# ETC Group Report

## *NanoGeoPolitics*
## ETC Group Surveys the Political Landscape


**At the Gleneagles Summit, the G(whiz)8 saw 'More Science' as the South's solution to poverty and global warming. Behind the scenes, the leading nano nations are rushing to set the rules for global nanotechnology governance**

etc group
action group on erosion, technology and concentration

**July/August 2005**

ETC Group Special Report – Communiqué No. 89

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Original artwork by Reymond Pagé. For more of his work, please see http://members.shaw.ca/reysart

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# Summary

**Issue:** Fearful that nanotech may face the same fate as biotech crops, the G8 used their Gleneagles summit to promote "new technologies" (including nanotech and biotech) as the magic bullet to "make poverty history" and to neutralize global warming. By hinting at the availability of billions for science capacity-building in the South, the North hopes to make allies of South governments, scientists, development NGOs, and environmentalists. Meanwhile, the real action is behind the scenes where various government/industry and scientific institutions are rushing to negotiate what the EU hopes will become a nanotech "code of conduct"(but, in light of US opposition may turn into a "framework of shared principles") and lay down the global standards, regulations, and market *modus operandi* for the greatest industrial revolution society has ever (not) seen coming. Social policy is being replaced by science policy. In this special report, ETC Group reviews the emerging nanogeopolitics landscape.

**Impact:** According to industry, nanotechnology will contribute to a commercial market exceeding $1 trillion by 2011 and $2.6 trillion (15% of global manufacturing output) by 2014 – 10 times biotech and equalling the combined informatics and telecom industries.[1] OECD countries – convinced that technological convergence at the nano-scale is the "future" – are in an all-out race to secure economic advantage: health and environmental considerations are secondary; socioeconomic impacts will have to wait; regulations, if they can't be avoided, must be voluntary to keep the train speeding from lab to marketplace on track. By some industry estimates, the die will have been cast for the strategic shape of a New Nano Economic Order within the next 12 to 24 months.

**Fora:** In keeping with the G8's pro-poor science push, the European Commission in Brussels hosted a second meeting to consider a draft Code of Conduct / Framework of Shared Principles for nanotechnology. In march-step, the OECD is conducting meetings in Paris to hammer out a global regulatory approach to address nano's unresolved (and increasingly worrisome) health and environmental issues. Only the Macro-South (i.e., Brazil, China, India, Korea, Singapore, South Africa, Argentina, Mexico, etc.) usually attend these closed-door nano policy-setting meetings. To date, the UN and its specialized agencies have been sidelined. If all South governments hope to have a say in this technological upheaval, the role of converging technologies should be discussed during the Millennium Development Goals Assessment in New York Sept. 14-16 and by each of the specialized UN agencies as soon as possible.

**Policies:** With public confidence in both private and government science at an all-time low, full societal dialogue on nano-scale technological convergence is critical. It is not for scientists to "educate" the public but for society to determine the goals and processes for the technologies they finance. There is no need for a *sui generis* (and inevitably voluntary) code of conduct for nanotech, but there is need for a much broader and legally-binding International Convention for the Evaluation of New Technologies (ICENT). South governments negotiating commodity and manufacturing trade-offs at the WTO Ministerial in Hong Kong in December will be asked to give away sovereignty in exchange for market access for raw materials or finished goods that may quickly become irrelevant with nanotechnology's development.

## Making Poverty Chemistry!
### *Poverty as a Science Policy Matter*

By making poverty (and global warming) a science problem, the G8 at Gleneagles, were admitting that – after decades supposedly committed to social justice solutions for poverty[2] -- they just can't do the heavy lifting needed for social policy change. Instead, the leaders seem to prefer a "trickle-down" technology solution: If properly promoted, the benefits of converging technologies will trickle-down to marginalized peoples in the South. To make sure the South is trickled down upon, the G8 will support a number of Centres of Excellence (particularly in sub-Saharan Africa) that, if Sudan's Mohamed Hassan, the President of the Third World Academy of Sciences has his way, will include at least one centre for nanotechnology.[3]

Hassan's enthusiasm for a nanotechnology centre harmonizes nicely with a recent UN report, *Innovation: Applying knowledge in development*, prepared by another nanotech booster, Calestous Juma, the Kenyan founder of the African Centre for Technology Studies (ACTS) now at Harvard's Kennedy School of Government; and by a well-timed article by John Mugabe, Juma's protégé and now a science advisor to NEPAD (New Partnership for Africa's Development) who is aggressively pushing Big Box science for Africa.[4] Support for a major science initiative by the G8 also comes from a blue-ribbon panel chaired by M. S. Swaminathan of India and Pedro Sanchez of Columbia University's Earth Institute (*Halving Hunger: It can be done*).[5] Of course, Tony Blair's own Commission for Africa (*Our Common Interest*)[6] also hails Centres of Excellence as an opportunity that daren't be dissed. In the run-up to Gleneagles, Blair's Science Advisor, Professor David King, wrote a guest commentary in *New Scientist* praising the promise of new African Centres of Excellence[7] and Gordon Conway, past president of the Rockefeller Foundation and science guru to the UK Department for International Development (DFID), specifically supported nanotech as a development tool in testimony before a House of Commons committee.[8]

The science-solves-all hypothesis was reinforced by US President George Bush when, en route to Gleneagles, he finally acknowledged that human activity is causing global warming. His solution? New technologies can be harnessed to modify the earth and atmosphere so that US industry won't be harmed.

A month before Gleneagles, Canada hosted the G8 science advisers under the Carnegie flag in Vancouver to discuss "Pro-Poor Science" and to support the work of the G8's national science academies in backing a new science strategy for Africa and the South in general. Interestingly, Hassan says he shares ETC Group's concern that the short-term impact of nanotechnology on the South could be negative if the technology undermines or distorts commodity trade. In the long-term, however, the scientist says that the South has no choice but to climb on the bandwagon. While ETC Group believes that both the positive and negative aspects of nano-scale technologies should be fully explored by the South, we do not see the technology as inevitable and we are concerned that its negative impacts – short-term or longer – could make the long-term irrelevant. If you're dead in the short-term, a rosy long-term outcome loses its lustre. The bottom line is that Africa – and the South – need not surrender to a new form of scientific imperialism but can make its own evaluation and set its own course.


## Overview: Nanogeopolitics

***Where are we now on the road to a mature nanopolitics?***

The G8 hopes its push for pro-poor science will give nano-scale technologies a positive public persona while governments and industry rush to protect the technology's trajectory for commercialization. On July 14-15, thirteen invited insider governments gathered in Brussels to contemplate a draft code of conduct for nanotechnology. Observers to global negotiations were likely astonished to learn that G8 governments – especially the United States – were actually willing to consider language such as "code of conduct." Following the acrimonious battle for an (extraordinarily weak and ineffective) biosafety protocol related to international trade in genetically modified products, gun-shy governments are now prepared to consider a nanotech code – primarily as a measure to pre-empt rigorous regulations and public controversy. What follows is a summary of recent political developments leading up to – and including – the July Brussels meeting.

Three years ago ETC published a report on possible toxicity of nanomaterials[9] and called for a moratorium on the release of manufactured nanoparticles until lab protocols are established to protect workers and until regulations are in place that take into account the special characteristics of these materials and until they are shown to be safe. It was a demand made in a policy and regulatory vacuum. This is both no longer the case and still absolutely the case. In the

intervening three years, the barren policy landscape around nanotech risks and issues has begun to take on features and shapes, new players have surfaced, international institutions are sniffing the air or claiming turf and there is a growing consensus that some sort of regulation is needed to deal with at least some of the risks posed by the world's most powerful technological platform.

But nanotechnology research and development (R&D) is now accelerating and hundreds of commercial products are on the market. The prevailing role of governments in nanotechnology policy remains that of cheerleader – not regulator – with the goal of accelerating commercialisation and winning first place in the global nano-race. According to Lux Research, 2005 will be the first year that private investment in nanotech outstrips public investment.[10] Last year the US National Science Foundation revised its estimate for future growth of the nanotech market -from $1 trillion in 2015 – to $1 trillion by 2011.[11] (Not to be out inflated by government, Lux Research opined that nanotech's market would trump $2.6 trillion by 2014.)[12] The nano-race now takes centre stage in government science and technology strategies worldwide (some 35 countries now have nanotech initiatives) as well as in corporate boardrooms (two thirds of the companies in the Dow Jones Industrial Average have nanotech R&D and/or investment[13]). Nanotech governance is definitely the slow-starting tortoise choking in the dust of the eager hare of commercial opportunism.

**Nanotech Governance – Three Approaches Emerging:** There is no unanimity on how to proceed with nanotech governance. Fixated on winning the industrial nano-race, OECD policymakers are loathe to move ahead with any legislative proposal that could put their technological advantage at risk. Against this backdrop, we see three broad and conflicting perspectives on how nanotech's development should be governed:

1) ***Optimists*** –"technology is good"– Full speed ahead (with "responsible" drivers at the wheel)
2) ***Realists*** –"technology is neutral"– Invite a few of the passengers to suggest alternative routes (the "upstream" approach)
3) ***Sceptics*** –"technology is political"– Get out the map and let everyone decide if they want to take a trip and if car, bike or bus is the best way to go

## 1. The Techno-Optimist's Motto: 'Responsible Nanotechnology'

"Responsible nanotechnology" is the dominant paradigm in nanotechnology policy, embracing a voluntary approach to managing nanotech risks. Techno-optimists argue that nanotechnologies are intrinsically good for society as a revolutionary source of health and wealth. Therefore, their development should not be constrained unnecessarily. Industry and scientists are regarded as trustworthy and sensible enough to handle risks such as nano-toxicity. In the event of some unforeseen hiccup (or political pressure), codes of conduct and practice as well as industry standards can be cobbled together and ethical studies can be appended to existing programmes. If regulation is unavoidable, it should be voluntary and consist of minimal tweaks to existing regulations. Only 'science-based' evaluations of risk should be considered, which can be handled by establishment technocrats. Other societal issues should be the charge of professional ethicists (with the desired result of smoothing public acceptance).

In sum, the techno-optimist approach is voluntary, industry-friendly and inclined to accept only 'science-based' risk issues as valid (e.g., toxicology of nanomaterials) while giving little more than lip-service to other societal risks and dangers. There is minimal questioning of whether the products of nano-scale technologies are needed or desired and even less discussion of who will determine research priorities. This is the 'trust the experts' approach in which civil society and social movements are excluded whenever possible.

## Box 1: *Who's Responsible*?

ETC Group suspects that the "responsible nanotechnology" motto was dreamed up by a public relations firm or issues management company. Vicki Colvin of Rice University's Center for Biological and Environmental Nanotechnology was the first prominent user of the term in an oft-cited article titled "Responsible Nanotechnology: Looking Beyond the Good News"[14] in which she argues that being visibly pro-active on toxicity questions could prevent a public backlash and avoid the fate of GM foods. This is not 'accountable nanotechnology' – rather, a fuzzy pledge of good behaviour. The use of the "R" word to avoid regulation and accountability is part of a long and dishonourable tradition that originates in the public relations arena. Consider these four recent examples:

**Chemicals:** The US chemical industry's voluntary "Responsible Care" program was established to head off worker-safety regulations.[15]

**Food:** The Council for Responsible Nutrition (composed of Bayer, Cargill, ADM, Monsanto and others) advocates self-regulation of the dietary supplement industry and opposes new FDA regulation.[16]

**CFCs:** In 1980 an industry coalition established the Alliance for Responsible Atmospheric Policy to prevent regulations on ozone-damaging ingredients.[17]

**Pesticides:** Established in 1991, Responsible Industry for a Sound Environment (RISE) is a US lobbying organization that defends the "urban usage" of pesticides in homes, schools, and landscapes.[18]

### 2. The Techno-Realist's Motto: "Upstream Engagement"

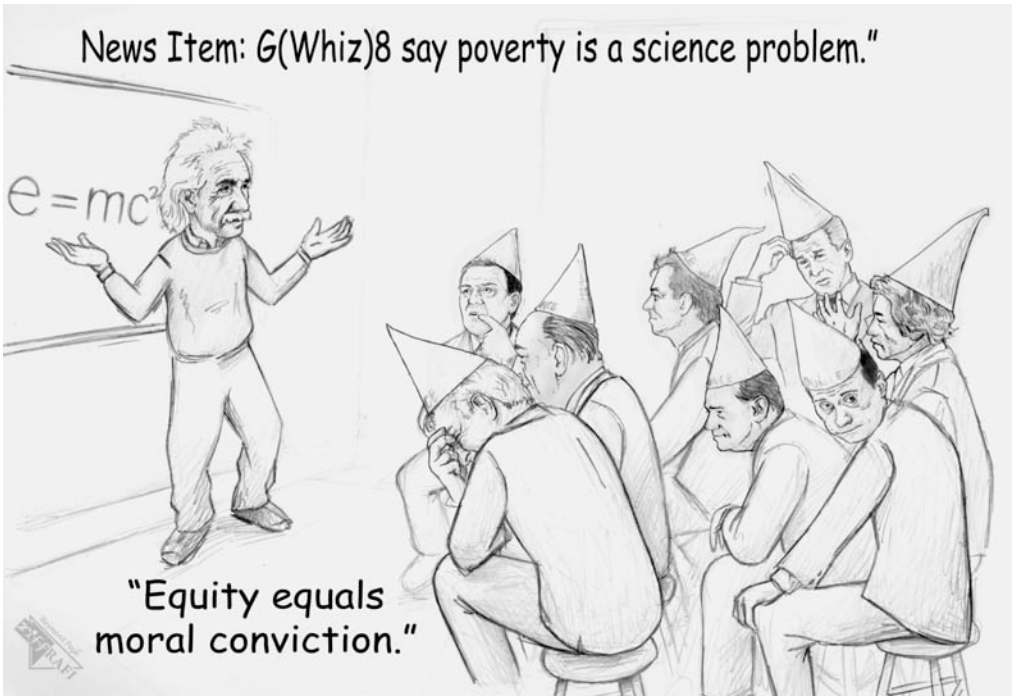
Techno-Realists see nanotechnologies as essentially neutral tools that can be harnessed equally for good or ill. They understand that, if left unchecked, nanotech could bring about harmful societal disruptions, but they believe the nano-revolution is unstoppable. For them it is more realistic to reduce the worst societal impacts while promoting socially and environmentally beneficial applications. One approach is to vigorously advocate in favour of environmental or "pro-poor" nano-applications such as solar power, water clean-up or cheap vaccines. A complementary approach is to advocate for "upstream engagement" – that is, explicit consideration of societal needs at an early stage in the innovation process by involving "the public" in dialogues and citizen juries. The possibility of rejecting the technology outright is not on the table for discussion. The techno-realist supports robust regulation on environmental and health risks, as well as the need to link government research priorities to societal needs. This approach hopes to bring industry into dialogue with society in order to build consensus and reach socially desirable outcomes. The Techno-Realist approach relies on the work of social scientists to elicit, measure and interpret public views and facilitate dialogue.

Upstream engagement faces several major obstacles: First, the more "upstream" the less "engaged" the public is, which means there's a heavy reliance on "technical experts" to convey information. Scientists involved in the development of a technology are usually not the best assessors of its problems or social implications. Nor is it clear which publics should be consulted – the knowledge of marginalised groups such as the disabled or indigenous are likely to be left out in favour of Northern consumer publics. Enthusiasm from industry and government in engaging in upstream dialogue on new technologies may be driven more by a desire to manage public acceptance than a willingness to listen and change trajectory. Focusing on applications and simply deciding between good and bad uses of nanotech hides some of the systemic problems of the technology platform as a whole (e.g., ownership and control of the technology). It may perpetuate a techno-fix approach to problems that have social causes displacing more appropriate but challenging non-technological solutions. (Perhaps there's a lesson to be learned from the salmon: struggle upstream, get screwed and die).

**3. The Techno-Sceptic's Motto: "Justice before Technology"**

This approach attempts to reframe nanotechnology development in the wider context of past technology introductions (biotech, nuclear, chemicals, etc.). Techno-sceptics are instinctively wary of grand promises for high technologies made by scientific and industrial elites. They reject claims for the neutrality of technologies as well as reject the infallibility of "science-based" decision making – seeing it as a limited and exclusionary form of knowledge. Those of this persuasion, including ETC Group, assert that technologies are inextricably bound with power and with the intentions and ideologies of those who develop and control them. Like techno-realists, techno-sceptics advocate strong governance for technological innovation. Techno-sceptics support a strong application of the precautionary principle insisting that the advocates of powerful technology platforms such as nanotech need to prove they do not harm the environment, human rights or the interests of communities. Some Techno-sceptics may conclude that some technologies should be rejected outright. Given the experience of previous technology revolutions, some may regard nanotechnology as yet another industrial strategy that will only serve to increase the power of the rich and privileged.

The Techno-Sceptics are often simplistically dismissed as "luddite" or "anti-technology." Observers are sometimes exasperated by the techno-sceptics' call for broader technology governance discussions as a break in "progress," charging that the critique is not specific to nanotech, but to wider social and economic systems that aren't appropriately addressed at the level of technology introduction. However, techno-sceptics see the need for broader democratic control over the trajectories of innovation through inclusive societal assessment mechanisms (such as an International Convention for the Evaluation of New Technologies -ICENT]). See page 36.




## Puzzling Pieces – Emerging Nano-policy

***Seven emerging initiatives may have an impact on nanotechnology policy:***

Over the past three years, new players, processes, and proposals have come on the scene, affecting both the trajectory of nanotech's development and societal understanding. Some of the pieces of the puzzle are summarized below:

1. **Name Games:** The high stakes (and politics) of setting nanotech standards;
2. **Lab Spats:** Finally, lab/workplace safety protocols are being discussed;
3. **Reg Roles:** The precautionary principle is blowing in the bureaucratic wind;
4. **Small Talk:** Dialoguing and diatribing over new technologies;
5. **Small Claims:** Can insurers underwrite the unseeable?
6. **Small Minds:** Ethicists and PR gurus are converging at the lowest common nanometer;
7. **Back Talk:** Civil society and social movements are finally learning to think small.

### 1. Name Games: The high stakes (and politics) of setting nanotech standards.

"When *I* use a word," Humpty Dumpty said, in rather a scornful tone, "it means just what I choose it to mean – neither more nor less."
"The question is," said Alice, "whether you *can* make words mean so many different things."
"The question is," said Humpty Dumpty, "which is to be master – that's all." – Lewis Carroll, *Through the Looking Glass, and What Alice Found There,* 1871

Nano-policy is so young that even the definition of *nanotech* is up for grabs. Everyone can agree that a nanometre (or nanogram or nanolitre) is one-billionth the size of the standard unit, but still under discussion is whose measuring stick to use and how to describe what's measured. Currently, nomenclature is more imaginative than regularised – with nanostructures being named by a kind of visual onomatopoeia – so far, nanostructures have been christened according to their resemblance to familiar structures – tubes, geodesic domes, egg yolks or whiskers. There are at least six different methods in use for determining particle size at the nano-scale and each method can result in a different measurement. And at the nano-scale, the measuring tool itself can interfere with the nano-scale material, having an effect on the measurement.[19]

Most players agree that uniform standards are necessary to sustain a global nanotech industry and are not simply a geeky technical preoccupation.[20] A common description and measurement for nano-things will have a major impact on trade in commodities (e.g., carbon nanotubes), international norms for nano-patent regimes, technology transfer, liability and labeling as well as international agreements and national regulations relating to control or safety-testing of nanomaterials. On a more mundane level, a standard for measuring and naming means that researchers in different labs can usefully compare their results.

With nanotech applications reaching across disparate industrial sectors, the establishment of international standards is complicated and could take four years or more to finalise. The process will be aggressively molded by industry and national interests. As attorneys from one US law firm recently explained:

"…The standards being developed …will have a tremendous impact on the future direction of nanotechnology development both in the US and internationally, especially in the area of environmental regulation. For this reason, entities interested in the development of nanomaterials should actively monitor and participate in the standards-development process for nanomaterials that is currently underway."[21]

In September 2004 a newly formed Nanotechnology Standards Panel of the American National Standards Institute (ANSI) met at National Institute for Standards and Technology to identify the most urgent areas of standardisation – including metrology, terminology and testing methods for toxicity – within a 1-year time frame.[22] ANSI is not a standards-writing organisation, however, so it is likely that the American nomenclature will be written by standards development organisation ASTM (originally the American Society for Testing and Materials), whose nanotechnology committee is now discussing and drafting proposals.[23]

Across the pond in Europe, too, establishing nano-standards is a high priority:

- The European Committee for Standardization (CEN) has established a task force to address nano-standards (CEN/BTWG 166) with its secretariat in the British Standards Institution.[24]

- The European Nanobusiness Association and Austrian Research Promotion Agency met in October 2004 to prioritise standard-setting for carbon nanotubes,[25] a matter also

prioritised by the international IEEE (Institute of Electrical and Electronics Engineers) Nanotechnology Standards Initiative.[26]

- European organizations EUROMET (European collaboration on measurement standards), Eurachem (a focus for analytical chemistry in Europe), EUROLAB (European Federation of National Association of Measurement, Testing, and Analytical laboratories), and Euspen (European Society for Precision Engineering and Nanotechnology) have also been addressing various aspects of nano-measurement and testing.[27]

**Whose Standards will rule?** Standardisation was a key regulatory issue discussed at the first international dialogue held between 25 national governments and the European Union in Alexandria, Virginia (USA) in June 2004.[28] Individual nations are fully aware that international standards can affect their own positions and are now jockeying to establish their standards first.

- The Japanese Industrial Standards Committee (JISC) has established a "Committee for Nanotechnology Standardization Research and Study,"[29] which is developing a roadmap for international standard setting on nanotechnology.
- On 1 April 2005 China's first national standards for nanomaterials (which includes a glossary) went into effect.[30] The Chinese Academy of Sciences is reportedly beefing up its standard-setting activity in an attempt to develop a package of standards to present internationally which might "reshape world nanotech competition" in China's favour.[31] Zhang Xian'en, director of the Science Ministry's basic research department, said, "It's wise for us to preemptively set our standards in nanotechnology, since it might produce big money in the coming two decades."[32]

**International Standards:** Ultimately, global standards will be settled and harmonised by bodies such as the International Organization for Standardization (ISO). In January 2005 the British Standards Institution (BSI) put forward a proposal for a new field of ISO activity on nanotechnology to cover "classification, terminology and nomenclature, basic metrology, characterization, including calibration and certification, risk and environmental issues."[33] BSI has since been awarded the task of coordinating that ISO effort.[34] Once an ISO standard is established it frequently takes on a quasi-regulatory status in judging subsequent international quality and safety regulations.

## 2. Lab Spats: Finally, lab/workplace safety protocols are being discussed.

ETC's call, three years ago, for a moratorium on nanotech lab research stirred anger and controversy – and, now, some regulatory action? Originally, we were surprised to learn that the safety procedures varied from "space suits" in some government institutions to "bare knuckles" in some private sector facilities. The absence of shared and monitored "best practices" between labs and the absence of government oversight - seemed to make the moratorium call modest.

Lab protocols are needed to protect nanotech workers and scientists from exposure to occupational health hazards. Even governments that acknowledge the likelihood that some

nanomaterials will turn out to be toxic are allowing continued human exposure for the greater good of scientific discovery and industrial innovation until the toxicology landscape can be clarified. While no health and safety agencies are making a move toward a moratorium, they are beginning to acknowledge that the absence of protocols is glaring enough to begin developing belated guidelines on handling of nanomaterials. However, the agencies are moving slowly, often tiptoeing around other more powerful agencies that are pushing accelerated development.

**UK's Health and Safety Executive (HSE):** When ETC first contacted UK HSE in early 2003 about lab protocols for handling manufactured nanomaterials the agency seemed oblivious to the issue.[35] Shortly afterwards HSE was asked to prepare a series of studies on nanotech risks. In a March 2004 paper HSE acknowledged[36] the routes for nanoparticles to cause harm in the workplace (through inhalation, ingestion or dermal exposure, unexpected chemical reactions, fire and explosion). However, HSE displayed a particular sensitivity to politics, despite its statutory duty to protect the public from potential harm: HSE acknowledged that an "over precautionary approach…would [ ] earn the opprobrium of the government, which is strongly committed to the development of nanotechnology."[37] By June 2004, HSE opted for a more precautionary stance, concluding: "as the risks arising from exposure to many types of nanoparticles are not yet completely understood, control strategies should be based on a principle of reducing exposure as much as possible."[38]

A report prepared by the UK government's Royal Society and Royal Academy of Engineering on nanotechnology, also released in July 2004, underscores a precautionary stance on manufactured nanoparticles.[39] The Royal Society asked the HSE to work towards setting lower official occupational exposure levels for nanoparticles, and to minimize and treat as hazardous any waste streams from laboratories or factories handling nanoparticles.[40] An October 2004 report by HSE found that about 500 workers in the UK might be exposed to nanoparticles during production with a further 10,000 potentially exposed through handling and that these numbers were likely to increase.[41] It also concluded that existing control methods for preventing ingestion or skin exposure may be ineffective and that current knowledge and methods for assessing the risk of nanoparticles in the workplace are inadequate. This critical report was published one day before an international nanomaterials symposium organized jointly by HSE and the US National Institute for Occupational Safety and Health (NIOSH), but the findings weren't discussed during the meeting. HSE spokesperson, John Ewins, delivered a speech reassuring industry that the HSE would be as accommodating as possible so as not to overburden the nanotech sector with extra measures. To emphasize his allegiance to industry (but confusing his British history in the process), Ewins declared, "We can't allow the Tolpuddle Martyrs to stop the machine revolution. We can't allow pressure groups to stop useful technologies."[42]

**US National Institute for Occupational Safety and Health (NIOSH):** HSE's transatlantic counterpart is NIOSH, headed by John Howard, who told a June 2004 conference:

"Very little is known currently about how dangerous nanomaterials are, or how we should protect workers in nanotech-related industries. But, research over the past few years has shown that nanometer-diameter particles are more toxic than larger particles on a mass basis. This fact, plus the combination of particle size, unique structures, and unique physical and chemical

properties, suggests that a great deal of care needs to be taken to ensure adequate worker protection when manufacturing and using nanomaterials."[43]

Howard added that nano-materials and devices in development "are so far from our current understanding that we can not easily apply existing paradigms to protecting workers."[44]

NIOSH is undertaking a range of studies into health and safety aspects of nanomaterials in the laboratory and workplace and has promised to issue guidelines for worker and laboratory handling of nanomaterials in mid-2005. Meanwhile the 13 research labs of the National Nanotechnology Infrastructure Network (those nanotech labs sponsored by the US National Science Foundation), met at Georgia Tech University in December 2004 to discuss best practice in laboratory safety.[45]

**European Union – Nanosafe Project:** The need for laboratory and safe-handling protocols for nanoparticles was considered by the EU Nanosafe project. Its mid-2004 report outlines strategies for minimizing contact with nanoparticles – including atmospheric extraction and filters and wearing personal protective equipment such as respirators and special clothing.[46] However, the report recognizes that it's still not possible to easily assess workplace exposure to nanoparticles or the risks of nanomaterials, which they maintain is necessary before regulations can be established.[47]

## 3. Reg Roles: The precautionary principle is blowing in the bureaucratic wind.

**Overview:** It's now clear that there will be nano-regulations at some point. That's the "good news." The bad news is that it doesn't look like regulations will be mandatory; they won't extend in scope beyond toxicology questions; and they won't be coming anytime soon. Indeed they may simply be re-interpreted versions of existing chemicals legislation. US and European governments are now busy developing nanotechnology policy co-ordination strategies. The formulation of cross-government acronym bodies such as the US NNCO (National Nanotechnology Coordination Office), the UK NIDG (Nano Issues Dialogue Group) and the newly announced European 'focal point' on Nanotechnology are a belated recognition that the exciting high science funded by one sector of government has started to bite on the policies of other departments.

**USA – New acronyms, new funding, no action:** In December 2003 President George W. Bush signed the "21st Century Nanotechnology Research and Development Act" (NRDA) putting his presidential stamp on nanotech as clearly as Bill Clinton had done three years earlier in founding the National Nanotechnology Initiative (NNI). This new law establishes a re-arranged set of institutions and new funding for nanotechnology research.

The NNI[48] has been the locus of the US government's nanotech activity, led by Dr. Mihail Roco of the National Science Foundation and reporting to the Nanoscale Science, Engineering and Technology (NSET) Subcommittee of the National Science and Technology Council (NSTC) – a cabinet level body. NSET has four working groups including one on health and environment issues and another on public engagement.

The NNI continues to dish out federal research funds across 11 federal agencies. In 2006 NNI's funding for nanotechnology research will exceed $1 billion.[49] In 2004 NNI updated its strategic plan with the aim of creating "a future in which the ability to understand and control matter on the nanoscale leads to a revolution in technology and industry."[50] For the NNI, societal governance questions are literally last on the list although the new strategic plan identifies a goal of supporting "responsible development of nanotechnology" and designates "societal dimensions" as a major subject area for investment with 8% of funding earmarked for this area.[51] In practice this amounts to funding ethical studies and supporting techno-fix approaches such as environmental remediation technologies.

Under the 21st Century NRDA, the National Nanotechnology Coordination Office (NNCO) has emerged as the heart of the NNI under the directorship of Clayton Teague. NNCO is now responsible for ensuring that 21 federal departments and agencies are joining up their nano-policy efforts. NNCO retains oversight of NNI and is charged with public outreach on nanotechnology, which consists of "regular and ongoing public discussions, through mechanisms such as citizens' panels, consensus conferences and educational events."[52]

Also taking an active role in nano-policy is the Science Advisor to the President, John Marburger, who is also director of the Office of Science and Technology Policy. He chairs the President's Council of Advisors on Science and Technology (PCAST), whose Nanotechnology Technical Advisory Group is composed of 45 leading nano-scientists and nano-industrialists. PCAST is charged with reviewing the National Nanotechnology Initiative. Its first review was published in May 2005.[53]

In the 21st Century NRDA only two sections hint at the possibility of future regulatory needs, though neither promises regulatory action: first, the National Research Council is charged with conducting a one-time study to "assess the need for standards, guidelines, or strategies for ensuring the responsible development of nanotechnology," focusing on self-replication, defense applications and the use of nanotech in enhancing human and artificial intelligence. Second, a "Nanotechnology Preparedness Center" is to be established to "identify anticipated issues related to the responsible research, development, and application of nanotechnology, as well as provide recommendations for preventing or addressing such issues."[54]

**Nanotech and the Environmental Protection Agency (EPA):** From the get-go the US government has sought to avoid new regulation despite the fact that many agencies tacitly admit that commercial nanomaterials are currently escaping safety oversight – the magnitude of which is difficult to track in the absence of standards for naming and identifying nano-scale materials.

In August 2003, the NNCO and the Office of Science and Technology Policy convened an interagency focus group to examine whether existing regulatory mechanisms covered nanomaterials and to share

> *"It seems unlikely… that the current system for identifying, registering, and controlling hazardous chemicals will need to be changed very much to accommodate this new category of substances." – John Marburger, White House Science Advisor, December 2003*[55]

information between agencies.[56] By December 2003 White House Science Advisor John Marburger was downplaying the need for new regulations:

**The Limitations of EPA's Toxic Substances Control Act for Nano-scale Materials:**
EPA's Toxic Substances Control Act (TSCA) has emerged as the most likely option for adapting existing legislation to regulate nano-engineered chemicals and compounds. Under TSCA, new chemical substances are subject to notification requirements and review for potential human health and environmental risks before they are manufactured and commercialized. EPA has made clear that new, nanoscale chemical substances that are not on TSCA's inventory would be subject to TSCA review.[57] But what about nanoscale materials composed of existing chemical compounds that are already approved under TSCA? The molecular identity of the nano-scale chemical may be identical to its larger-scale counterpart, but the small particle size creates property changes through quantum effects or surface chemistry – and unknown risks for human health, safety and the environment.

TSCA came into being nearly 30 years ago, and several features make it inadequate for regulating engineered nanomaterials:

- TSCA offers an exemption from Premanufacture Notice for low volume chemicals. TSCA's low-volume exemption for smaller quantities of a new chemical doesn't make sense for nanomaterials because it is their extremely small size that defines them – the large surface area of nanoscale particles makes them more chemically reactive. EPA reportedly received one application for a Low Volume Exemption (for carbon nanotubes) last year, which was requested on the basis that less than 10,000 kilograms are produced per year.[58] As of June 2005, no decision had been made on the exemption.

- Nanomaterials have diverse applications across many industry sectors, and not all nanomaterials are regulated as chemicals. For example, many common uses of nanoparticles will fall outside TSCA because they are regulated as cosmetics, food, drugs, medical devices or pesticides (see FDA section below).

With no regulatory willpower on the horizon the EPA is currently exploring a voluntary approach to nanosafety regulation. In a note issued in May 2005 the EPA explained that it was "considering a potential voluntary pilot program for nanoscale materials that are existing chemical substances."[59] The proposed voluntary initiative was slammed as "inadequate and inappropriate" by the Natural Resources Defense Council in comments submitted with 17 other environmental, health and civil society groups including Sierra Club, Greenpeace, Friends of the Earth, Pesticide Action Network and ETC Group.[60]

In detailed comments to the EPA, civil society groups pointed out that EPA is not currently using its legal authority under TSCA to regulate nanomaterials, and that additional regulations are needed beyond TSCA to insure that public health and the environment are protected.[61] The NRDC recommends that <u>all</u> engineered nanomaterials be considered "new chemical substances" under TSCA (including those composed of existing chemical substances), thus requiring EPA to review activities associated with the manufacture, processing, use, distribution in commerce and

disposal of any new chemical substance prior to commercialisation, and requiring pre-manufacture notice prior to commercial manufacture or import. The groups also recommend that nanomaterials should be given no exemptions under TSCA.

> *"We recommend that all nanomaterials be considered hazardous until demonstrated otherwise, and we recommend that those lacking demonstrated safety be prevented from entering commerce unless they can be used in a safe manner so as to prevent human exposures or releases to the environment."* – Natural Resources Defense Council (USA) and 17 other civil society organizations, comments to EPA, June 9, 2005.

Discussions will continue on whether TSCA is an appropriate tool for nanotoxicity regulation, and whether voluntary regulation is sufficient for nanomaterials composed of existing chemical substances. No changes in current practice are expected soon. Many in the US nano-policy establishment are anxious to reassure industry that regulation or constraints on nanotechnology shouldn't begin until more data are generated about mechanisms of nano-toxicology. Arun Majumdar, a professor of mechanical engineering at the University of California at Berkeley and a member of the Nanotechnology Technical Advisory Group of PCAST summed up this wait-and-see approach as "Do research before we do anything."[62] A more accurate summation might be "Do nothing for as long as possible." Clayton Teague of the NNCO has estimated that it would take a minimum of five years to begin to sort out the toxicology of nanomaterials.[63]

For the foreseeable future, un-assessed nanomaterials will continue to enter the US marketplace and environment with, at best, an unenforceable voluntary scheme to regulate them.

**Other areas of US nano-regulatory activity:**

**US Food and Drug Administration (FDA) – cosmetics, foods, drugs, devices and veterinary products**: Many current and close-to-market uses of nanomaterials are outside the purview of TSCA (food, food additives, drugs, cosmetics and some medical devices) and fall under product-specific regulations of the FDA which is responsible for around 20% of consumer products on the US domestic market. The FDA faces an enormous challenge trying to regulate nanotechnology. Nanoparticles for cosmetics and sunscreens should go through general cosmetics regulation but may escape scrutiny because some nanomaterials have already been approved for cosmetics use in a larger form (e.g., metal oxide powders for sunscreen filters). A nanoparticle-based drug-delivery system used in combination with a drug already on the market may not trigger a requirement for the product to undergo clinical trials since the drug has already been approved. And no standard tests exist for drugs formulated as nanoparticles. On its website, the FDA (dis)claims that "the FDA has traditionally regulated many products with particulate materials in this size range. FDA believes that the existing battery of pharmacotoxicity tests is *probably* adequate for *most* nanotechnology products that we will regulate. Particle size is not the issue" (emphasis added).[64]

The FDA has issued a series of caveats to this business-as-usual approach:

- Firstly, FDA offers that "as new toxicological risks that derive from the new materials

and/or new conformations of existing materials are identified, new tests will be required."

- Secondly, FDA explains that it only regulates products not technologies and admits it may not even be aware that it is regulating a nanotech product unless specific claims are made to that effect by the producer. Hence it might overlook nano-aspects.
- Thirdly, and most surprisingly, FDA appears to wash its hands of effectively regulating nano-cosmetics, which it regards as high risk, explaining that it doesn't have the resources or means to assess the risk to the public. The full text of this caveat amounts to an explicit and astonishing disclaimer:

> *"FDA has only limited authority over some potentially high-risk products, e.g. cosmetics. As we noted earlier in this discussion, many products are regulated only if they cause adverse health-related events in use. To date there have been comparatively few resources available to assess the risks of these products. Other government agencies have different missions with regards to nanotechnology, e.g. to solve environmental problems, improve technology to address disease, etc. Few resources currently exist to assess the risks that would derive to the general population from the wide-scale deployment of nanotechnology products."*[65]

**Export controls:** While the nanotech establishment wends its way as slowly as possible towards regulation of nanotech founded on safety issues, it may well be the security establishment that presses the "start button" on US nano-regulation. In late 2004 the President's Export Council Subcommittee on Export Administration (PECSEA) formed a group to explore whether nanotechnology products require export regulation in the interests of national security.[66]

PECSEA falls under the US Commerce Department's Bureau of Industry and Security. The concern is that nanotechnology products could have dual uses that could be used for military purposes by foreign governments or "non-state actors." The group also intends to consider the competitiveness of foreign nanotechnology industries. PECSEA has good reason to be worried – almost half of the US government's investment in nanotech research has been military-focused and many applications first developed for military use are now crossing into the civilian market – including sensors, chemical delivery mechanisms and nanoparticle ballistics.

Export control measures for nanotech could range from restrictions on international trade to rules on staffing foreign nationals. The study will also look more broadly at how other countries are assisting their nanotech industries, market access, environmental concerns and energy.

PECSEA is expected to make advisory recommendations that will be open to citizen comment but are unlikely to come to any conclusions before 2006. Nonetheless key nanotech leaders are already firing warning shots across PECSEA's bow, warning that even the talk of export controls or regulations could have a chilling effect on US nanotech industry or could freeze US firms out of foreign markets. US Senator Ron Wyden of Oregon urged the Commerce Department not to enact export controls on nanotech: "I don't think anything would chill investment in American nanotechnology faster than putting in place export control," Wyden said. It's a "prescription for our country to lose jobs."[67] Nanotech's favourite Wall Street wunderkind, Josh Wolfe of Lux

Capital has called export controls "short-sighted and regrettable" and waxed metaphorically: "You wouldn't stunt your own child's growth by starving them and locking them in a room."[68]

**European Nano-Policy:** European nanotech policy direction, so far as it exists, is located in the European Commission's Directorate-General (DG) for Research and in particular in its "Nanosciences and Nanotechnologies Unit," headed by Renzo Tomellini, whose current task is to build Europe's nanotech capacity in line with the Community's aspiration to be the world's leading knowledge economy (an objective defined in the Lisbon Agenda of 2000). In 2004 the European Commission adopted a Communication entitled "Towards a European Strategy for Nanotechnology"[69] that set the tone for European nano-policy. The Communication was formally endorsed by the Council of Ministers for Competitiveness (representing member states) in September 2004 and was recently supplemented by another Communication, "Nanosciences and nanotechnologies: An action plan for Europe 2005-2009" published in June 2005. The new Action Plan promises the creation of a European "focal point" on nanotech policy.[70]

Both documents set the stage for the nanoscience component of the next European Framework Programme (2007-2013) on Research and Technological Development (Framework Programme 7 or FP7).[71] This programme allocates most of the money for European science and technology with nanotech receiving over 7% of specified research funding. Over six years FP7 is expected to allocate 4.8 billion Euros to a priority research area in Nanosciences and Nanotechnologies with further money for nano-electronics and more still for nano-scale research under the separate themes of Health, Energy, Food, Agriculture and Biotech. Combined with individual member state research funding (e.g., by governments of Germany, UK, France) European funds invested in nanotech reach $1.05 billion – closely rivaling the USA's investment and exceeding Japan's.[72]

**Estimated Government R&D Investment in Nanotechnology, 1997-2005 ($ millions)**

| Region | 1997 | 1998 | 1999 | 2000 | 2001 | 2002 | 2003 | 2004 | 2005 |
|---|---|---|---|---|---|---|---|---|---|
| EU | 126 | 151 | 179 | 200 | ~225 | ~400 | ~650 | ~950 | ~1,050 |
| Japan | 120 | 135 | 157 | 245 | ~465 | ~720 | ~800 | ~900 | ~950 |
| USA | 116 | 190 | 255 | 270 | 465 | 697 | 862 | 989 | 1,081 |
| Others | 70 | 83 | 96 | 110 | ~380 | ~550 | ~800 | ~900 | ~1,000 |
| **Total** (%of 1997) | **432** (100%) | **559** (129%) | **687** (159%) | **825** (191%) | **~1,535** (355%) | **~2,350** (547%) | **~3,100** (720%) | **~3,700** (866%) | **~4,100** (945%) |

Source: M. Roco, US National Science Foundation[73]

**Nanomaterials health and safety regulation in Europe:** European policymakers are belatedly recognizing that the unusual behaviour of nanomaterials, particularly nanoparticles, pose risks that cannot be addressed by current regulations. The broad agreement of four authoritative studies into the matter (by the UK Royal Society and Royal Academy of Engineers[74], the German Institute of Engineers,[75] the Royal Netherlands Academy of Arts and Sciences [76] and by the European Commission[77]) means that the question is now one of 'how' rather than 'if' to regulate nanomaterials.

DG SANCO made its first move toward nanomaterial regulation in February 2005, sending a formal request in February 2005 to the EU's senior toxicology committee, the newly formed

Scientific Committee on Emerging and Newly Identified Health Risks (SCENIHR). The request notes that "Experts are of the unanimous opinion that the adverse effects of nanoparticles cannot be predicted (or derived) from the known toxicity of material of macroscopic size, which obey the laws of classical physics."[78] Therefore, it acknowledges that nanoparticles may have to be considered as new substances and risk assessment methodologies re-examined.[79] A response is expected later this year.

In the meantime regulators are grappling with product-specific nanosafety questions – particularly in cosmetics. For example, in May 2003 ETC Group reported that the EU's Scientific Committee on Cosmetics and Non-food Products (SCCNFP) had already approved nanoparticles of titanium dioxide for sunscreens regardless of size, shape or coating based on a private meeting with the industry representatives.[80] (The industry studies backing up the safety of titanium dioxide for sunscreens were not made available to the public.) More recently the Scientific Committee on Consumer Products has been asked to review and, if appropriate, to amend its safety guidelines for the testing of cosmetic ingredients in the form of nanomaterials.[81]

Compared to their transatlantic counterpart (The 21st Century Nanotechnology Research and Development Act), the European Communication on Nanotechnology Strategy and the Action Plan seem more open to addressing societal, environmental, health, safety and international considerations. The Communication acknowledges that future regulations for health, safety and environmental risks are likely, and explicitly calls on member states "to review existing regulation to take into account any specificities of nanotechnology and adopt a common European approach."[82] It also states that the precautionary principle "could be applied in the event that realistic and serious risks are identified."[83] (The definitions of "realistic and serious" will thus be of paramount importance.) In fact, it is possible that European regulations will ultimately adopt a stronger interpretation of the Precautionary Principle. A recent study of the European approach to nanotechnology found that studies in Switzerland, UK and Germany all independently argue for "adoption of the precautionary principle as a guiding ideology when data on the health and environmental impacts of nanotechnology is lacking."[84]

The EC's Communication on nano-strategy, however, explicitly rejects ETC Group's call for a moratorium arguing that this would be "severely counter-productive" to the public good:

"Apart from denying society the possible benefits, it may lead to the constitution of 'technological paradises,' i.e., zones where research is carried out without regulatory frameworks and is open to possible misuse. Our consequent inability to follow developments and intervene under such circumstances could lead to even worse consequences."[85]

EU officials have privately expressed this view in a different way: that only by leading nanotechnology research and development can European policymakers exercise strong control over which technologies are and are not developed.

While the Communication does not make any concrete suggestions for regulations, it aims to elaborate a set of principles under which nanotechnology can be carried out in "a *responsible* and transparent manner" (emphasis added).[86] For example, basic research on nanoparticles would be

expected to include toxicology assessments and lifecycle questions; a researcher seeking European funding to develop nano-sensors would stand a better chance if s/he were collaborating with an ethicist or social scientist examining privacy questions. The assumption is that problems can be 'designed out' one application at a time.

In contrast to the US rhetoric of 'nanotechnology preparedness' aimed at one-way education of the public, the European Union appears more open to public views in molding research priorities and regulation. A 2004 "Preliminary Risk Analysis"[87] based on a workshop by the Emerging Risks Unit of DG SANCO suggests the establishment of a European "observatory of nanotechnologies" to monitor the scientific, technological, economic and social development of nanotechnologies.[88] The EC strategy plan explains:

> *"While the potential applications of nanotechnology can improve our quality of life, there may be some risk associated with it, as with any new technology – this should be openly acknowledged and investigated. At the same time the public's perception of nanotechnology and its risks should be properly assessed and addressed. It is in the common interest to adopt a proactive stance and fully integrate societal-considerations into the R&D process, exploring its benefits, risks and deeper implications for society."*[89]

**REACHing Out to Nano?** The EU is in a period of transition with regards to chemical safety regulation and that larger uncertainty may delay nano-regulation. The newly proposed REACH regulation (Registration, Evaluation and Authorisation of Chemicals) is still being finalised under fierce attack from the chemical industry and US government threatening action through the World Trade Organization. It will replace the current Notification of New Substances (NONS) act. Unlike TSCA, which essentially allows new chemicals until they are shown to be unsafe, REACH reverses the burden of proof requiring chemical producers to explicitly prove the safety of a new chemical. In the absence of convincing safety data new chemicals should theoretically be denied a market under REACH – enacting the principle of "no data, no market."

Unfortunately REACH was negotiated before nanomaterials hit the radar and, like TSCA, many nanoparticles will be waved on through without assessment if their larger forms have already been declared safe. Naturally occurring substances and chemical elements (e.g. gold nanoparticles) would also escape consideration by REACH. Nor is it clear that REACH can be tweaked so that nanomaterials can be each treated as "new chemicals." In a note prepared for the Royal Society and Royal Academy of Engineering, Greenpeace Chief Scientist Dr. Doug Parr outlined why REACH is an inappropriate management tool for nanomaterial risks.[90] In summary:

- The hazards of nanomaterials are not fully understood and likely differ from the larger materials that REACH was designed to assess. Given this lack of knowledge and lack of agreement on toxicity testing, any new nanomaterial should fail the "no data, no market" rule.
- Nanoparticles can change their properties when they agglomerate (stick together) and REACH doesn't address this.

- Nanoparticles of the same substance can have very different properties at different sizes and shapes – REACH has no mechanism for distinguishing between the ranges of sizes and shapes that could all have different properties.
- REACH has thresholds for allowing small quantities [analogous to the low volume exemption under TSCA]. We know from air pollution studies that such thresholds are inappropriate for nanoparticles, which can be more active in small numbers.

**United Kingdom – So Near and Yet So Far:** As with previous debates on genetically modified foods and vaccinations (and partly because of them) the issue of nanotechnology has registered higher on government and public radar in the UK than in any other country so far. The UK's Royal Society and Royal Academy of Engineering produced a comprehensive report on nanotech in 2004, which was commissioned by Science Minister Lord Sainsbury in response to concerns raised by heir to the throne, Prince Charles. The process of creating the RS/RAE report was unusual because it involved stakeholders and was overseen by a fairly diverse panel of experts including a prominent environmentalist, a consumer advocate and a social scientist known for his work on risk. Its publication in July 2004 surprised everyone by taking a strong precautionary tone on health and safety risks. The RS/RAE report calls for new assessment processes and consumer labeling to deal with nanomaterials and an interim prohibition (i.e., a *de facto* moratorium) on environmental uses of nanoparticles such as water clean-up. The report was limited in its consideration of societal aspects such as privacy, monopoly, disability and impacts on the global South, but did flag them as areas for further investigation and recommended that public engagement processes help mould future nano-policy.[91]

In February 2005 the UK government formally responded, laying out its nano-policy plans for the short term. True to type, the UK bureaucrats chose to duck the harder challenges posed in the RS/RAE report and produced an uninspired set of business-as-usual plans around the promise of more studies and deferred regulation.[92]

At the heart of the UK's new nano-policy framework is an invisible cross-government group called the Nanotechnology Issues Dialogue Group (NIDG) that is charged with coordinating government policy. Based in the Office of Science and Technology (OST) in the UK Department of Trade and Industry, the NIDG holds regular, off-the-record meetings that are not accessible to the public. Its list of members is not publicly available but includes civil servants and representatives from the Department for Environment, Food and Rural Affairs, Department of Health, Home Office, Foreign and Commonwealth Office, Department for International Development, Environment Agency, Food Standards Agency and, of course, Trade and Industry. The Department for Environment, Food and Rural Affairs (DEFRA) is also participating. Its risk unit, which formerly dealt with GM crops and food and toxic chemicals, has now expanded to include a team focused on nanotechnology.

Specifically the UK government has committed to the following actions:

1) Another review will be undertaken to determine which regulations need to be changed or created and which agencies, departments and advisory bodies need to be thinking about nano-risks (due by end of 2005).
2) The government will work with industry and others to minimise the environmental release

of engineered nanoparticles (e.g., in waste streams) and to prevent the release of nanoparticles for environmental remediation (except for small experimental releases).
3) Work with 'the public and other interested parties' to consider whether labeling of consumer products containing nanomaterials is feasible or necessary (no timetable or clear process is offered).
4) Initiate via DEFRA a study on the implications of nanotechnologies on environmental regulations (2005).
5) Ask the new OST-based Centre of Excellence in Science and Technology Horizon Scanning to identify health, safety, environmental, social, ethical and regulatory issues associated with emerging technologies (no timetable is provided but work on establishing the Centre began in November 2004).
6) Ask European assessment committees (e.g., on cosmetics) to insist on public disclosure of methodologies for safety studies (no timetable provided).
7) DEFRA will conduct a detailed and ongoing review of the extent to which nanoparticles and nanotubes are being manufactured and used in the UK (due the end of 2005).
8) The UK Council for Science and Technology will review the government's approach to nanotechnology in 2 years and in 5 years.

The good news is that the UK will initiate some sort of regulatory action around nanomaterial risks (including possible consumer product labeling):

The bad news is that nothing will happen soon. UK officials have privately admitted that regulation is at least 3 or 4 years away and that in the meantime the UK government is unlikely to take any action against existing nanomaterials in commercial products, to prevent companies from releasing new nanoparticle-based products to the UK market or to remove unregulated products thereafter. The nanotech industry still has several years to rush its products to market before being subject to testing and regulation.

> *"The* [UK] *Government accepts that chemicals in the form of nanoparticles or nanotubes can exhibit different qualities to the bulk form…and that therefore individual regulations within the existing framework will need to be reviewed to reflect the possibility that nanoparticulate material may have greater toxicity than material in the larger size range...The government agrees that ingredients in the form of manufactured free nanoparticles should undergo a full safety assessment by the relevant scientific advisory body before they are used in consumer products."*[93]

The UK government's response is also silent on societal issues other than risk to health and safety. Monopoly, human rights and civil liberties, implications for the global South and international security concerns are not addressed by regulatory proposals although officials claim these will be dealt with by a parallel set of 'public engagement' processes due to be announced soon and filtered through a new body called the Nanotechnology Engagement Group (see dialogues section below).

In response to this process, some UK advisory committees have already begun to consider the relevance of nanotech to their work and their own suitability to assess nanotech applications. The

UK Advisory Committee on Novel Foods and Processes, which has the controversial role of advising the UK government on the safety of GM foods, is now beginning to turn its attention to nano-foods in response to a direct request by the UK government to include nanotechnology in its terms of reference.[94] The Committee on toxicity of Chemicals in Food, Consumer Products and the Environment is also beginning to consider nanomaterials and in particular mutagenicity (the ability to cause mutations in cells) of zinc oxide and titanium dioxide nanoparticles, as well as fullerenes.[95]

**Canada:**
Three years ago, ETC Group phoned around to various government departments in Canada to see who was doing what about nanotechnology. Those contacted pleaded ignorance and many admitted that they had never heard of nanotechnology. In 2004, however, a new prime minister established the Office of Scientific Advisor and a serious effort at science policy coordination got underway. Prime Minister Paul Martin has always been a techno-enthusiast and this combines with his long-term commitment to international development. Martin made it clear from the outset that he wants Canadian S&T to take on board the South's scientific needs. His office has called for 5 percent of Canadian R&D funding to be devoted to this end. At the same time, government departments have been slow to respond to the need for new regulations to govern the health and environmental aspects of nanotech. More recently, an interdepartmental "nanotech network" has been developed that is not only looking at regulatory issues but social and ethical concerns. Within the Prime Minister's Office of the Science Adviser, staff is also looking at the impact of converging technologies at the nano-scale. Public engagement is said to be a serious governmental commitment. Maybe someday the public – and CSOs – will be consulted.

Canada's Martin is understood to have been a major proponent of nanotechnology as part of the G(whiz)8's developing science strategy. Officials in Europe credit Martin with a leadership role (along with Tony Blair) in pressing for more scientific support for Africa in particular. At the G8 meeting in Canada a few years ago, this country pledged C$30 million to build a new science campus in Nairobi. To date, about $4.5 million has been spent on an environmental impact study that, so far, his only shown the need for better studies. To be known as the Biosciences Center for East and Central Africa (BECA), the actual focus of this Big Box science project remains unclear. At one FAO meeting in November 2004, a representative of CGIAR described BECA as a biotech center but Canadian officials insist that it is actually a "biosciences" center with a potentially wider mandate. Europeans who have followed the G8 science process believe that Canada and the UK are keen supporters of a network of Centers of Excellence and open to either establishing a specific center for nanotechnology (as enthused by the Third World Academy of Science) or attaching nanotech as one unit of a wider center.

## 4. Small Talk: Dialoguing – and diatribing – over the new technologies.

Scientists and industry have so often said that they don't want nanotech to follow in the footsteps of biotech (meaning the virulent debate over genetically modified crops) that the comparisons and commentary has become odious to almost everyone. At the same time, nanotech seems to have got off on the wrong foot with several hundred unregulated products in the marketplace –

being sprayed in fields, coated on skin, and eaten outright – that industry and governments both recognize they have scientific and social problems with the new technology that must be addressed with great caution.

As a result, virtually everyone is talking about talking – about creating multi-stakeholder dialogues that would either get issues on the table – or clear them off the table – depending on your starting perspective. With everybody wanting to talk, there should be no problem putting together a global gabfest – right? Wrong!

Overwhelmingly, industry wants to talk about environmental health and safety regulations concerning nanoparticles - and nothing else. They specifically don't want to talk about nano biotechnology (synthetic biology) or anything that smacks of molecular self-assembly. Industry is willing to talk about the potential benefits of nanotechnology for marginalized parties such as the South, people with disabilities, etc. But the focus is on a controlled dialogue to examine the best ways to maximize the greatest benefits. Negative (or risk) concerns can only be raised in the context of overcoming barriers to the positive goal shining brightly ahead. When Rice University convened its International Council on Nanotechnology (ICON) in October 2004, companies swarmed around the table eager to discuss regulation. Civil society observers to the meeting (including ETC Group) were less enthusiastic and insisted that the dialogue expand to include global social issues as well as OECD regulatory concerns. In preparation for the meeting, the Center for Biological and Environmental Nanotechnology (CBEN) put together a series of research proposals that looked more like focus group market studies then scientific research projects. By mid-day the market research projects had been quietly removed from the ICON web site. By the end of the day, industry was reluctantly prepared to talk globally about social issues but CSOs rightly doubted their commitment and stayed clear.

While industry wants to talk about "tweaking" existing regulation, government regulators would rather talk about how to assure society that everything is hunky-dory, and government aid agencies want to talk about how to get nanotechnology to the South without creating a GM "food aid" fiasco. Meanwhile, some NGOs are quite happy to talk about regulation and others insist that the dialogue be both global in its geography and in the issues it addresses.

At times, the dialogue-finding process has been a kind of shell game where the so-called "stakeholders" are left standing before the facilitator/magician guessing which shell the pea is under and where to place their bets. Individual companies were sometimes committing themselves to two or three dialogues of varying scope and dimension. One dialogue, supported by the Rockefeller Foundation and IDRC (Canada's International Development Research Center) still holds promise although its title has caused consternation in the South – the "Global Dialogue on Nanotechnology and the Poor." Because of the plethora of other dialogues, however, the nano and the poor initiative got off to a slow and staggering start only in June 2004. Somehow in the preparatory process, nano and the poor went from being a groundbreaking innovative effort bringing all the global actors together around one table to discuss the full dimensions of this powerful new set of technologies and, instead, risked becoming a "cheerleader" proposing to get nanotechnology to developing countries in the fields of water and energy. Organizers actually proposed that the "balanced" positive/negative (or risk/benefit) debate take place in the context

of possible barriers to getting this wonderful technology into the hands of the poor. While ETC Group continues to support the original goal of this dialogue, civil society in general has very little interest in becoming nanotech's cheerleaders. It is not clear how this dialogue will shape up.

The following chart outlines organized meetings, projects and discussions on nano-related policy worldwide. The list is not exhaustive, but illustrates current attempts to seek common ground (or public acceptance) or clarity in the nanotech policy arena.

## Box 2: Look who's talking to…?

***Passed, pending or proceeding global/national dialogues/monologues on nano-scale technologies*** *(by year)*

| Title | Timeline | Focus | Scope | Initiator(s) | Facilitator(s) | Comments |
|---|---|---|---|---|---|---|
| Rockefeller Foundation meetings on nanotechnology | 2003- ? | General | Global | Rockefeller Foundation | Meridian Institute | To inform RF leadership |
| Woodrow Wilson International Center Dialogue Series on Nanotechnology & Federal Regulations | 2003-04 | General, regulation | USA | Woodrow Wilson, US government agencies | Meridian Institute | Series of 3 1-day events |
| Small Talk, dialogues on nanotechnologies | 2004-mid-2006 | Public views | UK | British Assoc. for the Advancement of Science, Royal Institute, ECSITE-UK (network of science centres & museums), Cheltenham Fest. of Science, Think-Lab | Collaboration among initiators | Facilitating dialogue; sharing results with policymakers, science media |
| International Council on Nanotechnology (ICON) | 2004 - ? | Regulation, Standards | OECD plus | CBEN (Rice Univ.), DuPont, et. al. | Meridian Institute | Research, case studies, regulation |
| International Dialogue on Responsible R&D | 2004 | Regulation | Global | National Science Foundation (USA) | Meridian Institute | 25 countries plus European Union |
| CSIRO (Commonwealth Scientific & Industrial Research Org., Australia) | 2004 | General, public views | Australia | CSIRO | CSIRO | 2 1-day events: workshop; citizens' panel |
| Global Dialogue on Nanotech & the Poor | 2005-? | Marginalized peoples | Global South | Rockefeller, Int'l Development Research Center (Canada) | Meridian Institute | Risk/benefit case studies |
| ICS/UNIDO North-South Dialogue on Nanotech.: Challenges & Opportunities, Italy | 2005 | South participation | Global South | ICS/UNIDO, Academy of Sciences for the Developing World (TWAS), etc. | ICS/UNIDO | 3-Day conference, strategies for technology transfer |
| Intern'l Nanotechnology in Society Network (INSN) | 2005 | Societal implications | Japan, Europe, Americas | Arizona State Univ. (USA), Univ. of Twente (Netherlands), Lancaster Univ. (UK) | Consortium for Science, Policy, and Outcomes, Arizona State Univ. | 15 member institutions. Inaugural meeting Jan. 2005; 3 meetings planned; public launch of INSN at World Forum on Science and Civilization, Mar. 2006; research workshop, |

| Title | Timeline | Focus | Scope | Initiator(s) | Facilitator(s) | Comments |
|---|---|---|---|---|---|---|
| | | | | | | fall 2006 |
| Woodrow Wilson/Pew Nanotech Project on Emerging Nanotech | 2005-07 | Health, environment | USA plus | Pew Charitable Trust/ Woodrow Wilson Intl. Center | Woodrow Wilson Intl. Center | 2-year, $3 million project. Will convene dialogues; publish reports and case studies on nanotech risk management strategies. |
| Nanologue.net | 2005-06 | Ethical, legal, social aspects of nanotechnologies | Europe | Wuppertal Inst., EMPA (the Swiss Federal Laboratories for Materials Testing and Research), Forum for the Future, triple innova | European Commission | Mapping study, moderated dialogue; Scenarios |
| Nanotech Engagement Group (NEG) | 2005-07 | Societal, ethical research, public dialogue | UK | Sciencewise Grant Scheme | Involve, Cambridge Univ. NanoScience Centre, Univ. of East Anglia Policy Studies Inst., OST (Nano Issues Dialogue Group), Dept. for Environment, Food and Rural Affairs, Research Councils, Royal Society, Lancaster Univ. Newcastle Univ., Demos, Greenpeace, Dialogue by Design, NEF, Small Talk | Support e.g., government agencies, research councils via OST-led "Nanotech Issues Dialogue Group" |
| NanoDialogues | 2005-07 | "Upstream public engagement" | UK | Sciencewise Grant Scheme | Demos, Lancaster Univ., BBSRC, EPSRC, Environment Agency, ITDG, industrial partner | Multiple meetings, panels, citizen juries, expert-public workshops to engage public and encourage community participation in wide variety of nanotech-related issues. |
| NanoJury UK | 2005 (5 weeks) | General | UK | Sciencewise Grant Scheme | Interdisciplinary Research Centre (Cambridge Univ), Greenpeace UK, *The Guardian* and Newcastle Univ. | 20 randomly-chosen people considering scenarios |
| Initiative on Nanotech & Society | 2005 | Public engagement | USA | National Science Foundation | National Science Foundation, Univ. of Wisconsin | Reports; "Citizen Consensus Conference" – 13 citizens over 3 Sundays, April 2005 |

**Self-assembling International Nanofora:** As with biotech and synthetic chemicals, any governance of nano-scale technologies will assume a significant international dimension. The first small steps towards international engagement on nanotech governance have already been taken in the various standard-setting processes described previously. However, three other international initiatives/opportunities could play a major role. Unfortunately, both initiatives originate from the dominant nano-nations, are championed by elite institutions that aim to push voluntary regulations and codes and thus pre-empt attempts seeking broader, more rigorous governance.

**International Dialogue on Responsible Research and Development of Nanotechnology:** Most prominent amongst these is the International Dialogue on Responsible Research and Development of Nanotechnology that brought together representatives of 25 different national nanotech initiatives, plus the European Union, in June 2004 near Washington, DC.[96] The first meeting, held behind closed doors, found some agreement on the need for standards and societal dialogue and also proposed the creation of an international 'code of conduct' for nanotech development. This latter idea has since been vigorously championed by the European Union and incorporated into the latest European Communication and Action plan on Nanotechnology. Europe's Tomellini, a staunch supporter of the Code, helped convene a further meeting on July 14-15, 2005 in Brussels between the key nano-countries including China, USA, Japan and European States.[97] Surprisingly, for a time, it seemed as though the unilateralist US might commit to a code if only to pre-empt other more inclusive initiatives such as an International Convention for the Evaluation of New Technologies (ICENT – see below) as proposed by ETC Group and other CSOs. Fuel for code optimists was found in a recent high-level statement of co-operation between US President George Bush and European Commission President, Jose Manuel Barroso, when the two powers affirmed that they "support an international dialogue and cooperative activities for the responsible development and use of the emerging field of nanotechnology."[98]

Europe's enthusiasm for a Code of Conduct was dampened considerably by US opposition during the second "informal" meeting of the dialogue group in Brussels. Significantly, the 13 countries present were not able to produce a consensus statement and it was left to the EU host (acting as Chair) to provide a Chair's Report that could only suggest that governments were prepared to work together toward a "framework of shared principles" that may – or may not – become a code of conduct. Whether it's a code or a framework, it remains unclear where this document would reside – possibly at the OECD in Paris or with the next G8 meeting? More likely, the draft code/framework will be taken to the informal closed meeting of G8 science ministers (known as The Carnegie Group) in December 2005 in advance of the 2006 G8 summit in Russia. It seems highly unlikely that a pre-emptive set of agreements decided behind closed doors by nano-bureaucrats and rubber-stamped by the world's leading industrial nations will offer much in the way of democratic control or just and equitable decision-making over nanotechnology.

It is also possible that this "informal" dialogue of governments will carry on the process itself at its next meeting in Japan sometime in the coming months. Regardless, there is growing criticism, within civil society, of the governments' "informality". The officials attending are speaking in their personal capacities, they say. This is absurd. Travel costs are paid by governments. The

officials have not taken holiday time to attend. They are reporting back to their governments. The term "informal" makes it easier for for governments attending to explain to governments not invited why it is they have been excluded. The process subverts multilateralism and transparency.

**OECD:** Also taking an active interest in global nano-rules is the Organisation for Economic Co-operation and Development (OECD), representing the interests of the top 30 industrialised nations. At a special session of the OECD's two chemicals committees, held in Paris in the first week of June 2005, member countries agreed to move ahead with a process for developing and harmonising risk assessment procedures for nanomaterials.[99] The OECD will coordinate a workshop in late 2005 on potential regulatory responses to the challenges posed by nanomaterials. Hosted in the USA, this workshop will explore existing or potential regulatory frameworks. The OECD's Directorate of Science, Technology and Industry has also been encouraged by its Business Advisory Industry Council (BAIC) to initiate a project considering the role of intellectual property rights in the context of converging technologies.[100] Meanwhile the International Risk Governance Council, a business-friendly organization based in Geneva with close links to the OECD will be publishing a report for governments and industry on how to govern nano-risks while heading off the 'threat' of a moratorium.[101]

**UN – Missing the Action?** To ETC Group's knowledge, the UN system has yet to wake up to the need to control and govern nanotechnology through their institutions. National delegates at the Convention on Biological Diversity and at FAO have expressed concern outside the plenaries and suggestions have also been made that UNEP's new Strategic Approach to International Chemicals Management (SAICM) should consider nanotoxicity in its scope before national ministers approve it in Dubai in February 2006. Unfortunately none of these bodies nor the United Nations Conference on Trade and Development (UNCTAD), the International Labour Organization (ILO), the World Health Organization (WHO) or the Commission on Human Rights have yet begun to consider nanotechnology risk issues or economic, societal, human rights and workforce implications. In February 2005, UNIDO's research Center at Trieste did convene a small meeting of South and North scientists to discuss the potential application of nanotechnology to development issues. Unhappily, this was more a cheerleaders' and fund-seekers' gathering than a real discussion of the pros and cons – risks and opportunities of the new technology. UNESCO, too, seems to be preparing itself to play some role in either technology transfer or ethical evaluation. Perhaps more significantly, the UN University – on the eve of Gleneagles – announced its own report warning that the accelerated introduction of new technologies is actually outrunning governments' capacity to understand them - and could actually pose great risks for both society and the environment.[102] The South, especially, needs a coherent UN approach to nanotechnology. When governments come together in September 2005 to review the Millennium Development Goals (where nanotechnology is seen as an enabling technology) the South will have an opportunity to encourage a full UN debate on its merits and risks.

## 5. Small Claims: Can insurers underwrite the unseeable?

If the nanotech industry is slowly owning-up to its 'responsibility' in the realm of toxicity and showing a willingness to 'dialogue,' it is in large part because the insurance industry is prodding them to the table, concerned about its own exposure to asbestos-like injury claims.

- **Munich Re** was the first re-insurance giant to address the liability issues raised by nanomanufacturing, in a brief report published in 2002.[103]

- **Swiss Re**, the world's second largest re-insurance company, published a strongly-worded 80-page report in 2004 focusing on the toxicity risks of nanoparticles[104] that called for a new regulatory framework based on the precautionary principle and stringent risk management procedures. Swiss Re chose not to broach the touchy matter of insurance exclusion.

- **General Re**, followed Swiss Re's lead in raising nanotoxicity concerns and went further to suggest that "Insurers may start considering the pros and cons of nanomaterial exclusions for general liability, personal liability and commercial umbrella policies…"[105]

- **Allianz,** the giant German insurance and banking company, echoes Swiss Re's calls for the application of the precautionary principle and conscientious risk management in its June 2005 report, but argues it is not appropriate to be talking about general liability exclusions for nanotech because the field is so broad.[106] However, Allianz adds: "this does not rule out specific applications such as the use of nanoparticles in environmental remediation from being subject to more intense risk analysis—and possibly even being excluded from cover."[107]

## 6. Small Minds: Ethicists and PR gurus are converging at the lowest common nanometer.

There's a joke amongst nanotech insiders that the most accurate definition of 'nano' is this: "a tiny manufactured prefix engineered into funding proposals to exploit the unusually generous properties of science funds occurring at the nano-scale." Funding is also proliferating for academic work on nanotech in the disciplines of ethics, philosophy, theology, social science, communication and marketing resulting in a rapid profusion of self-assembling nano-ethicists. Both the US National Nanotechnology Initiative and the EU nanotech funding mechanisms are keen to include an ethics perspective in nanotech development – which sometimes means embedding an 'ethicist' in a nanotech lab.

In principle, "more ethics" is a good thing and some of the social science teams now pioneering well-founded critiques of the nano-revolution are making important contributions. For example, work by social scientists at Lancaster University (UK) on building public engagement into upstream decision-making on nanotech has already had some impact on the UK government's thinking about nanotech.[108] Citizen Juries such as the Nanojury UK co-sponsored by Greenpeace and the University of Cambridge, a similar citizens' conference in Madison, Wisconsin and another hosted by the Loka Institute (USA) have opened up genuinely reflective space for public

values to be discussed. Meanwhile other social scientists and bioethicists such as Michael Mehta at the University of Saskatchewan (Canada)[109] or Gregor Wolbring at the University of Calgary (Canada)[110] are helping to define new areas of the nanotech debate on privacy and disability rights, respectively, by asking questions that examine the power relations inherent in some nanotechnologies.

On the other hand, much of the "nano-ethics" work so far is hardly distinguishable from public relations – perhaps because it is too comfortably embedded with the beast it is studying, or maybe because funders are often champions of nanotech development so that the focus becomes public acceptance rather than critical analysis and vigorous debate.

At a March 2005 "Nano-Ethics" conference at the University of South Carolina (USA), Jean-Pierre Dupuy of Ecole Polytechnique (Paris) and Stanford University (USA) gave a clear lesson in the difference between "ethics" and "prudence."[111] He explained to the nano-ethics community that smoothing public acceptance or managing/analyzing risk is not the job of ethicists. In Dupuy's view, confronting the fundamental change to the human condition that may come about through technological convergence should be the focus of ethical debate.

Dupuy didn't accuse his peers of becoming PR agents for nanotechnology development, but he would have had reason to do so. Speaking in the session following Dupuy's plenary talk was David Berube, associate director of Nano Science and Technology Studies (nanoSTS) at the University of South Carolina. Berube epitomises the industry-friendly academic re-born as ethicist. Berube is a professor in the department of Communication Studies and the founder of a management consultancy firm called Nano-Ethics.com ("Strategic Consultants in Nanoscience and Nanotechnology") that offers advice to "organizations" that need to navigate the turbulent nano-controversies.[112] Far from being circumspect about mixing publicly-funded ethics research and industry PR activity, the Nano-Ethics.com website boasts that many of its staff have received "substantial federal grant money" and is able to offer cheap services since they have low overhead – "No need to find revenue to pay a large staff and expensive office locations." In a recent public comment to the EPA, Berube offered advice on how to quiet critics, a group he ambiguously labeled "relevant public actors."[113] He argues that these "troublemakers" would "benefit the most from targeted deliberation polling and experiments like consensus conferences and citizen juries."[114] Berube explains, "This group needs to be sated and demobilized."[115]

In Canada, the Joint Center for Bioethics at the University of Toronto, led by Peter Singer, has become one of North America's leading cheerleaders for nanotechnology and its use in the South. Canada's prime minister, Paul Martin, has made it clear that he would like to see 5 percent of the government's R&D budget devoted to addressing the South's problems. Recently, the Canadian government has undergone an internal exercise to determine what this might mean department by department and program by program. The process has caused anxiety in some quarters and a feeding frenzy in others. Singer's group hopes to be among the feeders. The Joint Center on Bioethics comes by its role naturally as it has also been a cheerleader for biotechnology in the South.[116]

> *"The media is the crux of this issue. It's how people form perceptions. Organizations like Greenpeace and ETC [Group] know about this. If you create the story by opposing the groups, you create something to write about. If you agree and avoid the sensationalism, you take the wind out of the sails. 'Gee, there's a lot we don't know, we share the concerns, we've been thinking about this for the past few years.' My advice has been not make a public media fight and avoid playing into that script."*[117]
>
> - Vicki Colvin, CBEN, 2005

Not only are professors sometimes devoted to smoothing public acceptance, so are scientists. Vicki Colvin, for example, is a chemist and director of Rice University's Center for Biological and Environmental Nanotechnology. She has played a central role in defining the "responsible nanotechnology" approach to nano-governance.[118] Colvin's candid views on how to strategically demobilize oppositional voices appear in an interview with Lux Research.[119]

Colvin's CBEN launched the International Council on Nanotechnology (ICON) in October 2004 – an industry-funded platform envisioned as a collaboration between civil society, academia, government and industry on questions of nanosafety, though its first activity will be focused on establishing standards for nanomaterials. ICON's efforts to "collaborate" got off to a rocky start when it prematurely listed three NGOs (including ETC Group) as members without prior consultation. Ultimately, the NGOs declined to participate, expressing significant reservations about the project.[120]

A whole industry of communicators, advocates and public relations firms are following the nano-money. These include familiar public relations firms such as Burson Marstellar (BM), whose previous jobs include greenwashing the Bhopal disaster, the Exxon Valdez oil spill and designing international strategies for political acceptance of GM food. BM warns that Nanotechnology is "in danger of failing to get off to a good start because of poor public acceptance."[121] Drawing on their experience defending the biotech industry, they have "set up a network of science communicators who follow scientific and socially relevant developments in nanotechnology" to advise companies on managing the issue.[122]

Also crossing over from GM battles is UK-based Lexington Communications whose founder designed the European PR campaign for patents on life and who now runs two biotech industry-sponsored front groups: The Agricultural Biotechnology Council and CropGEN.[123] In Feb 2005 Lexington also launched The Nanotech Association fronted by ex-Monsanto PR spokesman Bernard Marantelli – a man who now has the unenviable job of speaking on behalf of both the nanotech and agbiotech industries in the UK. Another ex-Monsanto PR man, Harry Swann, is now nanotechnology manager at UK's leading carbon nanotube producer, Thomas Swan & Co., and only recently left a biotech PR firm, Regester Larkin, that handles nanotech clients as well.[124]

In the US, too, there is a revolving door between the GMO and nano PR worlds. PR firm Brodeur Worldwide has set up a specialist nanotech practice headed by Michael Brewer who handled the PR for early agbiotech. He says the nanotech industry can learn lessons from the way that GM critics spread "fear, uncertainty, doubt."[125] Many of the PR folks advise that nanotech

should keep away from its sci-fi image and emphasize positive applications, particularly medical applications. According to Maureen Blanc of Hill and Knowlton's Technology practice, "It could use a name change as well."[126] At least one company, Nanocure, seems to agree: In May 2005 Nanocure changed its name to the less catchy "Avidimer Therapeutics."[127] Nanocure's technology didn't change, but losing the 'nano' prefix might take the company out of the firing line of public concern. ETC expects to see others ditching the 'N' word as controversy grows.

## Box 3: Synthetic Ethics?

***Look What's* Not *Talked About - Nanobiotechnology***

The PR gurus are unanimous that the focus of public debate (and international dialogues) be kept firmly confined to nanoparticles – not nanobiotechnology (synthetic biology). The excuse is that industry and governments only want to deal with products and processes that are already in the marketplace or are expected within the next few years. Nanobiotechnology is already a driving force in venture capital investment – and is now creating excitement and debate within the scientific community. But since commercialization may be ten or more years away, industry and government don't want it discussed. The issue, of course, is that the link between nanotech and biotech – the merger of living and non-living materials – opens up a whole range of ethical and environmental concerns that ethicists and PR gurus don't know how to manage.

Propelled by venture capital and taxpayer dollars, the field of nanobiotechnology is advancing rapidly in the absence of public scrutiny or regulatory oversight. For most governments, nanobiotechnology isn't even a blip on the radar. But synthetic biology is rapidly coming to life:

Today, researchers are building biological machines – or hybrid organisms employing both biological and non-biological matter. The implications of human-directed, made-to-order life forms are breathtaking:

- Engineer Carlo Montemango has created a device, less than a millimetre long, made from rat heart cells combined with silicon.[128] Muscle tissue growing on the device's "robotic skeleton" allows it to move, and researchers believe it could someday power computer chips. Montemagno describes his creations as "absolutely alive...the cells actually grow, multiply and assemble – they form the structure themselves."[129]
- Scientists at the University of California's new synthetic biology department are designing and constructing "biobots" – autonomous robots designed for a special purpose that are the size of a virus or cell, and composed of both biological and artificial parts.[130]
- Chemists at New York University have created a two-legged, DNA robot capable of bi-pedal motion.[131] In the future, the researchers hope that they can coax cells to manufacture DNA-based robots. If nano-scale manufacturing is to become a reality, molecular-scale robots will need to assembly other nanomachines and be able to move molecules.
- With funding from the US Department of Energy, Craig Venter's Institute for

Continued next page

Biological Energy Alternatives is building a new type of bacterium using DNA manufactured in the laboratory. His goal is to build synthetic organisms that can be programmed to produce hydrogen or be used in the environment to sequester carbon dioxide.[132] In the wake of startling advances in the field of synthetic biology, the potential "for abuse or inadvertent disaster" is enormous.[133] In January 2005 scientists unveiled a new, automated technique that makes it faster and easier to synthesise long molecules of DNA.[134] But researchers warn that this revolutionary advance for synthesising DNA will also permit the rapid synthesis of any small genome, including the smallpox virus or other dangerous pathogens that could be used for bioterrorism. Nanobiotechnology raises many potential concerns: Will new, self-replicating life forms, especially those that are designed to function autonomously in the environment, open a Pandora's box of unforeseen and uncontrollable consequences? Some researchers in the field have begun to acknowledge potential risks and ethical implications of their work. In 2004 the editors of *Nature* called on members of the synthetic biology community "to consult and reflect carefully about risk – both perceived and genuine – and to moderate their actions accordingly."[135]

**Confluence of Interests?** In late 2004 ETC Group called for a moratorium on synthetic biology and warned that discussion of the far-reaching social, ethical and environmental implications of synthetic biology must not be confined to a group of self-appointed experts. In June 2005 the J. Craig Venter Institute, the Center for Stategic & International Studies, and the Massachusetts Institute of Technology announced that they will jointly undertake a new project to examine the societal implications of synthetic genomics and regulatory needs.[136] Unfortunately, those who are stepping up to assess the societal implications of synthetic biology are closely linked to those seeking to profit from it. One of the projects' directors, Drew Endy of MIT, is co-founder of Codon Devices, a company that synthesizes customized DNA segments.[137] Another project director, Robert Friedman, is employed by the Venter Institute, whose founder, Craig Venter, recently raised $30 million from private investors to establish Synthetic Genomics, Inc., a company that aims to manufacture organisms for industrial purposes.

## 7. Back talk: Civil society/social movements are finally learning to think small.

It is no longer just government, industry, scientists and PR firms taking a view of the tiny-tech revolution. Civil society is beginning to examine nanotech's implications for human health, development, human rights and the environment – at the local, national and international levels. A list of action groups, CSOs, think tanks, churches and social movements that are gearing up to engage on these issues would be too long, and we risk leaving out many names that should be included. Instead, ETC Group offers a sampling of diverse CSO activities in June 2005:

- The first week of June ETC Group hosted a series of seminars on nanoscale technologies in Geneva with the World Council of Churches, the South Centre, the United Nations NGLS (Non-Governmental Liaison Service) and representatives from Geneva-based UN

bodies. Representatives of more than 30 Geneva-based international NGOs attended ETC's nanotech briefing.

- On 9 June 2005, 17 North American civil society organisations spearheaded by the Natural Resources Defense Council submitted a detailed critique of the US government's proposed voluntary regulation of nanomaterials.

- Civil society organizations from North America met the same week in Silicon Valley to share information and strategy on how to incorporate nanotechnology in their campaigns;

- In mid-June municipal authorities in Grenoble, France sponsored two full days of high profile public meetings on technology and democracy, held in response to public resistance to nanotechnology.[138] Last year activist group Pièces et Main d'Oeuvre (PMO) occupied cranes at the building site of Minatec, Europe's largest nanotech lab, based in Grenoble.

- Also in June, concerned individuals from several European countries congregated in Leeds, England for the first Technopolis gathering, an opportunity to discuss grassroots resistance to nanotech and converging technologies.

- A fortnight earlier in Paraná, Brazil hundreds of people drawn from Latin American social movements met to consider the implications of nanotech and converging technologies for agro-ecology.

- On June 22 the Australian Senate announced it would conduct an investigation into the impact of workplace exposure to toxic dust, including nanoparticles. The inquiry was prompted by Australian civil society groups including Genethics Network and Friends of the Earth Australia.[139]

# Conclusion:

## *A call for an early warning/early listening system*

Just before going to Gleneagles and the G8 Summit, US President George Bush publicly conceded that human activity was leading to Global Warming. This "no-brainer" admission earned Bush few accolades. Enthusiasm was especially muted because the US President suggested that new technologies would come on stream in time to ameliorate the worst effects of climate change. There would be no need to adopt the Kyoto Accord or any other economic initiatives that could imperil US industry. Bush's faith in new technologies is a cause for concern.

In June 2005 ETC Group began discussions with a number of governments, intergovernmental agencies, and civil society organizations in Geneva and elsewhere with the intent of developing a long-term strategy to address the introduction of significant new technologies. Although some parties would like to see a *sui generis* Nanotech Protocol similar to the Biosafety Protocol, there is growing sympathy for ending the "crisis cycle" that has dogged new technologies in recent years by establishing an intergovernmental framework that would allow for the monitoring and

evaluation of new technologies as they evolve from initial scientific discovery through to possible commercialization. A generic, transparent, facility could earn the confidence of governments and society as well as of the scientific community and could reduce unproductive posturing and polemic debate. For the purpose of discussion, ETC group has called this new facility ICENT. A description of this facility is summarized below.

## ICENT: International Convention for the Evaluation of New Technologies

**What is ICENT?** A legally-binding United Nations Treaty either negotiated through a Specialized Agency such as UNCTAD or the ILO, or through ECOSOC's Commission on Sustainable Development (CSD), ICENT is designed to provide an early warning/early listening system capable of monitoring any significant new technology.

**Why ICENT?** South governments will welcome the early warning, open assessment, and facilitated access elements of the initiative. Some risk assessment and regulatory expenses would be secured at the international level. The North – including scientific organizations, industry, and governments will welcome an end to unpredictability and societal distrust and the establishment of a generalized, non-crisis approach to technology diffusion. Civil society will welcome a transparent and participatory process with both early listening and technology conservation/diversification potential.

**Objective**: To create a socio-political and scientific environment for the sound and timely evaluation of new technologies in a participatory and transparent process that supports societal understanding, encourages scientific discovery, and facilitates equitable benefit-sharing. Further, to ensure the conservation of useful, conventional or culturally-distinct technologies and, in particular, to promote technological diversification and decentralization.

Additionally, the process objective is to clarify the need for such a convention; to stimulate high-level and societal discussion, and, to encourage national and regional legislative and institutional initiatives that would compliment an international agreement.

**Timeline**: The political process should begin in late 2005 or early 2006. ETC Group estimates that governments will take 8-10 years to conclude Treaty negotiations and the ratification process – meaning that ICENT's work is unlikely to get underway until 2015 or later. Given the tremendous developments expected in technological convergence at the nano-scale and, in particular, developments in nanobiotechnology (synthetic biology), it is important that negotiations begin as soon as possible. ICENT's work horizon should run 10-20 years ahead of the likely introduction/commercialization of significant new technologies.

**Elements:** The member states will form a Conference of the Parties to the Convention. COP will be supported by a modest Secretariat and enabled by a Bureau comprised of regionally-determined representative states. COP will meet biennially while the Bureau will meet semi-annually. Two expert permanent committees, consisting of all members, will convene annually and will ordinarily report to COP through the Bureau.

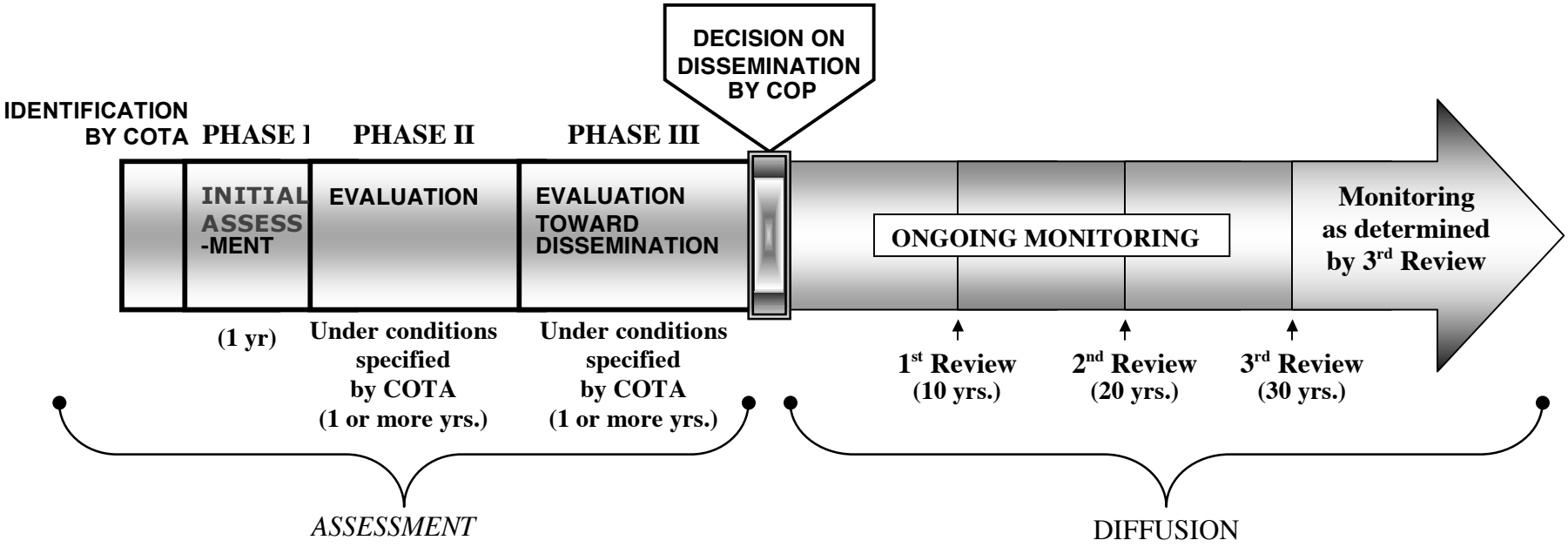
COTA, the Committee on Technology Assessment, will identify significant new technologies; establish appropriate evaluation processes for each identified technology; review progress; and recommend each technology's dismissal, delay or diffusion to COP.

COTDAC, the Committee on Technological Diffusion and Conservation, will promote the conservation and enhancement of conventional/cultural technologies; encourage technological diversification; promote public participation and understanding; and support the diffusion of appropriate new technologies. COTDAC will have the financial resources to support national capacity-building in science and technology, and to encourage broad and equitable dissemination.

Although it will function financially and politically as an independent nongovernmental agency, ACSENT (Advisory Committee for the Socio-Economic and Ecological Evaluation of New Technologies) will be a centre of scientific excellence dedicated to the independent monitoring of science and technology and will have the necessary resources to offer the international community an alternative or additional perspective on technologies and their dissemination.

**Process:** Assuming an effective early listening process, the intent is to identify potentially significant new technologies as the science is emerging so that the assessment process runs parallel to – and need not constrain – the research and development process. Preferably, even "high-impact" technologies would clear the assessment process as or before the technology is ready for commercialization.

## Box 4: STANDARD TECHNOLOGY ASSESSMENT PROCEDURE



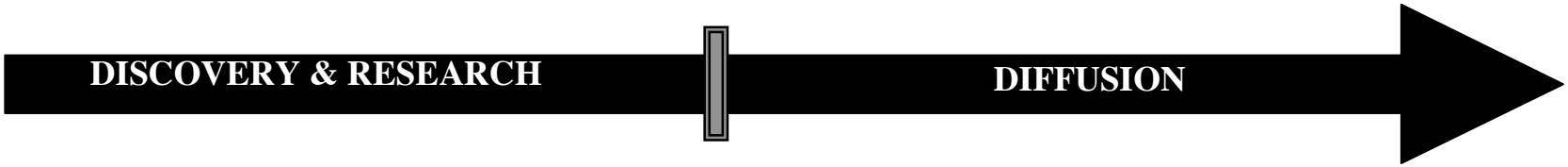

## Assessment Issues

- Evaluation takes place as scientific development continues unless otherwise required by COTA;
- Each phase requires COTA approval;
- Specific conditions for each phase to be set by COTA;
- Promoter's projections to be received for each phase;
- Diffusion approval by COP;
- Monitoring, following diffusion, at three, 10-year intervals

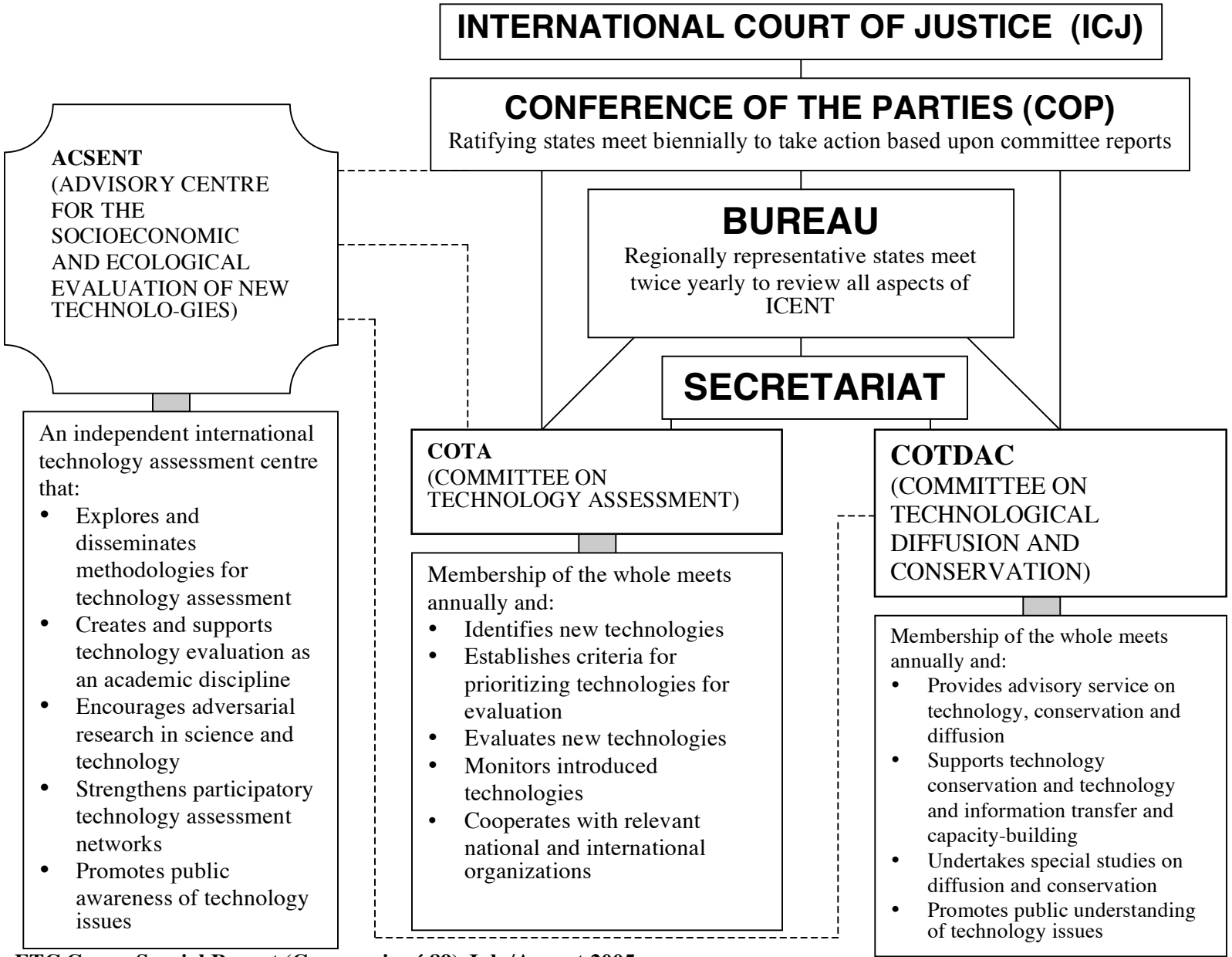
## Diffusion Issues

- Credible impact/recall scenarios provided;
- Socio-economic benefits;
- Environmental safety;
- Technological diversity enhanced;
- Ecosystem applicability assured

## TECHNOLOGY DEVELOPMENT PATH



# ICENT CHART



# Endnotes

[1] Anonymous, Lux Research, "Revenue from nanotechnology-enabled products to equal IT and telecom by 2014, exceed biotech by 10 times," October 25, 2004, available on the Internet: http://www.luxresearchinc.com/press/RELEASE_SizingReport.pdf

[2] In 1970, Canada's former Prime Minister and Nobel Peace Prize laureate, Lester Pearson, submitted his Commission report to the UN setting the OECD aid target at 0.7% of GNP. 0.7% became a global *cause celebre* now rekindled in the much co-opted "Make Poverty History" campaign.

[3] Mohamed H.A. Hassan, "Nanotechnology: Small Things and Big Changes in the Developing World," Policy Forum, *Science*, vol. 309,1 July 2005, pp. 65-66. www.sciencemag.org

[4] John Mugabe, "G8 leaders must help African science help itself," *SciDev.net*, 1 July 2005, available on the Internet: www.scidev.net

[5] Andy Coghlan, Rowan Hooper, Ehsan Masood, Fred Pearce, Curtis Abraham, "Africa focus: Foundations for a prosperous future," *New Scientist*, 2 July 2005, available on the Internet (subscription): http://www.newscientist.com/channel/health/hiv/mg18625064.600

[6] The title is an attempt to evoke the famous Brundtland Report, *Our Common Future,* 1987, which sparked the Rio Earth Summit of 1992. The Commission for Africa's report is available on the Internet: http://www.commissionforafrica.org/english/report/introduction.html

[7] David King, "Science to offer hope to Africa," *New Scientist*, 19 March 2005, available on the Internet (subscription): http://www.newscientist.com/channel/opinion/mg18524917.300

[8] Minutes of Evidence to House of Commons Select Committee on Science and Technology (UK), 23 March 2005, available on Internet: http://www.publications.parliament.uk/pa/cm200405/cmselect/cmsctech/487/5032303.htm

[9] ETC Group *Communiqué*, "No Small Matter," #76, May/June 2002, available on the Internet: http://www.etcgroup.org/search.asp?type=communique

[10] Lux Research, *The Nanotech Report 2004*, vol. 1, p. 2.

[11] The US National Science Foundation has predicted the market for nano-products would exceed $1 trillion by 2015. In 2004, the NSF revised its forecast, estimating that the $1 trillion mark would come and go in 2011. See, for example: www.memsnet.org/news/1032299214-3

[12] Anonymous, Lux Research, "Revenue from nanotechnology-enabled products to equal IT and telecom by 2014, exceed biotech by 10 times," October 25, 2004, available on the Internet: http://www.luxresearchinc.com/press/RELEASE_SizingReport.pdf

[13] Lux Research, *The Nanotechnology Report 2004*, vol. 2, p. 3.

[14] Vicki Colvin first used the term in a paper called "Responsible nanotechnology: looking beyond the good news," EurekaAlert, Nov. 2002, available on the Internet: http://www.eurekalert.org/context.php?context=nano&show=essays&essaydate=1102 Subsequently both Mike Roco (head of US NNI) and his European counterpart Renzo Tommelini have become fond of the phrase. Roco hosted a meeting of 26 governments entitled "International dialogue on responsible research and development of nanotechnology," 17-18 June 2004, where the idea of a voluntary code of conduct on nanotech research was discussed. See the report of the meeting, available on the Internet: http://www.nanoandthepoor.org/international.php

[15] US Public Interest Research Group (PIRG), "Irresponsible care: How the Chemical Industry Fails to Protect the Public from Chemical Accidents," April 2004, available on the Internet: http://uspirg.org/uspirgnewsroom.asp?id2=12864&id3=USPIRGnewsroom&. See also ILO, "Voluntary initiatives affecting training and education on safety, health and environment in the chemical industries," 1999, available on the Internet: http://www.ilo.org/public/english/dialogue/sector/techmeet/tmci99/tmcirep.htm

[16] See http://www.crnusa.org. For more information, see SourceWatch web site (a project of the Center for Media & Democracy, USA): http://www.sourcewatch.org/index.php?title=Council_for_Responsible_Nutrition

[17] See http://www.arap.org. For more information, see SourceWatch web site (a project of the Center for Media & Democracy, USA): http://www.sourcewatch.org/index.php?title=Alliance_for_Responsible_CFC_Policy

[18] See http://www.pestfacts.org. For more information, see SourceWatch web site (a project of the Center for Media & Democracy, USA): http://www.sourcewatch.org/index.php?title=Responsible_Industry_for_a_Sound_Environment

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