

Trusted authority should evaluate need for nanoregulation

Current trends in Communicating Nanoethics

**Interview with Dr Donald Bruce, Managing Director Edinethics Ltd.,
Edinburgh, Scotland, UK**

Ineke Malsch, postbus@malsch.demon.nl Interview 27-09-2011, published 2-11-2011

Abstract

The initial phase of public dialogue under the heading “nano” may have faded away, but there is a need for ongoing engagement by lay people and ethicists with nanotechnology, focused in specific domains, such as food, medicine and surveillance. That is the conclusion Dr Donald Bruce draws after several years of discussions on ethical and societal aspects of nanotechnology in the UK and Europe. He is concerned at the secrecy over nanotechnology in some sectors of industry, notably food and cosmetics, which could cause a public backlash. The EC needs more continuity than is being delivered by its discrete framework research projects which end and tend to get forgotten. He sees a need for a trusted authority that can examine the need for adapting regulations as nanotechnology is applied in different products and sectors.

Under the header of Communicating Nanoethics, ObservatoryNano aims to highlight key findings and developments in current dialogues and public engagement activities at EU level and in Member States and other countries. This way, emerging issues not discussed sufficiently and best practices in communication on ethical and societal aspects of nanotechnology can be identified and brought to the attention of policy makers in the fourth annual report on communicating nanoethics to be published online in the spring of 2012.

Ineke Malsch: The UK initiated international dialogue on nanotechnology and society from 2003 through the Royal Society / Royal Academy of Engineering project¹ and its follow-up. Dialogue activities have continued in the UK until mid 2010, but no evidence of more recent activities can be found on the internet. What happened?

Donald Bruce: The report by the Nanotechnology Engagement Group² is a central piece of work on public dialogue in the UK. This group was set up to analyse the results of a series of public engagement activities which

¹ www.nanotec.org.uk

² <http://www.sciencewise-erc.org.uk/cms/nanotechnology-engagement-group-neg/>

took place 2004-05, more or less in response to the Royal Society / Royal Academy of Engineering 2004 report on nanotechnology. The academies recommended that public engagement needed to be done and taken seriously. In the aftermath of the genetically modified food disaster, there also was a strong sense of: "Let's not have something similar happen over the next major new technology", which happened to be nanotechnology. The idea was to use nanotechnology as a test case for a concerted upstream public engagement about new technologies.

The Nanotechnology Engagement Group examined the outcomes, and concluded that nanotechnology probably was not a good example for a pilot upstream engagement exercise. It was very different from GM, because nanotechnology was a much more difficult concept for the public to understand, was hugely diverse and largely future in its applications. One of the problems was the word nanotechnology, which is not an identifiable phenomenon like genetic modification or stem cells. The only common denominator is the size of the structures and the word "technology".

The main findings were that participants in the dialogue in general warmed to idea of the potential benefits of nanotechnology, but this was tempered by two caveats. We are concerned about the potential risks of small invisible things, and so we want to be sure you know what you are doing with all this. And we want to be more engaged in decision making on it. This last recommendation may have been influenced by the organisations that organised the engagement, because engagement is more or less their *raison d'être*.

But did these public dialogues tell us something we did not know before? The general feeling was that it did not. Nanotechnology was too broad a subject to relate to, and often remote from people's experience. For a more fruitful dialogue, we need to look at particular fields of application, like food, medicine or surveillance, and what nanotechnology brings to those domains.

Enhancing reflectivity about priorities in nanoscience

A notable exception was an innovative public engagement on nanomedicine commissioned by the UK Engineering and Physical Sciences Research Council (EPSRC). EPSRC wanted to select two or three 'grand challenges' in nanotechnology as a focus for major funding investments over five years. The first was solar photovoltaics and the second nanomedicine. The Council proposed six areas of nanomedicine from which a targeted project would be selected. These included diagnostics for preventive medicine, targeted drug delivery, tissue regeneration, antibacterial silver in cleaning up hospital facilities, and theranostics. To select among such areas is normally the province of research scientists,

but EPSRC had set up a Societal Issues Panel to increase the involvement and awareness of ethical and social issues within the physical science and engineering research community. This panel suggested “why not also organise public consultation on what should be the priorities of a grand challenge on nanomedicine?” Richard Jones³ was the mastermind behind what turned out, in my opinion, to be one of the best recent examples of public engagement in an emerging technology.

The public focus groups were enthusiastic about such things as diagnostics and drug delivery, but also brought some unexpected perspectives which hardly anybody had seen coming. For example, they asked why use nanosilver in cleaning hospitals, instead of doing more routine cleaning? Why use a risky high tech solution rather than low tech solutions? The second concern was about theranostic devices that could detect an adverse change in a key body chemical and take therapeutic action to remedy it, combining diagnosis and therapy in one ‘smart’ device. People did not want such a device to be too smart or completely automatic. Either we as future patients, or our doctor, should be able to intervene and say: “Yes, we ought to now increase the level of this drug, or not”, rather than building such judgements permanently into some scientist’s algorithm. Scientists had not envisaged this as a problem: the more automated it was, the better the product. Interestingly a device manufacturer had already picked up some of the same concerns. The company was moving away from aiming to have a ‘black box’ device, because it was not sure that it could deliver the necessary reliability for a wide variety of patients.

This EPSRC public engagement on nanomedicine research was successful because it gave new insights on specific topics, rather than generalities of the previous engagement exercises.

Since then much less engagement has happened. The previous UK Government produced a strategy document, but the present Government has not done much with it, and seems less inclined to recommence dialogues. There are also no huge nano-issues emerging. Currently, more discussed issues are high tech medicine, novel foods or making biofuels etc. The issues are specific to given areas. These might not be seen as being “nano”. The discussions might be going on, but you can’t see them because they don’t refer to nano.

Finances are another reason why the nano-dialogue has faded away. The UK dialogue projects on nanotechnology were rather costly. Has anybody got enough money to continue this? One possible alternative is the successful DEMOCS / Decide card games for groups, and Open Up! Argument maps for individual use, on which I have worked with the New

³ See also ObservatoryNano interview with Richard Jones “Enhancing Reflectivity about Priorities in Nanoscience”, 27 March 2009, <http://www.observatorynano.eu/project/document/2182/>

Economics Foundation for many years. These are cheap to produce and use and once created, they remain available online free ever afterwards. We should look for other tools available for cheap dialogues like these.⁴

Ineke Malsch: How do you evaluate the nanodialogue in the UK between 2003 and 2010? And the European / international nanodialogues?

Donald Bruce: I answered this in my previous comments. I can't say much about the European dialogue, although I have seen data from good German and Swiss dialogues.

Ineke Malsch: Are there remaining issues or aspects of ethical nanogovernance that merit further specific public, political or stakeholder dialogue on nanotechnology? Or is a shift in focus needed? If so, in what way?

Donald Bruce: There are not so much remaining issues, as the fact that there is a need for *ongoing engagement* once we get more specific applications of nanotechnology, notably in food and food packaging, in medicine, or in ICT and surveillance. Perhaps there will be fewer issues in the materials field. Agriculture, veterinary medicine, biology have more ethical questions because of the nature of the area rather than their being nano.

A remaining generic question is how to handle uncertain risks of nanoparticles. It is extraordinarily difficult to get an exhaustive analysis of effects of nanoparticles on human health. How to balance the risks against benefits to environment, health, convenience and commercial gains? We have hardly begun to answer this question, partly because there is not enough data to make a risk-benefit analysis.

There is also a political question how to keep engaging the general public with new technology. What has emerged out of all those stakeholder dialogues and ethical analyses is that you need something ongoing here. We need ongoing focus groups for each of the applications of nanotechnology, in medicine, food, surveillance etc. At the moment, such groups don't exist. I would recommend installing them to the UK government and the European Commission.

⁴ <http://www.neweconomics.org/projects/democs>

Ineke Malsch: It appears that a wide variety of stakeholder groups and publics has been engaged in dialogue about nanotechnology in the UK and Europe. Have all relevant groups been included? Which groups should continue to be engaged according to you? In what way?

Donald Bruce: I think anyone who was interested had the opportunity to be engaged, but many were not aware that there were opportunities. In general, religious groups have not well-engaged with these issues, with the exception of the Society, Religion and Technology Project (SRT) of the Church of Scotland that I coordinated, which was engaged from the early stages of the nano debate (2003 onwards), and was unique at that time. Now, SRT is a new organisation, with a much lower level of engagement by the Church, perhaps more like other churches and religious groups. Islamic faith has tended to have much less tradition of engagement with new technologies, except in medicine, unless it has a direct impact on the lives of their believers. So I suspect that religious groups tend to be missing from the debate, and I fear this will get worse rather than better because of a lack of money.

Patients' groups were engaged in the NanoMed Roundtable, through contacts of Alistair Kent. What became clear is that some patients groups get the point of nanotechnology, whereas for others it remains rather remote. We organised a meeting with patients groups in Edinburgh which had to be cancelled because of a lack of interest. Another meeting in London was quite successful. I don't know why. Patients' groups should probably be more engaged.

In the UK, I was a member for several years of the Nanotechnology Stakeholder Forum for the Department of Environment, Food and Rural Affairs, although this has not met for well over a year, and may therefore be defunct. It was intended as a forum to bring together industry, regulators, environmental and other NGOs, consumer groups, etc. Greenpeace had participated initially, but stopped after a few years. I was one of a few remaining NGO's (initially for the Church of Scotland). I found it valuable but it had become more industry, developers and regulators talking to Government than the original idea of the Stakeholder Forum.

A determining factor in such stakeholder fora is how much the major environmental organisations like Greenpeace and Friends of the Earth see this as a flagship concern and whether the time spent is worthwhile to them. Greenpeace is currently more concerned about India and China than the UK. Unless they see an urgent problem, they will not start a major campaign. Friends of the Earth voiced a strong opinion on nanotechnology in some products a few years ago, but did not achieve much lasting public impact. The Soil Association (the leading UK promoter of organic farming) statement that nanotechnology did not fit in their

philosophy again did not get much wider support. Prince Charles' earlier comments on nanotechnology, which to some extent prompted the Royal Society study (and thus started the debate in the UK), did not have much coherence with the wider public, most of whom did not know what nanotechnology was. (Whereas his earlier interventions about Genetically Modified food seemed to capture the public feeling at that time)

In itself, 'nanotechnology' is not a major concern in the way that GM was. Its issues are more subtle. Nanotechnology in food does perhaps have the potential to be a 'showstopper', if some activist or newspaper wanted to take it up and try and make an issue with it. In this context, there is an important warning in the 2010 a UK House of Lords committee report on nanotechnology in food.⁵ It was chaired by Lord Krebs, the former head of the Food Standards Agency. The report was strongly critical of the secrecy of the food industry who kept quiet about using nanotechnology out of fear of a negative public reaction, similar to GMOs. On the contrary, the Lords' warned, such secrecy is likely to *cause* the very public concerns the industry wants to avoid.

The industrial response is an ongoing problem in areas like food and cosmetics where the main driving forces are in a highly competitive private sector. One of the reasons for the GM crisis was that industry did not find it worthwhile engaging with the public issues until too late. This created a vacuum into which NGO's could pour their viewpoints, initially largely uncontested. If there are serious applications of nanotechnology in food and if the industry insists on hiding them, it is treading on thin ice, I would say. The same applies with cosmetics. I think it is a highly risky strategy on the part of the companies, which could lead to a public backlash, which is not in anybody's interest.

In a very different field, I wonder if more groups should be involved in discussion of nanotechnology in surveillance technologies. There are some groups who are defending civil rights, which are established as major dialogue partners to the government, but not much wider debate. I think that is often the case, that the government tends to engage with established stakeholders, but there is not much debate with wider publics. That is an area where I think there needs to be a much wider discussion in public. It is not my field, so I am looking at it from a distance. But I don't like what I see. There is a too technocentric approach where each possibility of using technology seems to drive the field, rather than asking, "On balance, given it has a down side, do we need this extra security?" There ought to be much wider public engagement with any high tech surveillance technologies, not just nano.

⁵ <http://www.parliament.uk/business/news/2010/01/lords-committee-criticises-food-industry-over-nanotechnologies/>

Ineke Malsch: Has a need for particular new regulation or voluntary measures to govern ethical development of nanotechnology become apparent in the dialogue?

Donald Bruce: There is an interesting irony here. Nanotechnology is presented as a mega step forward, a step change in how technology is handled, almost a revolution. You can do almost anything you want to do using this much smaller. But we don't need any new regulations for this revolution. It is not plausible to commend such far-reaching scale of technological change, with devices that we can't see and whose effects might be long-term, and at the same time say we don't need new regulations. Either the high tech nano-revolution is hype and is not going to change very much, and we don't need new regulation; or, if it is really new, surely it will require new regulation?

What people need is an organisation they can look to that says, 'the buck stops here', something like the way the FDA is regarded in the United States. People should be able to trust that somebody out there is looking after us. If this is effective, it will be accepted. You have to have a body or institute or department that is visibly looking after this area.

The new European REACH regulation for chemicals did not cover nanomaterials, having no mechanism to cope with substances whose production is measured in kilograms rather than tonnes. This oversight was extraordinary, and raises doubts about the ability of governance at EU level to understand new problems, to look into the future and see that things may change.

The idea that present laws and regulations can simply be adapted can run into serious problems, when new technologies have to be squeezed into existing legislation for which it was not designed. Sometimes the two shapes don't fit. This happened with adaptation of the UK 1990 Human Fertilisation and Embryology Act to accommodate stem cell research in 2000. Parliament was told that legally the only way the Act could be amended was by offering an all or nothing vote: either a whole package of embryo research including creating embryos for research, cloned embryos, etc., or else no embryo stem cell research. There was apparently no legal possibility to vote for a halfway measure like using only spare IVF embryos for stem cell research. The result created the most liberal European climate for research by accident.

This gives a generic answer to your question. The actual details will have to be addressed for each particular technological application. E.g. regulating biomarkers depends on how they will be used. Somebody will have to judge whether a nanotechnology application can fit into an existing regulation, or if it has to be adapted. As another general point, policy makers should do much more to explain how regulation for nanotechnology is meant to work, and where the uncertainties are, rather than just say that no new regulation is needed.

Ineke Malsch: At which level should such measures be taken (national, EU, global)?

Donald Bruce: The level depends on the competence. National and cultural issues may have effect on legislation. EU member states sometimes differ widely on ethical issues. If nanotechnology in food applications might not be a problem, say, in the UK, but might be a problem in Austria, for example, it would be pointless to insist from Brussels that on all member states must act the same way, whether for or against. On the other hand, standards for manufacturing should be global. Nanoparticles should be handled the same in Lancashire, Shanghai and Rio de Janeiro. Risk assessments vary with situation. What the EU considers to be appropriate risk regulations for GMOs may be inappropriate for developing countries, where immediate need to feed the population leads to a different balance of risks and benefits.

Ineke Malsch: What can the European Commission or other governments interested in stimulating dialogue on ethical development of nanotechnology learn from the UK experience?

Donald Bruce: What the EC and government might learn:

a). Don't assume that having talked once about nanotechnology, you don't have to discuss it again. In the 2000s, the UK has been a leader in promoting nanotechnology public engagement, learning from the Netherlands and Denmark, where they had more experience of this approach. But there is now a risk that, once an issue has been the subject of public engagement activities, policy makers think 'we have done it, and don't have to repeat it'. But citizens take time to assimilate and think about ethical questions over unfamiliar technologies. A primary response is not the end of the matter. After thinking about it for a year, people may think differently about the issues. There is an ongoing need to keep working with the population. What is needed is ongoing dialogue.

b). Another problem in the EU is that between Framework Programme research projects, the wheel may be reinvented again and again. There is not enough learning or follow up from one project to the next. In the FP6 Nano2Life we did much ground breaking work in the ELSA aspect of nanobiotechnology. In the subsequent NanoMed Roundtable, much of the initial work was overlooked, because a new team wished to make its own statement. Such reinvention keeps happening. ObservatoryNano needs to be aware of this also. There is a need for a greater degree of continuity at EU level in ethics, social impacts and codes of conduct.

c). Some of us proposed an ongoing expert panel, a European Group on Ethics of Nanotechnology, to the European Commission, but the response was that these issues can be handled through framework research

projects. From the experience I have just recounted, this simply does not work! Neither can the existing European Group on Ethics of Science and Technology address the detailed questions that must be examined. There is a need for a continuous expert panel. In addition we need to have a series of focus groups of lay people that change every year, to prevent them each lay group become too much 'expert'.

d). A further problem is that when a consortium puts a research funding bid to a call for proposals, big names apply and get selected, but the Principal Investigator has no time, and the work is done by a post-doc who may not have anything like the experience. The big names applying for the projects should be obliged to do some of the ethical work themselves.

e). Don't talk about nano in general, but about nano in medicine, in food, the environment, etc. That is where people can understand the application and what it means for their life. Public engagement with nanotechnology has been a hard exercise because it is so abstract. GM food and stem cells were much easier.

f). The EC could use the Report of the Royal Commission on Environmental Pollution on nanotechnology from 2008. This commission was very influential because it reported to Her Majesty the Queen and the government has to respond. The commission pleads for adaptive regulation. Legislation should be easy to change under the influence of technological development.⁶

Ineke Malsch: How do you see your own role in the continuing dialogue on ethical (nano)innovation?

Donald Bruce: I am still engaged in an ongoing dialogue about Human Enhancement that is only nano-specific on the periphery. This will be an area where ethical and not just legal issues need to be addressed: human enhancement without a medical reason. How do you make sure that in products claimed to enhance the human body you don't get a lot of quack salesmen peddling snake oil? How do you know it does what it says on the package? Enhancement lies outside the scope of detailed medical device and pharmaceutical testing and regulation. Existing consumer law is unlikely to be adequate. There could be major legal issues here.

The concept "nano" has not really sustained itself. Some people are rather regretting that the term "nano" was invented, but now we have it, we must to work with it and its implications. There is also a difference between the scientist's understanding and the myths that can emerge in the culture about the same thing. Most people think that the cloned sheep

⁶The RCEP has ceased to exist in January 2011. Their report on nanotechnology is available here: <http://www.official-documents.gov.uk/document/cm74/7468/7468.pdf>

Dolly died of old age, or that GM 'Terminator' technologies are widely used in Africa and Latin America. Neither of these are true, but that are deeply embedded myths, even in our supposedly enlightened and scientific age. Nanotechnology should look out and avoid similar myths.

Identification

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Role in debate on nanotechnology, ethics and society:

Dr Donald Bruce has been a key opinion leader in the debate on nanotechnology, ethics and society in the UK and Europe since 2003. Until 2007, he contributed to the debate as director of the Society, Religion and Technology project of the Church of Scotland. Subsequently he has continued his engagement as director of his own consultancy Edinethics Ltd. He has participated in several projects listed at <http://www.edinethics.co.uk/director.htm>.

Relevant recent projects and publications

Edinethics is engaged in the ethics and public engagement of emerging technologies including synthetic biology, nanomedicine, stem cells (EC FP7 ESNATS project) and human enhancement (FP7 ETHENTECH project). Dr Donald Bruce was a partner or advisory board of several previous EU projects on nanotechnology including the Nano2Life, NanoBioRaise, Framing Nano, Nanomedroundtable and EuroNanoBio, and is an advisor on ethical and societal aspects to the ObservatoryNano project www.observatorynano.org. He is a member of the advisory board of the Institute of Nanotechnology www.nano.org.uk, and a member of the international Society for Study of Nanotechnologies and Emerging Technologies S.NET. He was a member of the Nanotechnology Stakeholder forum of the UK government Department for Environment, Food and Rural Affairs DEFRA www.defra.gov.uk, a member of the Scottish Science Advisory Committee, and the public affairs / societal issues panels of the Biotechnology and Engineering and Physical Science Research Councils.

Bruce, D. M. (2007), *Faster, Higher Stronger*, NanoNow, Issue 1, February 2007, pp.18-19.

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Bruce, D. M. (2006), *The Question of Ethics*, Nano Today, vol.9 (1), pp.58-59
Nano-2-Life Ethics: A Scoping Paper on Ethical and Social Issues in Nanobiotechnology, in 'Münsteraner Bioethik Studien, 6th ed.', Ach, J., Bruce, D., Jömann, N., Schroeder-Oeynhausen, F., Siep, L. and Weltring, K.-M., University of Münster, Germany, 2006.

Public Engagement Tools

Donald Bruce and Perry Walker, Human Enhancement DEMOCS Game, produced in the EC ETHETECH Project 2011

Donald Bruce and Perry Walker, Human Enhancement Open Up! Argument map, produced for Wellcome Trust 2009

Donald Bruce and Perry Walker, Synthetic Biology DEMOCS Game, produced for Genomics Forum, 2010

Donald Bruce, NanoBiotechnology DEMOCS Game, produced in NanoBioRaise 2005-2008 www.nanobioraise.org

<http://www.edinethics.co.uk/nano/nanoethics.html>

Donald and Ann Bruce, Genetically Modified Crops DEMOCS Game, produced for UK GM Nation? national consultation, 2003

Donald Bruce, Tom Shakespeare and Perry Walker, Stem Cells and Cloning DEMOCS Game, produced for Wellcome Trust, 2001, with 4 subsequent revisions

Donald Bruce, Ethical part of the website Nano&Me:

<http://www.nanoandme.org/home/>

Invited lectures on on ethics of nanobiotechnology and related issues

Donald Bruce, 2009-11, lecture on ethics at 2nd, 3rd and 4th European Conferences on Clinical NanoMedicine CLINAM, Basel, Switzerland, www.clinam.org

Donald Bruce, 2007, Martin Luther's blog, Risky Food and Enhanced Humans: Why ethical issues matter in nanotechnologies, paper presented at COMS 2007, Melbourne, Australia,

Institute of Nanotechnology 2007 Albert Franks lecture: Ethics and Nanotechnology, Royal Society, London

EC workshop on Nanotechnology and Security, Rome, February 2007.

European Science Foundation Conference on Nanomedicine, Barcelona, Sept.2006:

European Parliament, Brussels, June 2006, workshop on human enhancement

BIO 2006, US Biotechnology industry annual conference, Chicago April 2006.

Nanolreland, invited lecture to industry and government scenario planning group, Dublin, February 2006

European Commission European Group on Ethics in Science and New Technologies, December 2005 : invited presentations on recent developments in stem cell ethics and scoping paper in nanomedicine.

EuroNanoForum conference, Edinburgh, September 2005

NanoBiotechnology III, Nice, June 2005

Nano2Life Annual Meeting, Munster, March 2005

European Molecular Biology Laboratory, Heidelberg, Science and Society conference on Time and Ageing, 2004 : ideas of ageing and eternal life

Edinburgh International Science Festival 2003 : lecture on the notion of Human Perfection

Royal Institution, London : 2003 invited lecture on ethics of nanotechnology

Royal Institution, London, 2002 : lecture on the Ethics of Human Enhancement

About observatoryNano

The observatoryNANO project is funded under FP7 for four years from April 1st 2008. Its primary aim is to support European decision-makers with information and analysis on developments in nanoscience and nanotechnology (N&N). It will collate and analyze data regarding scientific and technological (ST) trends (including peer-reviewed publications, patents, roadmaps, and published company data) and economic realities and expectations (including market analysis and economic performance, public and private funding strategies). The ST and economic analysis will be further supported by assessment of ethical and societal aspects, impacts on environment, health and safety, as well as developments in regulation and standardization. Although much of this work will be performed within the consortium, the project is working cooperatively with other initiatives to ensure that effort is not duplicated and that resource sharing and output are maximized. To date liaisons have been established with international organizations including the EPO, OECD, and ISO, and will continue to be established with other relevant organizations such as European Technology Platforms (ETPs), ERA NETs, and other EU-funded projects.

The observatoryNANO project is led by the Institute of Nanotechnology (IoN) (UK), and includes: VDI Technologiezentrum (DE), Commissariat à l'énergie atomique (CEA) (FR), Institute of Occupational Medicine (IOM) (UK), Malsch TechnoValuation (MTV) (NL), triple innova (DE), Spinverse (FI), Bax and Willems Consulting Venturing (B&W) (ES), Dutch National Institute for Public Health and the Environment (RIVM) (NL), Technical University of Darmstadt (TUD) (DE), Associazione Italiana per la Ricerca Industriale (AIRI) (IT), Nano and Micro Technology Consulting (NMTC) (DE), Swiss Federal Laboratories for Materials Testing and Research (EMPA) (CH), University of Aarhus (DK), MERIT - Universiteit Maastricht (NL), Technology Centre AS CR (CR).

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