, therefore a strong government (regional, national) direction and legislation is the only option. To counter competitive disadvantage fears, government will need policies of international technological aid to countries such as China, India and Brazil, encouraging them to purchase state of the art clean technologies instead of older and dirtier ones. Public procurement of environmentally advantageous technologies should be promoted and coordinated across national boundaries.

REACH will have to deal with a number of gaps in regulation and blend in with other regulatory regimes to cover new materials more effectively. For example: proper governmental review before marketing of materials/products; enhancing of programmes which currently cover 'new' substances so that more and better data must be provided by producers; triggering by mass-based thresholds or standards is clearly inapplicable for nanomaterials and must change very soon; some potential nanomaterials may escape between the jurisdictions of multiple regulatory programmes (medical, environmental, consumer, public health etc).

17. Are the regulations which affect novel materials fit for purpose? Is existing legislation sufficient to deal with potential problems that could arise during the different stages of the novel material's life cycle, i.e. manufacture, use and disposal?

No, not fit for purpose. See above (16). Regulations do not currently take account of the newness of nanoscale materials, nor of the newness of the kind of newness (i.e. ramifications of nanoscale). Regulations need to be coordinated, cut down at the same time, made fit for purpose, and made as global as possible. E.g. Environmental law and consumer law sometimes overlap, but new materials present hazards to consumers through the environment, and environment through consumers.

Regulation in this area must be put on a novel conceptual footing, namely a recognition of *complexity and emergence*. Since the biological interactivity of particles increases as the particle size decreases the biokinetics of engineered nanostructures will be extremely complex, and in an unprecedented fashion. As we approach the nanoscale and smaller, this interactivity becomes critical in a

novel way. Therefore, at this scale a complex systems approach is vital, and reductionist thinking inappropriate and potentially harmful. It may be legitimate for all parties involved to raise the question of whether the hazards are too complex and unpredictable to be manageable at certain points, and therefore whether market-driven technologization should be subdued by domestic, regional and international regulation. Just as nuclear technology has posed regulatory challenges because of unprecedented long-term hazards and risks, as well as actual large-scale harms, owing in part to the physical fundamentality at which it operates, so too nanotechnology, squeezed in between the nuclear and the micro-levels may force us to re-think our understanding of the implications of all nanoscale technologies.

18. Is the UK, EU and global science and knowledge base sufficient to support current legislation frameworks and any future regulation? Where are the gaps and what are the research priorities?

The knowledge base is grossly inadequate, providing manufacturers and industry with the unreasonable legal protection that 'there was insufficient scientific knowledge at the time' (i.e. now) when environmental and public health damage is done in the next few decades (see my 24 below). There has to be coordinated international substantially funded research into environmental impacts *before* commercialisation of nanomaterials goes further. Any economic and political measures which counteract fears of competitive economic disadvantage will provide a space for international cooperation on such research. No one is disadvantaged by a regulation-levelled playing field.

An international open-source database on characteristics etc of nanomaterials should be launched, by a new international agency (see my 25 below).

Regulators must recognise that nanotechnology is converging with biotechnology, and other technological domains. Nanotechnology will undoubtedly raise several social and ethical issues that go beyond the mandate, and core competencies, of regulatory bodies that have traditionally dealt with agricultural, medical and environmental issues in isolation (and who have traditionally defined social and ethical issues as non-regulatory). Regulation may be thought of as a barrier to 'progress' by some, however, while slowing down specific developments, regulation can be used also to coordinate the evolution of new technologies in socially desirable directions. For example, if we decide to take advantage of the hydrogen fuel cell, to which new materials will contribute efficiency.

19. Is the UK's and EU's research funding sufficient in this area? Is it being delivered in the right way?

No, it is not adequate, but very inadequate. It is not being delivered in the right way because there has not been (except for recent DEFRA initiative) a prioritisation of nanotechnologies in respect of environmental benefits (solar cells, hydrogen economy, strong lightweight materials, etc) or a proper scrutiny of the hazards presented by the burgeoning consumer use of nanomaterials in cosmetics, healthcare products, medicines, foods, food packaging, and drinks. (And these consumer uses will impact environmental through waste water, sewage etc). The coming public reaction to these uses of nanomaterials (next 5 to 10 in my view)

will hinder the development of environmentally beneficial nanotechnologies. UK and EC should show by example through its funding and *procurement* priorities that the nanomaterials that interest it are those that are environmentally beneficial.

20. Can novel materials and technologies be effectively governed and regulated if it is not possible to obtain exposure data before products containing novel materials are produced and made available to consumers?

No, they can't. Governments and regional and international agencies must massively fund research to obtain such data. A specific nano materials international coordinating agency is needed.

21. What is the role for engaging the range of different interests and perspectives, commercial, political, public and societal, on the development of novel materials in the context of global markets?

'Public engagement' is only as helpful to the environmental situation as the ethical level of those doing the informing. If the informers have little or no sense of ethical priority then engagement will turn into the mere promotion that serves powerful interests, and 'public engagement' will be counter-productive in the long term. Appeals to 'public engagement' in development of new materials that emphasize 'fighting cancer', 'super tennis balls', 'ever-clean surfaces' and instant-buzz sports drinks, trivialise the urgency of the environmental crisis, and will eventually produce a rebound on the real utility of nanomaterials and technologies (strong lightweight materials, aerogel insulation, low-energy low-waste manufacturing process, nano-catalysts, hydrogen economy, safer nuclear energy, fusion research, etc.) The interests that count are large corporations, governments, regional bodies, international agencies and some large and reasonably well-informed NGOs.

22. Are there general lessons to be learned from the development and use of other novel technologies, e.g. the development of genetically modified organisms?

Yes. The public suspicion of GMOs is not due to the fact that the public is ignorant, but because of the inherent nature of GMOs and suspicion of the powerful interests promoting them. When there is a similar public reaction to the nano-frivolous (see above) then we are left with the problem that all nanotechnology, including that vital to solving critical problems, may be viewed with suspicion.

23. How can an appropriate balance be achieved in the design of regulatory systems to effectively manage uncertainty?

By strong national and regional government, and international agencies with a global welfare agenda.

24. What are the implications for liability when problems arise even if procedures are properly followed in good faith: who should bear responsibility and what issues arise for insurance and redress?

The UK's consumer protection law arises out of the European Union requiring its member states to enhance consumer protection and the approximation of laws to permit the proper functioning of the common market. This Act could apply to products of nanotechnology. It provides for strict (or automatic) liability for death or personal injury caused by a defect in a product, as opposed to injury caused by the intended use of a product. It is a subtle distinction but the Act renders liable anyone who produced the product, endorsed it (by putting a name or trademark on it) or, imported the product from outside the European Commission and refused to identify the exporter. Here one envisages injury caused by a design flaw or manufacturing flaw in the nano-product, for example, by the escape of its inherent toxic materials, or emissions from it. So the nano-product may achieve its intended purpose but cause injury in doing so. As liability is strict, informed consent of the possibility of a design flaw or a defect would not permit a defence as that would offend the Unfair Contract Terms Act. Note that there is incorporated into the Consumer Protection Act the common law 'Roe v Minister of Health' defence, which provides a defence to a claim where: '. . . the state of scientific and technical knowledge at the relevant time was not such that a producer of products of the same description as the product in question might be expected to have discovered the defect if it had existed in his products while they were under his control'.

25. How would you apply the precautionary principle to the management and regulation of novel materials?

I recommend that the United Nations, or some other similar constituted body, should convene an international conference with a view to the creation of a permanent international multi-stakeholder body (for example, International Nanotechnology Agency) to review, monitor and regulate developments in nanotechnology. There is as much reason to create such a body now as there was to create the International Atomic Energy Agency in 1957 to promote 'the achievement and maintenance of high levels of safety in applications of nuclear energy, as well as the protection of human health and the environment against ionizing radiation'. Such an agency must not be restricted to the representatives of governments, corporations and research institutions, but must involve non-governmental organizations, representatives of major world religions and members of the public. The Agency will function on the principles of organizational accountability, 'a right to know', a duty to inform, openness and transparency. Furthermore, such an agency must not adopt the typical 'sound science only' position common amongst regulators but embrace sustainability and precaution, and show how to implement them.

26. In debate about new technologies, questions of need and control, as well as questions about consequences, have emerged as being important. To what extent should our study engage with questions about the need for

novel and novel uses of materials; about who exercises control over such technologies; and about public trust in the institutions involved?

Vital to engage with the question of need. Ask the public: 'Do you want a better tennis ball and long-lasting tyre or do you want solutions to global warming'. We can't do it all, here's the information, make your choice.

Scientists, technologists, researchers and technicians are for the most part materially supported by large organizations (corporations, government agencies), of limited public accountability, who are inducted at an early age into the ideology of these organizations (as well as the general 19th century ideology of never-ending material progress), and almost by 'instinct' react to whatever they perceive as an attack on their interests with claims that no non-scientist (or non-specialist) could possibly have anything authoritative or serious to say about 'their' work. An international and transparent agency could help to change this problem of accountability and communication.

And finally:

27. Are there any other major questions or issues that the Commission should examine?

Firstly, the relationship between nano and other new materials in developing military applications needs attention: Diversion of resources (military procurement and research funds) needed for the environmental crisis; environmental impact of war; military manufacture also has impact on environment, etc. A large proportion of nanotechnology development funding in the USA in particular goes to military applications. Allies of the USA may benefit from nano-weaponry, but other countries such as China and India will seek to 'catch up'. One should not underestimate the rate at which nanotechnological advances in materials and electronics and other areas are being applied in many military areas such as toughened armour, tiny surveillance devices, enhanced battleground management, sensors for defence against biological and chemical weapons, enhanced interfacing and targeting for soldiers and fighter/bomber pilots (See writings of Jurgen Altmann).

Secondly, environmental impact of high tech solutions may unnecessarily (and long-term harmfully) substitute for intermediate technologies (some environmentally friendly) in some cases. Thus, hypothetically, a nanotechnology based system for water-purification may be promoted as a hi-tech (and profitable) solution when in fact better overall use of existing water resources (for example water-shed adjustment) may be less expensive when one puts into the cost–benefit pricing the energy requirements, potential health effects, and so on of the hi-tech solution. In other words, generally speaking, nanotechnologies are only likely in most cases to be a human welfare benefit if the traditional social and economic assumptions are challenged. Grafted uncritically onto old ways of thinking and doing things they may simply intensify, through greater input-output efficiency, the sustainability problems we have already.

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