

The Big Downturn?



Nanogeopolitics

etc group 



Seurat & Shtig

“Nanomaterials exemplify the kind of challenge for which attention to closing gaps in knowledge and regulation is necessary but insufficient. Effective governance will mean looking beyond traditional regulation for other, more imaginative solutions, often involving a wider range of actors and institutions than has been customary in the past...Ultimately however, many of the questions raised...extend beyond the (important) issues of risk and risk management to questions about the direction, application and control of innovation.”

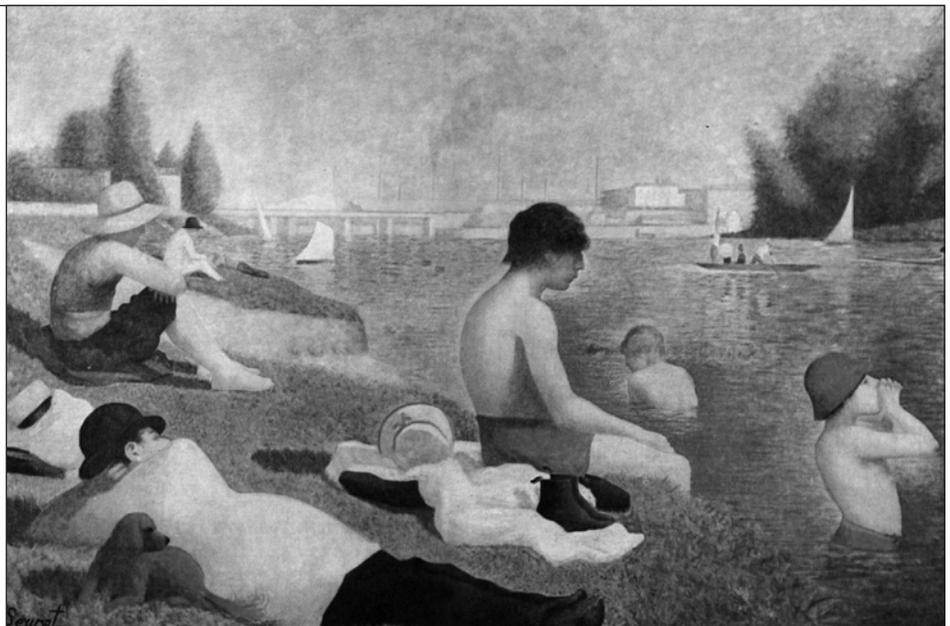
– The UK’s Royal Commission on Environmental Pollution (RCEP),
Novel Materials in the Environment: The Case of Nanotechnology, November 2008.
 (In July 2010, the UK’s Environment Secretary Caroline Spelman announced she was abolishing the RCEP as part of a deficit reduction effort.)

About the cover

From Georges Seurat’s ‘*Bathers at Asnières*’ (National Gallery, London) painted in 1884 (as shown here). Against a backdrop of smokestacks spewing industrial pollution, Seurat’s anonymous workers from a suburb of Paris relax along and in the River Seine. In Shtig’s adaptation for our cover, the scene of workers at leisure is made ominous by nanotech’s new form of industrial pollution, visible only by its effects on the environment and human health.

Acknowledgements

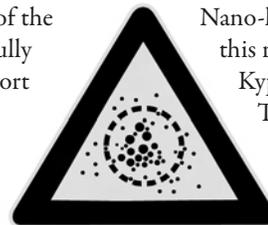
ETC Group owes a tremendous debt of gratitude to Stephanie Howard, whose careful, original and comprehensive research forms the basis of this report. We have also benefitted from discussions that took place during a series of meetings organized to explore the implications of BANG (converging technologies), including an international seminar in Montpellier, France, in November 2008 convened by ETC Group, The What Next? Project, BEDE, Fondation Sciences Citoyennes, as well as subsequent regional meetings convened by (among others) Centro Ecológico (Brazil), FASE (Brazil), African Biodiversity Network, African Centre for Biosafety (South Africa), CASIFOP (Mexico), Alliance for Humane Biotechnology (USA), EQUINET, SEARICE (Philippines), Friends of the Earth (USA), ICTA (USA), Center for Genetics and Society (USA) and Movement Generation (USA).



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ETC Group is solely responsible for the views expressed in this document.

Copy-edited by Leila Marshy
 Design by Shtig (.net)



Nano-hazard symbol (reproduced on this report’s cover) by Kypros Kyprianou.

This symbol was one of three winners of ETC Group’s 2007 Nano-Hazard Symbol Contest. All entries can be seen here:

www.etcgroup.org/gallery2/main.php?g2

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The Big Downturn?

Nanogeopolitics

ETC Group revisits nanotech's geopolitical landscape and provides a snapshot of current investment, governance and control, including intellectual property.

Overview

Issue

Is Tiny Tech down in the dumps or just lying low? ETC concludes that even though the market is soft and industry is increasingly nervous about its health and environmental exposure, the world's governments have invested too much (more than \$50 billion through 2009) to retreat from a technology they've claimed will not only help end the recession but rescue the climate and resolve Peak Oil. With Europe and the U.S. divided on regulation, industry wants to dump its self-inflicted "nanotechnology" moniker, determined not to draw unwelcome public attention until the regulatory nano-dust settles. Far from settling, the clouds are gathering to rain on little nano's surprisingly ponderous parade.

At Stake

Nanotech is still positioned as the multi-trillion dollar game-changer that will restructure global commodity markets. History makes clear that new technologies don't have to work particularly well to be profitable and transformative. Estimates of today's commercial market range irrationally between a meager \$12 billion and a whopping \$224 billion. The lower figure is closer to reality. In the absence of labeling rules (or common sense) nobody knows how many products contain what types (or sizes) of nanoparticles but one survey has identified at least 1600 products. ETC believes the number of products – which includes foods, feeds, pesticides and skin care products – is substantially higher. In the past couple of years, private nano investment has exceeded public funding so that, in 2010, total global investment probably exceeds \$20 billion. So, "at stake" is our environment and the health of both our economies and our societies.

Actors

The ground has shifted considerably in the five years since ETC Group published its first survey of nano's geopolitical landscape. Despite bleak – and largely rhetorical – forecasts of the U.S.'s diminishing stature in nanoworld, the USA (including the public and private parts of corporatized America) still spends the most money on R&D, though China fields more scientists. Meanwhile, Russia has suddenly emerged as the biggest (but, perhaps, not the brightest or most consistent) public spender. Europe and Japan are still in the game, but lagging. At least 60 countries have state nanotech initiatives, including newcomers Nepal, Sri Lanka and Pakistan. In 2010, nano is bigger in Asia than in either North America or Europe. Worldwide, there are more than 2000 nanotech enterprises researching and/or manufacturing nanoparticles utilizing a largely uncounted (and unprotected) workforce. Partial estimates include: 35,000 nanotech researchers in the global chemistry sector alone but, also, 63,000 workers in Germany and another 2 million or so in the U.S. – all exposed to potentially hazardous nano-scale particles. Five years from now, the number of workers is predicted to reach 10 million. (How many jobs nanotech's commodity market disruptions could make obsolete is still not a topic for polite conversation.) Trade unions, such as IUF, ETUC and United Steelworkers, are taking a tough stance on nano and civil society organizations have campaigned for strong oversight grounded in precaution.

History makes clear that new technologies don't have to work particularly well to be profitable and transformative.

What is Nanotechnology?

Nanotechnology is a suite of techniques used to manipulate matter on the scale of atoms and molecules. Nanotechnology speaks solely to scale: *Nano* refers to a measurement, not an object. A “nanometer” (nm) equals one-billionth of a meter. Ten atoms of hydrogen lined up side-by-side equal one nanometer.

A DNA molecule is about 2.5 nm wide. A red blood cell is enormous in comparison: about 5,000 nm in diameter. Everything on the nanoscale is invisible to the unaided eye and even to all but the most powerful microscopes.

Key to understanding the potential of nanotech is that, at the nanoscale, a material's properties can change dramatically; the changes are called “quantum effects.” With only a reduction in size (to something smaller than 1000 nm in at least one dimension) and no change in substance, materials can exhibit new characteristics – such as electrical conductivity, increased bioavailability, elasticity, greater strength or reactivity – properties that the very same substances may not exhibit at the micro or macro scales.

For example:

- Carbon in the form of graphite (like pencil “lead”) is soft and malleable; at the nanoscale, carbon can be stronger than steel – somewhere between 10 and 500 times stronger, according to the science press – and is six times lighter.
- Nanoscale copper is elastic at room temperature, able to stretch to 50 times its original length without breaking.
- Aluminum – the material of soft drink cans – can spontaneously combust at the nanoscale.

Researchers celebrate their “new, expanded periodic table” of elements and are exploiting nanoscale property changes to create new materials and modify existing ones. Companies now manufacture engineered nanoparticles that are used in thousands of commercial products. Nanotech tools and processes are being applied across all industry sectors. Products on the market or in the pipeline include cell-specific drugs; new chemical catalysts (used in the processing of petroleum, for example); foods containing nanoscale ingredients; nano-scaffolds for tissue engineering; sensors to monitor everything in the land, sea and air as well as everything in and on our bodies.

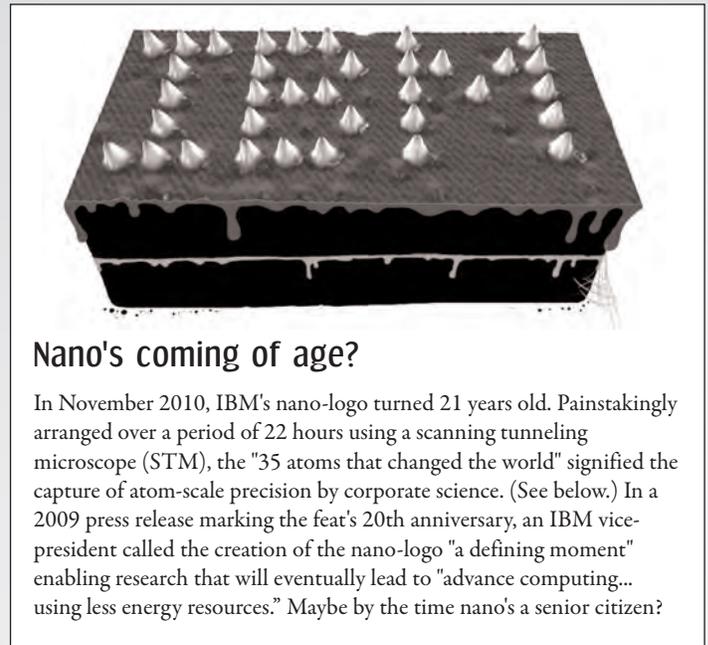
Fora

Most activity is still aimed at facilitating nano's path from lab to market, through research collaborations, standards development, and reportedly by early 2011, a formal commodity exchange for trade in nanomaterials. In 2008, political differences on the meaning of responsible stopped (or at least stalled) the International Dialogue on Responsible Nanotechnology Development: EU representatives are feeling pressure to talk regulation; U.S. reps, not so much. About the same time, the UK's DFID, Canada's IDRC and the Rockefeller Foundation hung up on the Global Dialogue on Nanotechnology and the Poor. Luckily, the International Conference on Chemicals Management (ICCM), egged on by civil society, rebelled against regulatory inactivity on nano at its 2008 meeting in Senegal.

Since then, however, OECD efforts – led by the U.S. – have focused on containing the ICCM rebellion. More recently, the UN Food and Agriculture Organization (FAO) and the World Health Organization (WHO) have gotten into the act and the International Labour Organization (ILO) will take up nano's invisible hazards at its XIX World Congress on Safety and Health at Work in Istanbul in September 2011. Importantly, the UN's Rio+20 Summit in 2012 will scrutinize nano's claim to be central to the future “Green Economy” – one of two Summit themes. Even if the G8/G-20 countries are indifferent or incompetent, the UN and the G77 seem willing to act.

Policies

Ten years, \$50 billion, and a couple of thousand products since the nanotech boom began in 2000, the 60+ governments with national programs still lack an agreed definition for nano; an accepted measurement standard; replicable research models; public health and environmental safety regulations; and the remotest understanding of the potential social-economic, intellectual property or competition issues involved in the several hundred nanomaterials under research or manufacture. Barring catastrophe, it is increasingly unlikely that OECD country regulators will have the courage or the clout to provide the governance nanotechnology requires. Although the European Parliament is prodding reluctant EC regulators, and even some U.S. government agencies show signs of acknowledging their mandates, industry is still telling OECD states to back off. Eight years ago, ETC Group called for a moratorium until exposed researchers and workers could proceed with reasonable safety assurances and we asked for the withdrawal of all products being sprayed in the environment, ingested by people or animals, or used on the skin until proven safe. We continue to call for this moratorium. Without effective intergovernmental action, CSOs will redub the Rio(plus)20 Summit “Silent Spring(minus)50” marking the publication of Rachel Carson’s groundbreaking book in 1962.



Nano's coming of age?

In November 2010, IBM's nano-logo turned 21 years old. Painstakingly arranged over a period of 22 hours using a scanning tunneling microscope (STM), the "35 atoms that changed the world" signified the capture of atom-scale precision by corporate science. (See below.) In a 2009 press release marking the feat's 20th anniversary, an IBM vice-president called the creation of the nano-logo "a defining moment" enabling research that will eventually lead to "advance computing... using less energy resources." Maybe by the time nano's a senior citizen?

Why this report? When ETC Group began investigating nanoscale technologies in 2000, an iconic image showing 35 xenon atoms arranged to form the letters I B M appeared everywhere in the popular press – demonstrating, according to scientists and journalists, an ability (by corporate researchers) to control individual atoms and arrange them in any desired configuration. The commercial potential of unprecedented, precise atomic-level manipulations was both obvious and great, and to jumpstart the nano-revolution, the U.S. government launched its ambitious National Nanotechnology Initiative in 2001. When, in mid-2002, ETC Group called for a moratorium on the commercialization of new nano products for health and safety reasons, the response bordered on hysteria. Our publication early the next year of *The Big Down*, in which we reiterated our call for a moratorium and warned of possible downsides to a nanotech revolution – including the privatization of the earth’s fundamental building blocks and the displacement of workers dependent on markets for traditional commodities – didn’t win us any more love from nanophiles.

Since our call for a moratorium, science has cast nano’s safety even further in doubt, with hundreds of studies now demonstrating harmful effects from exposure to nanoparticles.

Tiny Tech's Titanic Impacts

The fledgling U.S. nanotech trade journal, *Small Times*, featured articles characterizing ETC Group as a “merry band of miscreants” with “avowed Maoist sympathies” whose “bizarre beliefs seem to be driving their attacks on legitimate science and social advances to the detriment of all of us.”¹ In the intervening eight years since our call for a moratorium, science has cast nano’s safety even further in doubt, with hundreds of studies now demonstrating harmful effects from exposure to nanoparticles.

In 2005, our merry band published *Nanogeopolitics*, a global survey of the (sad) state of nanoregulations. In 2007, a broad coalition of civil society, public interest, environmental and labor organizations from across the globe worked out a set of *Principles for the Oversight of Nanotechnologies and Nanomaterials* grounded in the Precautionary Principle.² 2010 marks nearly a decade that governments have been patting themselves on the back with one hand – for being “pro-active” – and waving away red flags raised by scientists and civil society organizations with the other hand. Industry has generally refused to lend a hand at all, consistently declining to provide information on activities or release data on toxicity.

Manipulating matter at the nanoscale has turned out to be more complicated than IBM’s nano-logo led us all to believe, and investment in nanotech R&D has yet to return a “world-saving” application. Policymakers – some kicking and screaming – are beginning to acknowledge that fast-tracking nanotech has come at a price and that some sort of regulation is needed to deal with at least some of the risks it poses. But governments and industry, hand in hand, have come too far and invested too much to give up on nanotech’s promise of becoming the strategic platform for global control of manufacturing, food, agriculture and health – a pillar of the 21st century’s “green economy.” This report revisits nano’s geopolitical landscape, providing a snapshot of global investment, governance and control, including intellectual property, in 2010.

1. New designer nanomaterials mean multiple raw material options for industrial manufacturers and the potential, theoretically, to upend traditional commodity markets. By using nanotech to build from the “bottom up” rather than processing down, the quantity of raw materials required could be sharply reduced. New nano-enabled platforms for industrial manufacturing could make geography (i.e., local natural resources) irrelevant and destroy livelihoods that are dependent on traditional commodities.
2. What makes nanomaterials so attractive to researchers and industry across a wide range of fields – their small size, mobility and unusual properties – turns out to be the same qualities that could make them harmful to the environment and to human health.
3. But the real power of nanoscale science is in the convergence of diverse technologies, which can involve biology, biotechnology and synthetic biology, physics, chemistry, cognitive sciences, informatics, geoen지니어ing, electronics and robotics, among others. Scientists and governments in the U.S. and Europe have a strategy to merge the sciences based on a theoretical “material unity at the nanoscale.” Since all materials and all processes operate from the “bottom up,” proponents of convergence believe they can control events on the macroscale by manipulating events at the nanoscale. According to this reductionist view, every substance, as well as every biological or cultural system, is the result of molecular processes operating on different levels. ETC Group refers to the quest to control all matter, life and knowledge by working from the nanoscale as BANG: Bits, Atoms, Neurons and Genes – the stuff of various converging technologies.

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Part 1. The State of the NanoNation

“To promote industrial growth, a vibrant economy, and social welfare, Europe must maintain its leading position in all fields of Nanotechnologies, Materials Science and Engineering and Production Systems (NMP).”

– NMP Expert Advisory Group (EAG) Position paper on future RTD activities of NMP for the period 2010 – 2015, November 2009

Nanotech has had a tough time over the last couple of years: raising capital funds and turning a profit were uphill battles, and commercialization faltered as no blockbuster products emerged to rally the markets.³ In 2009, venture capital investment had dropped 43% from 2008 levels.⁴ By some accounts, public funding is still to peak as more states enter the arena,⁵ but the rate of investment that marked the first half of the nanotech decade has dropped sharply.⁶ According to one industry analyst assessing nano’s performance in 2009, “Nanotechnology treaded water, barely staying afloat.”⁷ Meanwhile, rankings placed nano as one of three major technological risks facing the planet;⁸ as Europe’s top emerging workplace risk;⁹ and one of the new global environmental threats to child health.¹⁰

The sea may be rough, but there’s no doubt nanotech is keeping its head above water, buoyed by greater government investment with an eye toward moving products to market. For Brussels, Moscow, Washington and Beijing, dominance in nanotech is still synonymous with economic competitiveness, industrial growth and even social wellbeing.¹¹ Nanotechnologies remain a fixture of the future – a platform promising to permeate every sector of the economy. By the end of 2009, governments had pumped more than \$50 billion of public funds – including a colossal \$9.75 billion in 2009 by one count¹² – into the technology. At least 60 countries now have state nanotech initiatives, investment programmes and/or publicly funded research programs.¹³

NanoNation Roundup – Public Sector Investment

2001 marked the beginning of the United States’ interagency National Nanotechnology Initiative; since then the federal government has invested around \$12 billion dollars of public funds, including \$1.6 billion in 2010.¹⁴ The Department of Defense has gotten the biggest allowance with \$3.4 billion (or just under 30% of the total nano R&D funds); the National Science Foundation just over 25%; the Department of Energy 18%, and the Department of Health and Human Services/National Institutes of Health 15% of the NNI funds.¹⁵ President Obama’s budget for 2011 gives nanotech another \$1.8 billion. Some state governments, including Georgia, New York, Oklahoma and Illinois, are funding nanotech initiatives out of their own budgets, to the tune of an estimated \$400 million per year¹⁶ – nudging all public funding per annum over the \$2 billion mark, but still below total public EU spending.

The European Commission has invested around €5.1 billion through its Framework Programmes, with the current Framework (FP7, 2007 through 2013) earmarking a total of €3.5 billion for nanotechnology.¹⁷ In 2008, total public funding (from the 27 member state governments and the Commission) was \$2.6 billion, accounting for 30% of global public funding and putting it ahead of the U.S.’s federal investment. The EU maintained its lead in 2009, although its slice of the public-funding pie shrunk to just over one-quarter of global R&D.¹⁸ Germany, one of the world’s largest chemical economies, leads the Europack with €441.2 million invested from all public sources in 2009.¹⁹ A 2010 review of the EU’s investment in nano R&D under the previous funding programme (FP6, 2002-2006) hints at lowered expectations, however. The report’s title: “Strategic impact, no revolution.”²⁰

Japan is a longstanding member of the NanoNation-triumvirate with per annum investment hovering just above or below the \$1 billion mark over the past five years. According to some analysts, 2009 saw Japan surpassing the U.S. in successful commercialization of nanotech products.²¹

Come on Down: NanoNation Contenders

While the U.S., the EU and Japan are still out in front in terms of expertise, infrastructure, and capacity, market analyst firm Cientifica reports that the share of the top three in R&D was just 58% of global R&D spending by governments by 2009, compared with 85% in 2004.²² Other emerging economies are beginning to shake up the NanoNation league table:

Russia exploded onto the scene in 2007 with a massive cash injection (and the detonation of what was billed as the first “nanobomb”).²³ The Kremlin established a state corporation focused on nanotechnologies, Rusnano, and reportedly handed it almost \$4 billion to invest. The aim was to capture 3% of the global nano market by 2015.²⁴ Russia’s nano-investment became less certain when, in 2009, some Rusnano funds were shifted back to state coffers to plug wider funding gaps; then, in July 2010 – in the wake of a federal investigation of all state corporations – Rusnano was reorganized into a publicly traded company.²⁵ According to one commentator, Russia remains a “minor league” player, despite its investment, due to poor performance in IP and other aspects of technology development, including so-called brain drain.²⁶

The figures on China’s nano investment vary,²⁷ but there is no doubt that the country is committed to the technology. The Chinese Academy of Sciences reports public nano-investment of \$180 million per annum.²⁸ London-based consultancy Cientifica estimated China’s investment for 2008 at around \$510 million, which, when adjusted for so-called “purchasing power parity,” put it in third place, tied with the U.S. and behind the EU and Russia (see table).²⁹ In 2009, nano commanded a greater portion of the science R&D budget in China than in the U.S.³⁰

South Africa has had its eye on nanotech for the better part of the last decade, paying particular attention to the impact new nanomaterials could have on minerals markets (e.g., platinum, palladium). The government launched its National Nanotechnology Strategy in 2005, funding R&D through the Department of Science & Technology whose overall budget for 2009/10 neared \$600 million.

Brazil is a leader of nano development in Latin America. In 2009, the government invested over \$44 million in nanoscale technologies through the Ministry of Science & Technology, which doled out funds equalling 1.4% of GDP to all areas of science R&D.³¹

In general, Asian countries are big on nano. South Korea has invested US\$1.4 billion in the technology over the past eight years and has announced its intention to become one of the top three nanoindustry leaders by 2015.³²

Undeterred, Thailand plans to be the focus of nano industrial activity in the ASEAN region,³³ and Sri Lanka has recently made known its plan to become the Asian hub of sustainable nanotech.³⁴ As a region, Asia’s investment had topped that of the U.S. by 2007. By 2008, investment in nano R&D from all sources – public, private, including venture capital – in Asian countries reached \$6.6 billion (with Japan responsible for a weighty \$4.7 billion) according to U.S.-based consultancy

Lux Research, compared to an estimated \$5.7 billion from all sources (public and private) in the U.S.³⁵

Germany’s future competitiveness in industries such as automotives, chemicals, pharmaceuticals, medicine technology, information and communication technology, and optics, and in traditional industries such as engineering, textiles, and construction, will largely depend on the realisation of nanotechnological innovations.

– Federal Ministry of Research and Education, *Nano-Initiative – Action Plan 2010*, 2007

Government Investment in Nanotechnology 2009³⁶

	% of total	% of total adjusted for PPP*
EU (27 members + FP7)	27%	27%
Russia	23%	25%
U.S.A	19%	16%
Japan	12%	9%
China	10%	18%
Korea	4%	
Taiwan	1%	
India	(<1%)	
Rest of world	4%	

(Cientifica’s 2009 white paper on global funding of nanotech R&D³⁷ did not see the global recession having an immediate effect on government funding. Cientifica sees the slowdown as reflecting a shift from basic research to application-focused investment.)

Military Nano: War Games

The U.S. is understood to be making the world's largest investment in military applications of nanotechnology – accounting for as much as 90% of global nano-military R&D by one estimate³⁸ – though the UK, Netherlands, Sweden, France, Israel, India, China, Malaysia and Iran are all said to be investing some public funds in military research as well.

The U.S. Department of Defense (DOD) has reportedly invested in “sub-micron technologies” since the 1980s³⁹ and, in the first decade of NNI funding, received a total \$3.4 billion for nano R&D – around 30% of the total federal investment for that period.⁴⁰ The White House has proposed cutting the DOD's nano R&D funds for the 2011 fiscal (in favour of greater funds for energy and health-related research),⁴¹ but still leaving the Department with some \$349 million to spend.

Projects in the UK's Defence Technology Plan that both likely and explicitly include tiny tech suggest the Ministry of Defence is investing between £29.6 million and £73 million over a three-year period (2009-2012), though nano may not be a significant component of some of the projects; on the other hand, these projects may not reflect the entire nano R&D portfolio.⁴²

Russia declared military applications to be high on its nanotech R&D agenda⁴³ – an interest it punctuated with the televised detonation, in 2007, of what the Kremlin declared to be the world's first nanobomb – a fuel-air explosive with reportedly nanometer-sized features endearingly dubbed the Father Of All Bombs.⁴⁴ The bomb carried almost 8 tonnes of explosives and flattened a four-storey building.⁴⁵

Military applications are also within the Indian government's sights. The Department of Science and Technology (DST) has commandeered the Agharkar Research Institute (ARI) to provide nanoparticles to the defence establishment⁴⁶ and the Indian Defence Research & Development Organization (DRDO) is developing manufacturing capacity in fullerenes and carbon nanotubes for use in stealth, smart materials and nanoelectronics.⁴⁷

Nano, Inc. – Private Sector Investment

More than once, decision-makers in Washington have been warned that the U.S. risks losing its lead in the nano race to the EU, China, India, or Japan – or that the lead has already been lost.⁴⁸ In commercializing tiny tech, the U.S. is reportedly trailing Japan, Germany and South Korea.⁴⁹ Stepped up adoption by the private sector, they say, is key to securing dominance.⁵⁰ Across the Atlantic, the European Commission is similarly insecure about the EU's position and, too, has called for greater involvement and investment by the private sector.⁵¹

While investment by the private sector is less transparent and therefore more difficult to calculate – especially without the benefit of proprietary market reports, just one of which can cost several thousand dollars – it is now agreed that corporate investment in nanotech R&D outstrips government spending. Lux Research predicted that global private sector investment would outpace government spending by 2005,⁵² but it was not until 2007 that the consultancy reported corporate R&D investment had nudged ahead.⁵³ Cientifica reported corporate funding had indeed pulled ahead by 2005 and estimates the private sector will foot the bill for 83% of all nano R&D investment by the end of 2010.⁵⁴

According to the European Commission (relying on figures from Lux Research) private sector investment in nano R&D is highest in the Asia region (\$2.8 billion), closely followed by the U.S. (\$2.7 billion), with European companies less enthusiastic, at \$1.7 billion.⁵⁵ The U.S. is the clear leader in venture capital funding, cornering 80% of all investment from that source.⁵⁶

Most Fortune 100 companies are said to be running nano R&D programmes or using nano commercially. According to a report by the U.S. President's Council of Advisors on Science and Technology (PCAST, also relying on Lux Research figures), the \$2.7 billion investment by U.S. corporations into nano R&D breaks down as follows: around half to electronics and IT, 37% to materials and manufacturing sector, 8% to healthcare and life sciences, and 4% to the energy and environment sector.⁵⁷

In 2008, Cientifica estimated that corporations across the globe would pump a staggering \$41 billion dollars into nano R&D in 2010, in the following sectors:⁵⁸

- The semiconductor industry would continue to see the largest share of corporate R&D investment, with a \$19.5 billion investment predicted for 2010.
- Pharmaceutical and health care industries would overtake the chemical industry in nano R&D, with a projected \$8.3 billion compared to \$7.4 billion by chemical companies. Major players in chemicals are BASF, DuPont, Dow, Syngenta, 3M. In pharmaceuticals: Johnson & Johnson, GlaxoSmithKline, AstraZeneca, Pfizer, Aventis.
- The aerospace and defense sectors would invest \$2.7 billion in nano R&D, while the electronics industry was heading for \$2.1 billion in 2010. The top corporate spenders in aerospace and defense are BAE Systems, Boeing, Lockheed Martin, EADS, Honeywell International.
- Food companies were expected to spend just \$22 million in nano R&D in 2010.

More than Money Matters: Other Indicators

Investment by government and companies – however fuzzy the math – is the most obvious factor in assessing so-called technology leadership, but analysts are also watching closely the league tables in intellectual property (IP), science journal publications, research infrastructure, educational indicators and commercialization data.

On the IP front, the U.S. is believed to lead in total number of granted patents.⁶² European Commission analysis has the EU trailing well behind the U.S. in IP.⁶³ Regarding patent applications – “the forward indicator” of technology-capture – a different picture emerges, with China in the lead.⁶⁴ Over the 1991-2008 period, applicants in China had filed more applications in total (16,348) than applicants in the U.S. (12,696) had filed, at their respective patent offices.⁶⁵ (Mr. Yang Mengjun alone accounts for more than 900 patents related to nano-scale formulations of traditional Chinese medicines.⁶⁶) In 2008, Chinese applicants filed almost twice as many applications (4,409) as U.S. applicants did (2,228). This, however, could also be an indication of the broad scope of patent claims filed by U.S. applicants compared to the more narrow claims made by inventors in other countries.

According to an OECD assessment, the U.S. leads in scientific publications, with 22% of all journal papers related to nanoscience and technology; China (11%), Japan (10%), as well as Germany (8%), France (6%), and the UK (5%). China, however, is closing the gap.⁶⁷ According to assessments cited in the PCAST report, the U.S. lags China and the EU in total number of publications, although, they argue, numbers do not signify quality or influence nor are the many publications by Chinese scientists appearing in the canon of twelve or so core nanoscience journals – all English language publications – where EU and U.S. scientists predominate.⁶⁸ That said, China’s share of publications in these journals is increasing at about the same rate as the U.S.’s share is decreasing.

Irreconcilable Differences? Buyer Beware

While the two most prominent nano-consultancies – Lux Research in the U.S. and Europe-based Cientifica – agree on general points (e.g., nanotech will play a critical role in the 21st century economy; private investment now exceeds public investment), there is more than an ocean separating them. The discrepancy between their investment figures is anything but nanoscale, with Cientifica estimating that the global private sector would invest \$41 billion in nano R&D just in 2010 – that’s nearly as much as the global public sector has invested over a decade. While Cientifica’s major nano-market report is proprietary, the \$41 billion figure was presented in a (formerly) freely-available Executive Summary.⁵⁹ Lux Research puts private investment in nano R&D at about \$7.2 billion. Lux’s 2009 report, which provides private sector investment figures by region,⁶⁰ is also proprietary – and ETC Group didn’t buy it – so the timeframe in question is not clear to us. We’re guessing the \$7.2 billion refers to recent per annum investment, but publicly-available reports that relied on Lux for private investment figures – such as reports from the EC Directorate-General for Research and the U.S. President’s Council of Advisors for Science and Technology⁶¹ – aren’t explicit. In light of the discrepancy between the Lux and Cientifica figures, it seems that somebody (or maybe everybody?) who handed over thousands of dollars for insider information on the nano-market is getting a bum steer.

Part 2. Market Forecasts: From Banal to Bloated

Enthusiastic predictions of nano's commercial returns continue to spur government investment. The figure said to have launched a thousand nanotechnology initiatives is the U.S. National Science Foundation's 2001 prediction that the world market for nano-based products would reach US\$1 trillion by 2015. That landmark projection has since been raised to \$1.5 trillion,⁶⁹ though U.S.-based Lux Research's visions of \$3.1 trillion have been recently trimmed to \$2.5 trillion due to the global economic recession.⁷⁰ (See below.)

Playing the Nano Numbers

Assessing market value of nano is not a dark art, but it may require some creative accounting alchemy, not least because formal definitions of what constitutes nano are under negotiation and because the level of market activity is not fully known.⁷¹ Indeed, like private investment calculations – and even in hindsight – accounts of nano's market share vary wildly: In 2007, the market value for nano was either \$11.6 billion or \$147 billion, depending on whom you consult.⁷²

In general, estimates from Lux Research occupy the high end of the scale and are among the most widely cited. Lux developed a “value chain” approach that combines the value of the (raw) nanomaterials, the “intermediates” they are incorporated into, as well as the final, “nano-enabled” product to arrive at the total market value. The potential for bloat from this method is considerable. For example, if a housebuilder installs a kitchen countertop that incorporates antimicrobial silver nanoparticles, should nano's contribution be understood as the value of the silver nanoparticles, the countertop, or the value of the whole house? Lux Research would count all three.⁷³

Lux's estimate for the total market value of nanotech in 2009 may be \$253 billion, but a teeny \$1.1 billion (or 0.42%) of that arises from nanomaterials themselves; and that's about as good as it gets for the predicted value of nanomaterials until 2015, where these account for just 0.11% of the total value chain.

These figures would tend to support Lux's assessment that the big money is not to be made manufacturing nanoparticles,⁷⁵ but they also confirm the OECD's caution that such approaches are likely to generate “significant overstatements,”⁷⁶ or, as one industry member put it, “terribly deceiving numbers.”⁷⁷

Nevertheless, value chain predictions have received considerable uncritical airtime unaccompanied by the more sobering breakdown of the value chain. This incautious repetition may be due – at least partially – to the fact that the detail is typically inside the cover of proprietary consultancy reports that are so expensive even governments are known to rely on the free summaries.

The Foggy Commercial Bottom?

The lack of labeling requirements, consensus on terminology, pre-market assessment and post-market monitoring by governments – as well as industry's uncompromising lack of transparency – also contribute to the fog around nano's market impact. Most governments rely on charity – a freely available online inventory of consumer products developed by the U.S.-based Project on Emerging Nanotechnologies (PEN).⁷⁸ According to that inventory, there were just over one thousand product lines on the market as of August 2009 (when the inventory was last updated). That number is significantly lower than the actual number of commercialized products as

the inventory lists only those products the manufacturer claims to incorporate nano and does not cover intermediate products (such as coatings used in the automotive industry). A survey conducted by two government agencies in Canada a few months earlier than PEN's latest assessment identified roughly 1600 nanoprodut lines on the Canadian market.⁷⁹

Lux Research's Nano Value Chain⁷⁴ (US\$ millions)

Product	Value 2009	% of value chain 2009	Value 2012	% of value chain 2012	Value 2015	% of value chain 2015
Nanomaterials	1,074	0.42%	1,798	0.2%	2,916	0.11%
Nanointermediates	28,839	11.36%	120,206	13.6%	498,023	20.2%
Nano-enabled products	223,785	88.22%	762,204	86.2%	1,962,950	79.66%
Total Value Chain	253,699		884,208		2,463,890	

Based on PEN's product inventory, nanosilver is the most common nanomaterial in commercial circulation, accounting for one-quarter of available nanoproducts. This is followed by carbon nanomaterials (82), titanium (50), silica (35), zinc (30) and gold (27).⁸⁰ Over half (540) of the products in the inventory are produced in the U.S.; Asia accounts for around 25% of the production (240) and Europe 15% (154).

Whatever the actual number of consumer products, it is agreed that tiny tech is at an early stage of development – laying claim to mostly trivial achievements when set against the technology's revolutionary aspirations. In 2008, stain-resistant trousers had been, for one commentator, the best the technology had to offer in terms of “real life” products for half a decade, aside from early commercial successes in semiconductor applications.⁸¹

Despite the lack of clarity regarding nano's market, it appears that the explosion in nano sales has not happened, “at least not at the projected levels of the original NNI business model.”⁸³ In addition to the worldwide financial slowdown, analysts point to a handful of challenges before nano can deliver the promised profits:

- Far horizons: Nano's revolutionary or ‘disruptive’ applications will require a long haul in R&D before big money can be made.⁸⁴ The nature of much of the revolutionary nano research agenda is characterized as ‘high-risk, high-reward’ – one reason it tends to sit outside private sector investment horizons and budgets.⁸⁵
- Mass production, scaling up and quality control are fundamental for cost-effective nanomaterials that the wider manufacturing industry will use. At present, nanomaterial production is typically a low-volume affair, generating considerable waste and byproducts making some nanomaterials, at least, prohibitively expensive.⁸⁶ The nanomanufacturing industry, according to an OECD assessment, “is still in its infancy and characterised by [...] lack of infrastructure equipment for nanomanufacturing, and few efficient manufacturing methods especially in bottom-up approaches to nanoscale engineering.”⁸⁷

“Bulk Nano?” – A New Commodity Exchange for Nanomaterials

According to the web site of the Integrated Nano-Science and Commodity Exchange (INSCX), a formal commodity exchange trading platform for trading a wide range of nanomaterials will be launched in Europe and the United States early in 2011.⁸² Based in the UK, the exchange will cover basic raw materials as well as finished products. The goal of the exchange “is to be the focal point of the emerging world trade in nanomaterials,” assuring “quality and competitive prices” for nanomaterials.

- Technologies without a product: According to Lux Research, nanotech is widely seen as “a technology without a product.”⁸⁸ An advisory group to the EU points to the “need for clear market drivers, for example, industrial problems that can be solved by the application of nanotechnologies.”⁸⁹ Without governments, investors and the like lining up to purchase early stage products, “disruptive nanotechnologies will primarily remain as science projects and underfunded start-ups.”⁹⁰
- Wider industry wariness of nanotech: Stimulating industries to incorporate nanotech in their product lines has proved difficult. The news that in many cases, nanoproducts “will be only marginally profitable” hasn't helped.⁹¹ More significantly, Lloyd's of London, the OECD and re-insurer SwissRe all report wider industry concerns about nanosafety, regulatory uncertainty and public perceptions.⁹² Companies considering using nanomaterials in their product lines are advised to be especially diligent to avoid liabilities down the road.⁹³ President Obama's science advisors also point to industry's reticence for fear of a consumer backlash.⁹⁴ Despite reportedly holding the largest stack of patents, Procter & Gamble, for example, appears to be holding off on nanotech because of potential liabilities.⁹⁵

Despite reportedly holding the largest stack of patents, Procter & Gamble, for example, appears to be holding off on nanotech because of potential liabilities.

The Price of Tubes

Governments, universities and companies are proposing to use carbon nanotubes in every product from the mundane to the Martian, including fertilizers, home cleaning products, drug delivery systems, combat gear, fuel cells and space elevators.

To begin generating real profits, nanotubes will need to become affordable. Prices have been reportedly going down – one source describes ‘nosedives’ of 43% for multiwalled tubes (MWNTs) since 2005 and 33% for single-walled tubes (SWNTs).⁹⁶ Another commentator reports prices dropping “by three orders of magnitude” over the past few years.⁹⁷ Lux Research predicted in late 2009 that the price for standard grade MWNTs will drop to approximately \$50 per kilogram at some unspecified point in the future,⁹⁸ while another estimate predicted the price would drop to \$30/kg-\$40/kg in the next three-four years.⁹⁹ The industry will have to get cracking to meet those projections. In 2004, the price of carbon nanotubes was predicted to fall to \$284/kg by 2007.¹⁰⁰ That has yet to happen, even for low-grade multi-walled tubes.

Cheap Tubes Inc., the bargain-basement retailer for CNT in the U.S., is on a mission “to help usher in the Carbon Nanotubes-CNTs Application Age.” In November 2010, Cheap Tubes offered multiwalled nanotubes for as little \$600/kg (for non-functionalized varieties) and ~\$1,500/kg for high purity tubes.¹⁰¹ (Bargain shoppers may be able to get even cheaper tubes from the Hanoi-based Institute for Material Sciences if the half-price sale they announced in 2009 is still on.¹⁰²)

Industrial demand is currently low, with applications relegated to the low hanging ‘fruit-of-the-loom’ until the industrial sector shows greater interest.¹⁰³ The potential for some types of tubes to behave like asbestos fibres has, rightly, not helped whet the appetite of potential buyers. In addition, hefty technological hurdles stand in the way of scaling up nanotube production for widespread commercial use.¹⁰⁴ Although a number of companies have boosted production capacity (Bayer and Arkema, among others), manufacture of multi-walled nanotubes – the most widely used commercially – is generally operating at “single-digit percent utilisation.”¹⁰⁵

Part 3. Jobs, Jobs, Jobs: But Do We Want Them?

Enthusiastic characterizations of nanotech as job creator abound. Forecasts from the turn of the millennium include the National Science Foundation’s estimate of two million new workers by 2015¹⁰⁶ (or seven million assuming that for each nanotech worker another 2.5 positions are created in related areas).¹⁰⁷ What the OECD labels “even more optimistic forecasts” are from Lux Research, which estimates that 10 million manufacturing jobs related to nanotechnology will emerge within the next four years.¹⁰⁸

In any case, attempts to put numbers on the current nano workforce are rare. As with market analysis, assessments related to employment are difficult due to lack of government oversight of nanotech R&D and commercial activity as well as the lack of a consensus definition for nano. In 2008, Cientifica estimated that 35,000 researchers in the worldwide chemicals sector were engaged in nanotech R&D.¹⁰⁹ The German government put the number of people involved in nano R&D and commercial activity within its borders at 63,000.¹¹⁰ An OECD review takes the position that there is “a large discrepancy” between the projections and the state of the workforce.¹¹¹

In short supply, too, are assessments of the jobs that nanotech may take away – particularly in countries of the global South – so net job creation is not known. In a 2005 report prepared for the Geneva-based South Centre, *The Potential Impacts of Nano-Scale Technologies on Commodity Markets: The Implications for Commodity Dependent Developing Countries*,¹¹² ETC Group provided a preliminary look at the potentially devastating socio-economic impacts if nano’s promise to up-end traditional markets is realized and governments are not prepared. The report focused on rubber, platinum and copper because those markets have been identified as likely to be dramatically affected by the introduction of new nanomaterials and because the materials are currently heavily sourced from the global South. More recently, social scientists Guillermo Foladori and Noela Invernizzi have examined nano’s implications for labour and development, focusing on Latin America.¹¹³



What About Worker Safety?

In 2000 – pre-nanotech boom – an estimated 2 million people were already being exposed to nanoscale particles at work in the United States (e.g., in by-products of diesel combustion, sanding or abrasion of metals, wood, plastic).¹¹⁴ Production, handling and use of engineered nanoparticles have created new venues for workplace exposure, with poorly understood consequences. The most dramatic case to date involved seven female workers in China who were exposed to polyacrylate (a polymer/plastic ingredient in an adhesive paint) containing nanoparticles. All of the women became sick with breathing problems; two of them died. A team of Chinese scientists examined the lung tissue of all seven women, found nanoparticles lodged in cells of the lungs and concluded, cautiously, that the seven cases “arouse concern that long-term exposure to some nanoparticles without protective measures may be related to serious damage to human lungs.”¹¹⁵

The publication of the Chinese study in the peer-reviewed *European Respiratory Journal* in 2009 sparked a storm of speculation on its implications, with several commentators taking the “precautionary” position that unknowns about the specific workplace conditions, including the absence of worker protections, cast doubt on the usefulness of the study and prevented conclusions from being drawn.¹¹⁶ No one, however, ventured to categorically exonerate nanoparticles.

Workers (and consumers), of course, do not have the luxury of waiting for experts to come to a consensus on the health effects of nanoparticle exposure. In 2007, IUF (International United Food, Farm, Hotel workers) called for a moratorium on commercial uses of nanotechnology in food and agriculture until they could be shown to be safe and

ETUC (European Trade Union Confederation) has also demanded the application of the Precautionary Principle. United Steelworkers International (North America) has called for regular medical screenings of workers exposed to nanoparticles. In 2007, a broad coalition of civil society, public interest, environmental and labor organizations published a set of *Principles for the Oversight of Nanotechnologies and Nanomaterials* grounded in the Precautionary Principle.¹¹⁷

“We have only scratched the surface of nanotechnology’s potential to create jobs.”

– U.S. Congressman Dan Lipinski, pledging support for nanotechnology at the 8th annual NanoBusiness Conference, Chicago, September 2009
Perhaps Rep. Lipinski’s most memorable endorsement of nanotech came in April 2009 at the NanoNow Science and Technology Leadership Forum, hosted by the University of Chicago:

“I have drunk the nanotech kool-aid. I believe it’s the next Industrial Revolution.”

Calls to make nano products liable as part of a regulatory regime have been issued by ETUC and the European Parliament’s Committee on Employment and Social Affairs, among others.¹¹⁸

Part 4. Nano in the Age of Crisis

Financial Crisis

The global recession may have deflated an industry prone to 'bubbling,' but the financial crisis hasn't been all bad news for nanotech. It has provided a stimulus to increase government funding in some areas, drawing on the theory that investment in innovation is a sure route out of recession. In India, government officials cast nanotech as "the answer for future recessions as it helps in reducing wastage of material and enhancing quality by almost 40 per cent."¹¹⁹ In the U.S., nano has been heralded as the "rejuvenating fuel in the economy's engine" and the "road out of the recession."¹²⁰ Government stimulus packages have responded accordingly, particularly in energy and environment-related nano R&D. Indeed, according to one industry member, the U.S.'s alternative energy policy "cannot advance without the successful commercialization of nanotech."¹²¹

The American Recovery and Reinvestment Act (ARRA) directed an additional \$140 million toward nanotechnology research and infrastructure investments in 2009. That included a \$40 million cash injection to the Department of Energy for nano R&D, which comes on top of funding increases to the Department.¹²² The Obama administration has proclaimed nanotech "a very powerful tool for achieving some of the president's goals such as accelerating the transition to a low-carbon economy and reducing death and suffering from cancer."¹²³

The European Union has come up with a €200 billion Recovery Plan, with three public-private-partnership R&D programs aimed at accelerating progress in energy efficient cars and buildings and future manufacturing. (The programme will run on funds redirected from FP7 nano-manufacturing budgets.¹²⁴)

Climate Crisis and Peak Oil: Nano "Cleantech" to the Rescue

The nano industry has leapt onto the Cleantech (hybrid)bandwagon with both feet. The convergence of government support of nanotech and venture capital funding of cleantech is a boon for the industry as nanotechnologies are claimed to provide "clean" solutions through miniaturization (reduced raw material requirements), reduced energy usage, greater efficiencies in solar energy generation (i.e., photovoltaics), biofuels, greenhouse gas transformation and use and greater capacity in water and bioremediation.

Miniaturization has already been achieved in certain commercial applications (particularly in ICT), but for the rest, nano's role in "clean technologies" remains aspirational and contingent. Lux Research estimated cleantech would account for just 1.8% of the market value that nano is expected to earn by 2015.¹²⁵ In 2007, Cientifica estimated that 0.00027% could be shaved off emissions by 2010 using currently available nanotech, but that future revolutionary applications will result in fewer greenhouse gas emissions.¹²⁶

Big NanoNations, such as USA, Germany and Japan, are said to be leading the charge in cleantech investment. Signature initiatives in the U.S. federal budget proposal for 2011 include Nanotechnology Applications for Solar Energy (a joint agency initiative to receive \$51 million) and Sustainable Nano manufacturing (\$23 million), which is to focus on "high-speed communication and computation, solar energy harvesting, waste heat management and recovery, and energy storage."¹³⁵

The rush into nano-cleantech investment is of particular concern because there is, as yet, little to support the assertion that nano is inherently clean.

What Exactly Is Cleantech?

For some, cleantech is a fundamentally new approach that “addresses the roots of ecological problems with new science, emphasizing natural approaches such as biomimicry and biology.”¹²⁷ For others, the brand is like a smokestack scrubber – a laundering service for problematic technologies (such as nuclear, coal) that could make business-as-usual ‘sustainable.’ Rather than referring to a specific set of technologies, the term cleantech almost always points to a new market opportunity that has emerged from the eye of the perfect storm created by climate change and peak oil.

There appears to be a consensus within industry that cleantech refers to applications that “add economic value compared to traditional alternatives.”¹²⁸ It has been described as “the largest economic opportunity of the 21st century”¹²⁹ and a “natural fit” between economic growth and projected environmental gains.¹³⁰ At the moment, however, cleantech is effectively a fundraising slogan. The mere announcement of government research grants for cleantech projects including nano-pesticide production was claimed to have made the Canadian economy “instantly cleaner.”¹³¹

Gift Horse Dental Exam: Should civil society welcome governments’ new emphasis on cleantech investment and the effect that funding incentives may have on the orientation of some nano R&D?

The rhetoric is certainly seductive. After all, “who wouldn’t want a technology that is ‘safe by design,’ that can deliver clean water to billions, or enable consumption without negative effects on ourselves or our environment?”¹³²

Included under the cleantech banner is nuclear power generation – the technology that was to provide electricity “too cheap to meter” but persists as the technology too difficult to decommission and too difficult to clean up after. That should be sufficient to encourage critical evaluation of the cleantech concept. But the rush into nano-cleantech investment is of particular concern because there is, as yet, little to support the assertion that nano is inherently clean, including the accumulating data on the health effects of exposure to nanomaterials and the absence of lifecycle analyses.

The nano-cleantech hype also casts a long shadow in R&D investment and blocks out the sun on a range of other competing strategies and approaches with the potential to deliver less risky alternatives. Consultants to the UK Government advised that nano applications in energy efficiency and generation due to come online in the longer-term may offer significant gains, but that these may not necessarily outperform competing technologies and “they probably underestimate technological advances in non-nanotechnological innovations.”¹³³ “It is important,” says one commentator, “that we do not choose too early the winners and losers among technologies.”¹³⁴

Fuel cell technology involving nano alone is attracting \$1 billion per annum investment in International Energy Agency (i.e., OECD) countries.¹³⁶ A 2008 United Nations University report listed 70 hydrogen fuel cell projects in varying stages, from R&D to pilot commercialization.¹³⁷

The EU’s Seventh Framework Programme (2007-2013) embraces nano cleantech and includes a €55 million fund to produce biofuels.¹³⁸ Among the projects funded is ROD SOL – a three-year, €4 million project to boost solar power efficiency using inorganic nano-rod based thin-film solar cells.

In the U.S., a new lobby launched this year to leverage more funds for nano cleantech. Pitched from the politically potent intersection of energy security and national security, the NanoAssociation for Natural Resources and Energy Security (NANRES) is a self-described group of “forward-thinking leaders” with a shared interest in bringing nano to market. The lobby is on a member-recruitment drive, but the chair has already been supplied by arms manufacturer Lockheed Martin and the CEO by the Washington-based thinktank, Center for a New American Security. The group is not short on optimism: “Nanotechnology is the answer that will empower, strengthen, and secure our nation’s energy security condition.”¹³⁹

Part 5. Nano Neo Governance: Tiny Technologies / Big World

At the close of the first decade of government pledges to govern nanotechnology responsibly, nano-specific regulation remains rare, and regulatory scrutiny of nanomaterials rarer still. However, patience is running thin for the laissez-faire approach and governments may not be able to extend the regulatory holiday much longer.

Knowing What to Regulate Would Be a Start

What is Nano?

The conventional “100 nm” definition of nano – ascribing to the theory that unique properties occur only in substances below that size threshold in at least one dimension – has had considerable play since the U.S. National Nanotech Initiative adopted it in 2001. Yet, from a toxicological perspective, it would appear to be an arbitrary limit. According to a leading nanotoxicologist, “The idea that a 102 nm particle is safe and a 99 nm particle is not is just plain daft...”¹⁴⁰ At the beginning of 2009, the European Union’s Scientific Committee on Emerging and Newly Identified Health Risks (SCENIHR) stated that “the definition of what is ‘nano’ is still under debate.”¹⁴¹

Not everyone agrees. German chemical giant Evonik, for example, claims that not only is there no quantum action above the 100 nm mark, but also that 100 nm is a generous threshold.¹⁴² In October 2010, the European Commission put forward its draft definition – citing 100 nm as the upper size threshold – to a public consultation. Earlier in 2010, the UK House of Lords explicitly rejected the 100 nm threshold and recommended that regulatory coverage of nanoparticles should encompass anything under 1,000 nm.¹⁴³ The Swiss Federal Office for Public Health and the Federal Office for the Environment recommend that 500 nm be used as the upper limit in order to avoid excluding any nano-specific risks.¹⁴⁴ Across the Atlantic, U.S. federal agencies differ. The Food and Drug Administration (FDA) has chosen not to place size limits on nano in order to avoid arbitrary cut-off points.¹⁴⁵ Trade unions and civil society organizations have also been calling for official definitions to reflect developments in scientific understanding, both in terms of size and other physical properties.

The UK Soil Association has called for an upper limit of 200 nm; Friends of the Earth believes that 300 nm is an acceptable threshold.¹⁴⁶

Size is not the only relevant factor determining whether a substance exhibits quantum effects. Other factors include shape/morphology, chemical composition, solubility, surface area, particle concentration, degree of bio-degradability and bio-persistence and the presence of impurities such as residual catalyst.¹⁴⁷ Then there is the question of nanoparticles that form aggregates (collections of strongly bound particles) or agglomerates (collections of weakly bound particles) larger than 100 nm. At present these do not appear to fall within any regulatory frame, although as the EU’s SCENIHR stated, clusters of nanoparticles are still ‘nano’ from a risk perspective.¹⁴⁸

Where is Nano?

In addition to the definitional quandary, governments are hard pressed to identify which nanomaterials are on the market within their borders.

It is not simply that detection-technology has yet to make its way to the light of day. Nor is it that legislation does not provide regulators with a mandate to require information from producers or from companies incorporating nanomaterials into their products. Industry is currently playing a large-scale game of hide-and-seek, claiming “confidential business information” and leaving governments either receiving favours from NGOs that have compiled product inventories, or at the mercy of industry consultants who would seem to have the inside track. The latter is an expensive avenue, as the European Parliament knows. In 2006, a parliamentary committee attempting to pinpoint consumer nanoproducts on the European market was stymied by the refusal of food companies to share such information.¹⁴⁹ The committee was forced to turn to industry but had not budgeted for the expensive consultancy reports and had to rely on the free summaries.¹⁵⁰ Now the European Commission appears to have decided that it should have some grasp on what is on the market and has hired some industry guns to scout the territory.¹⁵¹

Nano Regulation in Europe: Tiny Steps in the Right Direction?

Or REACH: No Data, No Regulation

The Registration, Evaluation, Authorisation and Restriction of Chemical Substances, or REACH, Directive is the primary regulatory framework for nanomaterials in the EU. In spirit, the directive is commendable with its overarching operating principle being, “no data, no market.” It also transfers the burden of proof of safety to chemical manufacturers and processors. So far, however, the EU has managed to assess only 3,000 of the 30,000 bulk chemicals in common use¹⁵² and there are doubts about the capacity of the new European Chemical Agency (ECHA) to bring to life the 849-page REACH Directive,¹⁵³ particularly given the resourcing woes and revenue shortfalls predicted.¹⁵⁴ Due to lack of nano-specific provisions (despite a last ditch effort by the European Parliament’s Environment Committee¹⁵⁵), REACH’s guiding principle appears to have morphed into “no data, no regulation,” and nanomaterials have passed through the directive largely unregulated since its introduction in 2006.

End of the Regulatory Holiday?

REACH’s de facto exemption for nanomaterials is at odds with the Commission’s pledge that “appropriate ex ante assessments should be carried out and risk management procedures elaborated before ... commencing with the mass production of engineered nanomaterials.”¹⁵⁹ The Commission’s view that “Europe has been ‘talking with one voice’” on nano is stirring but not widely shared.¹⁶⁰ Trade unions, civil society, public science institutions and EU scientific committees¹⁶¹ have called for action.

There have also been rumblings from member states. In comments that outraged the food industry, an Austrian Ministry of Health official expressed frustration with the Commission for placing the burden of dealing with nanofoods on member states with so little available information on their safety. The Ministry’s position: there should be an EU-wide moratorium on the use of nanoparticles in food until appropriate methods for identification and risk assessment are developed.¹⁶²

Regulatory Loopholes: Nanotubes

Due to the lack of distinction in name or chemical formula between carbon’s nanoscale and bulk form, confusion has abounded even after efforts to make carbon nanotubes subject to active REACH scrutiny.

After a reportedly tense exchange between EU member states and the European Commission in 2008,¹⁵⁶ the Commission removed nano-scale carbon and nano-scale “graphite” from a list of exempt substances under REACH because “insufficient information is known about these substances for them to be considered as causing minimum risk because of their intrinsic properties.”¹⁵⁷

This does not appear to have caught on with some members of the industry. While one industry group is seeking to have CNTs registered as distinct chemicals, another – led by industry giants such as BASF and Arkema – was reportedly planning to register the nanomaterials as a form of bulk graphite so that a separate registration dossier for the nanoscale material would not be required.¹⁵⁸

Sweden used its Presidency of the Council of the EU (the last half of 2009) to crack the whip on nano regulation, with a five-point plan to “close the knowledge gap on nanosafety; update test methods; encourage sustainable nanotech; pursue mandatory reporting; and strengthen international cooperation.”¹⁶³ Belgium’s Minister for Energy, Environment, Sustainable Development and Consumer Protection made it clear in mid-September 2010 that Belgium’s EU Presidency would continue the momentum toward nano regulation. The Minister put forward five proposals: define the “obligation to inform the consumer of the presence of nanomaterials in consumer products;” ensure traceability, which entails maintaining a register of nanomaterials; identify “the most appropriate regulatory path at the EU level for risk evaluation and management;” encourage Member States to take responsibility and formulate “integrated national strategies and concrete measures in favour of risk management, information and monitoring;” and regulate nano-product claims.¹⁶⁴

*“Those
[current] rules are
about as effective in addressing
nanotechnology as trying to catch
plankton with a cod fishing net.”*

– European Parliament, *Draft Report on
Regulatory Aspects of Nanomaterials,
Committee on the Environment,
Public Health and Food
Safety*, 2009.

In April 2009, with an overwhelming majority, the Members of the European Parliament delivered a stinging critique of the Commission's review of the adequacy of nano regulation.¹⁶⁵ MEPs disputed the Commission's view that current legislation is sufficient to address nano risks; they called for mandatory reporting of all nanomaterials, including mandatory chemical safety reports; and insisted that nanomaterials that pose a risk to workers or consumers not be given commercial approval. Finally, the Parliament put the Commission on notice: it rejected the Commission's proposed timeframes for regulatory review¹⁶⁶ and demanded an official register of nanoproducts (with safety assessments) and labeling of consumer nanoproducts.¹⁶⁷

The Commission pledged to get back to the Parliament by 2011 with the intention of presenting a report on types and uses of nanomaterials and their safety.¹⁶⁸ And in a rare reality check, the Commission itself gave the EU the lowest score ("relatively little progress") for its performance in promoting measures to minimize worker, consumer and environmental exposure to nanoparticles as well as for its lack of support for research into such exposure.¹⁶⁹

Nanocosmetics: Regulatory Touch-Up

That Europe is inching forward on regulating nanocosmetic ingredients is largely due, at the institutional level, to the European Parliament's persistence.¹⁷⁰ Insiders say that stalling tactics on the part of the industry when asked to provide information helped firm Parliamentarians' resolve, resulting in labeling requirements and a public register by 2014. Still, the new European Union regulation on cosmetics is rather timid and has received, at best, cautious welcome from civil society organizations such as the European Consumers Union:¹⁷¹ only biopersistent or insoluble nanocosmetic ingredients are addressed; colorants, UV filters or preservatives are exempt; and while manufacturers must provide safety data, regulatory risk assessment does not follow as a matter of course. Finally, the directive does not come into effect until 2013.

(European Parliamentarians are not the only policymakers the cosmetics industry has kept waiting. The industry exasperated both the UK Royal Society and the EU's Scientific Committee on Consumer Products (SCCP), which requested a dossier on zinc oxide nanoparticles, widely used in cosmetics. It took the industry three years to submit the requested information.¹⁷²)

Nanofoods Still on the Shelf

In March 2009, a nearly unanimous European Parliament (658 votes of 684) echoed the Austrian Health Ministry and called for a moratorium on the commercialization of nanofoods. Parliamentarians called for changes to the Novel Foods Directive introducing nano-specific risk assessment methods and insisted that nanofoods not be allowed onto the European market "until such specific methods have been approved for use, and an adequate safety assessment on the basis of those methods has shown that the use of the respective foods is safe."¹⁷³ In response, the Council of Ministers (in this case, European agricultural ministers) took the low road on nanofoods. The Ministers agreed that nanofoods be explicitly regulated and that nano-specific test methods are required. However, the Council balked at the idea of a moratorium until such measures are in place and rejected the Parliament's proposals for mandatory labeling.¹⁷⁴ In July 2010, however, the Parliament, in a second reading of the Novel Foods Directive, maintained its call for a moratorium on nano foods.¹⁷⁵ In November, the Commission delivered its opinion, stating that it "can accept the principle of a mandatory and systematic labelling of all foods and food ingredients containing nanomaterials," but once more rejected the call for a moratorium, stating that current methodologies for risk assessment are valid for nano foodstuffs.¹⁷⁶

Regulating Nano's eHazards?

In June 2010, the Parliament's Committee on the Environment, Public Health and Food Safety proposed a ban on the use of nanosilver and long, multi-walled carbon nanotubes in electrical and electronic equipment on the basis that these constitute "a major hazard to people and the environment in the phases of production and/or use and recovery."¹⁷⁷ The Committee also proposed that electronic goods containing other types of nanomaterials be labeled. The measures would be implemented under a revision of the EU's Restriction of Hazardous Substances (RoHS) Directive – a final text is unlikely before the end of 2011.

The United States:

Giant Investor / Nanoscale Regulator

While several federal government agencies are responsible for regulating tiny tech, most are struggling with resourcing, regulatory mandate and anti-regulatory sentiment. Life-long environmental policy insider J. Clarence Davies has assessed the regulatory framework with respect to nano as “weak and inadequate” overall.¹⁷⁸

The primary legislation for regulating nanomaterials – the Toxic Substances Control Act (TSCA) – appears unequal to the task on several fronts. Although responsible for reviewing every chemical, the Act allows the Environmental Protection Agency (EPA) to require only the barest of details from producers. The burden of proof lies squarely with the regulator, which can require safety data from operators only if it can prove that there is “an unreasonable risk” to humans or the environment¹⁷⁹ or if the chemical will be produced in large quantities (measured in tons). Finally, it falls to the EPA to demonstrate that the regulation is the least burdensome option for risk management.¹⁸⁰ Given that by the mid-1990s, the EPA had managed to review only 1200 (2%) of the 62,000 chemicals in existence before 1979,¹⁸¹ there is little capacity to begin to address new applications coming over the horizon.¹⁸² The EPA reports that between 2005 and 2009, it received more than seventy “new chemical notices” for nanomaterials from product manufacturers.¹⁸³

Regulation was cast a minor role in the approach adopted by the EPA (set out in its 2007 Nanotechnology White Paper), with its preoccupations being to promote ‘green’ nano manufacturing and to work in partnership with the industry to promote nano stewardship.¹⁸⁷ However, there have been signs of regulatory life at the EPA of late. A comprehensive review of toxic substance legislation has resulted in a set of principles, which, though still banging on the drums of “sound science” and its ideological trappings, does begin to nudge the burden of proof to industry.¹⁸⁸ It proposes making stricter criteria for claiming confidential business information, and proposes giving the EPA a clearer mandate and more funds.

Nothing New About Nano?

Claiming newness has its downsides. While a plus for investment and IP, it can be a stigma in risk perception and regulation. Accordingly, the message for public consumption is that nano is nothing new. This draws upon a time-honoured tradition of emerging technology PR: just as the nuclear industry argued that there is background radiation everywhere (i.e., nuclear power generation is natural), and the agricultural biotechnology industry explains that humans have been modifying plants for millennia (i.e., genetic engineering is as old as agriculture), the nano industry and its associates are making us aware of the nano world around us. According to the European food industry alliance (CIAAA), “naturally occurring nanoparticles have always been present in food such as milk and fruit juice,”¹⁸⁴ while the South African government is naturalizing its nano agenda on the basis that “nano-assembly by self-replication at a molecular level is as old as Mother Nature.”¹⁸⁵ And in an attempt to ward off further action by the U.S. Environmental Protection Agency on nanosilver, the industry’s Silver Nanotechnology Working Group (SNWG) now holds that the EPA has been successfully regulating nanosilver for years.¹⁸⁶

After some squirmishes with industry, the Agency issued new Significant New Use Rules (SNURs) for two types of carbon nanotubes.¹⁸⁹ In addition, use of protective gear is now mandatory in workplaces using or manufacturing siloxane-modified alumina and silica nanoparticles.¹⁹⁰ The Agency has also taken to prosecuting companies making false claims in relation to nanoproducts. (In 2008, it sued a California company for unsubstantiated claims about the antimicrobial coatings on computer gear¹⁹¹ and announced legal action in 2009 against similar claims by a footwear company using nanosilver.¹⁹²) And following the release of a report commissioned by the Agency on nanosilver hazard evaluation, there are rumours that the Agency will be taking further regulatory action on nanosilver products.¹⁹³

Nanosilver Spin Cycles

The EPA initially rejected civil society organizations’ petitions that Samsung’s “Silvercare” washing machines, which release silver nanoparticles into the wash,¹⁹⁹ be regulated as pesticides – a call the agency initially dismissed on the basis of a legal technicality (a machine is a device, so therefore could not be a pesticide).²⁰⁰

Eventually, the agency came around and determined that the nanosilver generated in Samsung’s washer did indeed classify as a pesticide.²⁰¹

Further action is also being considered, such as:

- Reviewing the legal distinction between a nanoscale material and its bulkform¹⁹⁴
- Requiring safety testing for multi-walled carbon nanotubes¹⁹⁵
- Requiring pesticide manufacturers to notify where nanomaterials are used in their products¹⁹⁶
- Requiring safety testing for certain multi-wall carbon nanotubes and nanosized clays and alumina¹⁹⁷ and
- Making mandatory reporting of nanomaterial production and use.¹⁹⁸

The Occupational Safety and Health Administration (OSHA), a part of the Department of Labor, is EPA's counterpart with responsibility for the regulation of occupational human health risks. As with the EPA, the burden of gathering data and risk assessment is placed on the agency, not the employer. Without adequate funding, OSHA is equally hamstrung in carrying out its mandate and employers "have little incentive to reveal toxicity or exposure information."²⁰² The result is a process of standard setting "so slow that thousands of chemicals have no defined occupational exposure limits."²⁰³ Given this state of affairs, nanomaterials are not likely to become an exception.

Can't - or Won't?

The Food and Drug Administration (FDA) has rejected labeling of nanoproducts under its jurisdiction despite acknowledging that products may go to market with no regulatory scrutiny and may come to the FDA's attention only if particular product claims are made. Its justification is that not all nanomaterials will be hazardous.²⁰⁴ The Agency confirmed it is not ruling out making nanomaterials eligible for GRAS (Generally Recognized as Safe) status. The agency says that while it would be an uphill battle right now for industry to successfully argue the case for GRAS with the current lack of understanding about nanosafety, "two years down the line, it could be a slam dunk."²⁰⁵

The FDA has rejected labeling of nanoproducts under its jurisdiction despite acknowledging that products may go to market without regulatory scrutiny and may come to the FDA's attention only if particular product claims are made.

Meanwhile dietary supplements and cosmetics remain unregulated. The FDA has little or no regulatory authority over either: dietary supplements do not require FDA approval and the agency has no legal mandate to require monitoring or testing and no authority to recall unsafe products. Again, the burden of proof for demonstrating potential harm lies with the agency, which is forced to rely on voluntary industry compliance.²⁰⁶ By the FDA's own assessment, it "cannot fulfill its mission because its scientific base has eroded, its scientific workforce does not have sufficient capacity and capability and its information technology infrastructure is inadequate."²⁰⁷ The Nanotechnology Safety Act of 2010, which was introduced to the legislative circuit early this year, proposes a clear mandate for FDA to investigate food safety (along with a five-year \$125 million research budget) and might go some way to addressing such constraints. But it does not begin to tackle the agency's weak regulatory mandate.

U.S. Nanotech Regs: An Oversight?

There is no official cross-government regulatory coordination. The elusive federal Nanotechnology Policy Coordination Group may aspire to it, but as its meetings and activities are not public, what exactly it's coordinating is anyone's guess.

One publicly available output from the group is a toothless set of principles to guide federal policies for environmental, health, and safety oversight of nanotech.²⁰⁸ If oversight is the game, then the document is on track: the environment and public health are largely overlooked. The group couldn't bring itself to use the P word (precaution) and its focus is on getting the technology out the door.

The Consumer Product Safety Commission (CPSC),²⁰⁹ sister regulator to the FDA, is responsible for all non-food and drug consumer products – around half of the products currently known to be on the market. Due to its narrow legislative mandate and lack of resourcing,²¹⁰ the CPSC also relies on the cooperation and responsiveness of industry, which tends to take its sweet time.

An investigation by civil society organization Public Citizen found that over the period 2002-2007, it took companies an average 993 days to notify the Commission of product defects (that is, 992 days longer than required by law). Against this background, there is little hope for vigorous regulatory scrutiny of nanoproducts. In addition to being understaffed, the Commission has in the past been handed the small change from the vast federal nano budget²¹¹ – just \$2 million for nanosafety research in 2011.²¹²

Federal Inaction Prompts State Governments

Federal agency assurances that they are “ahead of the curve, or at least riding the wave”²¹³ in managing nanotech are evidently not convincing state governments. California is one of several U.S. states beginning to take legislative action on nano as a result of regulatory torpor at the federal level.²¹⁴ At the beginning of 2009, California’s government put carbon nanotube manufacturers on notice, giving them one year to provide information on their use of CNTs, workplace and environmental monitoring procedures, occupational safety and ecotoxicity over the lifecycle, waste-handling and disposal procedures.²¹⁵ At year-end, 24 companies had responded to the call, and two were listed as having missed the deadline.²¹⁶ The state has also sought information, on a voluntary basis, from manufacturers using reactive nanometal oxides (such as aluminum oxide, silicon dioxide, titanium dioxide, and zinc oxide) as well as nanosilver, nano zerovalent iron, and cerium oxide. Since 2006, nanomaterials have been classed as hazardous materials under the city of Berkeley’s hazardous material reporting legislation (apparently in response to an alleged lack of safe handling protocols at University of California at Berkeley and the Lawrence Berkeley National Laboratory).²¹⁷ The city now requires all nano manufacturers to provide a “written disclosure of the current toxicology of the materials reported, to the extent known, and how the facility will safely handle, monitor, contain, dispose, track inventory, prevent release and mitigate such materials.”²¹⁸ Wisconsin legislators have formed a Special Committee to explore the establishment of a state nanomaterials registry.²¹⁹ The Massachusetts Department of Environmental Protection, the Washington State Department of Ecology, and the states of Pennsylvania and South Carolina have all identified nanomaterials as emerging contaminants of concern.²²⁰ Collectively, state governments have also written to the federal government urging that nanosafety research funding match funding to develop uses for tiny tech and seeking a seat at the decision-making table alongside the federal government.²²¹

Nano’s Regulatory World Pass

Fears that nanotech will be regulated out of existence²²² are difficult to take seriously. NanoNations have taken baby steps if they’ve moved at all. Further, much regulation will remain toothless until nanosafety research begins to yield results that can be used to properly assess products. Nanobiotechnology, meanwhile, remains a regulatory orphan.

The extent to which commercial nanotech activity is now trackable and tracked, assessable and assessed, and regulated does not square with pledges governments have made. The justifications for regulatory inaction are multiple and ultimately contradictory: there is not enough information to develop nano-specific regulation; regulation will stifle development; existing legislation is sufficient; there is not sufficient evidence of harm to warrant regulation.

The European Union and the U.S. are not alone in giving nanotech a free pass:

Korea, ambitious nanotech investor and home to multinationals investing heavily in nanotech, has only lately begun to investigate what a regulatory framework would look like.²²³

Italy has at least been candid. Although there is general political agreement about the need to do something, nothing has been done: “the actual situation in the research and regulatory area on health and safety aspects of nanomaterials is characterized by a general scarcity of initiatives at both public and private levels.”²²⁴

South Africa also admits that risk assessment research, and presumably risk assessment, is “yet to take root” although worker exposure and commercialization are on the rise.²²⁵

India’s rollout of nanotech has been described as “a free for all” due to the lack of regulation.²²⁶ Particular concern has been expressed about lack of regulatory capacity with respect to pharmaceuticals,²²⁷ concerns exacerbated by the country’s reputation as “the world’s pharmaceutical guinea pig”²²⁸ following regulatory concessions. At the beginning of 2010, the government announced that a Nanotechnology Regulatory Board, appointed by the state nano promotional programme (the Nano Mission), will be formed and a regulatory agenda developed.²²⁹

Part 6. Voluntary Schemes: Discount Governance

Voluntary schemes and self-regulation are central to the governance culture many governments, in consultation with industry, have put forth as the responsible way to usher in the nanotech revolution.²³⁰ The political theory in vogue is that soft law is well suited to the early days of a new technology when information is scarce and changeable: adaptable instruments can tide a society over while information-intensive regulation and mandatory measures can be developed. “Hands off” governance – where governments agree not to coerce and industry agrees to cooperate – is held up as the essence of a responsible and mature innovation community. Its attractions for governments not wanting to burden their fledgling industry with tasks they claim could hamper performance in the technology race are obvious.

Explained as a move away from top-down regulation to a system where governments set the parameters within which industry regulates itself, the new approach to governance is described as a shift from “powers over” to “powers to” operators.²³⁶ That formulation is an upbeat apologia for self-regulation: instead of governments legislating what can and can’t be done, governments leave it to “the social ecosystem” to behave in such a way as to produce “desired outcomes.”²³⁷

A host of government-conceived and industry-crafted soft law schemes to foster nanotech have emerged in recent years. Below, we look at two types: reporting schemes and codes of conduct.

Uncle Sam Wants You! . . . To Buy Nanotech

Supporting the commercialization of nanotech by the private sector is an explicit goal of public funding, though not a topic of public debate:

- One of the four overarching goals of the U.S. government’s National Nanotechnology Initiative is “to foster the transfer of new technologies into products for commercial and public benefit.”²³¹
- Germany’s federal nanotech action plan aims to “[b]ring nanotechnology out of laboratory and into industry.”²³²
- Under its Nano Mission, India’s government intends “[t]o catalyze Applications and Technology Development Programmes leading to products and devices.”²³³

At first blush, the idea that product commercialisation is one avenue by which the wider community enjoys the benefits of the use of public funds in technology development seems reasonable. But with governments now in the business of product commercialisation, traditional boundaries between government and the commercial sector – already compromised by industry’s sway over public policy – are further blurred. As far as nano is concerned, governments are the industry, and this creates problems for the business of governing. State interest in product commercialisation – like the recommendation that U.S. federal agencies such as the FDA, whose role is assuring food safety, should “help accelerate technology transfer to the marketplace”²³⁴ – reflects an irreconcilable conflict and “a hidden developmental state.”²³⁵

Reporting Schemes: Industry’s a No-show

Knowing what nanomaterials are being used in research and commerce is fundamental to governance. Governments that have attempted to acquire such knowledge have invited nanotech developers to volunteer that information. Most have declined the invitation.

In the UK, the Department for Environment, Food and Rural Affairs (DEFRA) launched a two-year voluntary reporting scheme in 2006 to gather information on the risks associated with nanomaterials production. When early signs of industry resistance emerged, the Department tried to drum up participation by simplifying the forms and sending out beseeching letters from the Minister who, disappointed with the low turn-out, was moved to admit that “[i]n many respects we are ill-equipped to live with nanotechnologies.”²³⁸ Despite professed industry support for the scheme, Government efforts drew a near blank. After two years, there were just eleven submissions: nine from industry and two from academia.²³⁹ The scheme has been roundly pronounced a failure, including by the chair of the Royal Commission on Environmental Pollution who reportedly labelled it “pathetic” and called for a replacement that would be mandatory.²⁴⁰

Nano manufacturers across the Atlantic have not been any more forthcoming. At the close of 2008 – roughly the halfway mark of the U.S. Environmental Protection Agency’s two-year Nanoscale Materials Stewardship Program – 29 companies had signed up to a basic reporting program and just four to an in-depth program, a paltry turnout representing only around 5% of the 2,000 existing nanomaterials in R&D or manufacture.²⁴¹ In its interim report, the Agency endeavoured to be positive but was forced to conclude that “most companies are not inclined to voluntarily test their nanoscale materials.”²⁴²

EPA Scores its Nanomaterials Stewardship Program

95% of nanomaterials believed to be on the market have not been reported under the EPA’s program. For the nanomaterials that are reported on, there are likely numerous gaps and probable underreporting on the manufacture, processing, use and disposal. Many of the submissions did not contain the information that the entire program was developed to secure: exposure and hazard-related data.²⁴³

The Australian government has been similarly rebuffed by Industry. A voluntary reporting scheme introduced at the federal level in 2006 has been deemed a flop, despite claims by the government agency running the program that it has been “useful.”²⁴⁴ Finally, beginning January 2011, Australia’s National Industrial Chemicals Notification and Assessment Scheme (NICNAS) will require permits for “industrial nanomaterials” that are considered new chemicals – fullerenes and some forms of nanotubes – and may require additional reporting data.

Governments can take some comfort from the fact that even private-sector schemes are not proving popular. Swiss technology consultants Innovation Society and TÜV SÜD said there are few takers for the Cenarios voluntary risk management scheme launched in 2008 because there is no external pressure for companies to adopt risk management procedures.²⁴⁵

Why is Industry a No-show?

If, for argument’s sake, the alternative to voluntary reporting is mandatory reporting, why is the industry so recalcitrant? One theory is that companies are reluctant to put their hand up in case research shows their products to be hazardous (and it’s no wonder, with commercial law firms advising nano manufacturers to be cautious about reporting anything that could be incriminating.)²⁴⁶ Other commentators say that the voluntary schemes are poorly designed and do not provide the necessary incentives to induce industry participation.²⁴⁷ Not surprisingly, the great catch-all – “confidential business information” (CBI) – is front and centre. In the UK, the industry blamed its absence on the reporting requirements, which it claimed would put commercially sensitive information at risk.²⁴⁸ According to the Nanotechnology Industries Association, reporting also demanded considerable staff time “without any visible benefits.”²⁴⁹ And for those who believe that further featherbedding of the industry is required, there are calls for handouts to small and medium enterprises using nano to help them do their homework.²⁵⁰

Not unpredictably, from London to Washington to Ottawa, the industry has announced its opposition to mandatory reporting.²⁵¹

Have Mercy on the Start-Ups

Start-ups are one of the primary commercial engines of nanotechnology, bringing academic research from lab to marketplace. Governments are told that nano regulation could torpedo start-ups, which typically lack the resources and capacity to absorb regulatory costs. “The nanotechnology industry,” plead legal commentators, “is still struggling with how to manage nanomaterials during their lifecycle.”²⁵² Governments, they say, should hold off on regulation and focus on the safety issues, as ‘pre-emptive’ legislation could do more harm than good. To the industry, that is. Meanwhile, the larger corporations, for whom the cost argument does not apply, are no doubt content to enter the unregulated market on the coattails of the poor start-ups.

Gluttons for Punishment

Despite the failures of voluntary schemes, many governments remain wedded to the approach. The OECD Working Party on Manufactured Nanomaterials' report on information gathering initiatives is an exercise in optimism as it bravely ignores the failed initiatives thus far.²⁵³ Japan has a voluntary scheme for reporting safety data, and Norway has suffered no loss of faith in the voluntary path, introducing a notification scheme under the Norwegian Pollution Control Authority (SFT) that is "not strictly mandatory" as notification is only required legally if a significant risk has been identified.²⁵⁴

The UK Government, meanwhile, reversed its earlier pledge that the voluntary scheme would pave the way for mandatory reporting. The Ministerial Group on Nanotechnologies announced that it will not introduce a domestic mandatory reporting scheme, but is vying for one to be introduced at the EU level. Even if all goes well, this is not expected to emerge until 2012.²⁵⁵ In the meantime, the Ministerial Group has announced it will work with the industry to develop an information scheme that "all parties can participate in without too much pain."²⁵⁶ As industry has a particularly low threshold for regulatory-related pain, it is unlikely that the UK workaround will produce much.

The European Commission, meanwhile, has been reminded (in advice it sought) that its previous experiences with voluntary environmental agreements hold no great promise for an effective reporting scheme for nanomaterials. The Commission is advised to move immediately on a mandatory reporting scheme and introduce a voluntary scheme as an interim measure because of the time required to push through regulation.²⁵⁷ Nevertheless, the Commission is remaining with a series of vague pledges to create inventories of nanotech products, public databases, and market surveys.²⁵⁸ Clearly, these do not add up to a requirement for manufacturers to notify the use or presence of nanomaterials in their products.

The failure of U.S. and UK attempts to get industry to volunteer information has, however, apparently prompted some governments to now take the plunge:

- In 2009, the French Government introduced a bill that would place mandatory information requirements on the nanotech industry, including the volume and uses of nanoparticles in commercialized products and provision of toxicological data on request.²⁵⁹

- Canada is introducing a "mandatory information gathering survey" on import or manufacture of nanomaterials for commercial circulation from calendar year 2008, which requires identification of nanomaterials on or soon to enter the Canadian market, including information on their use (volumes, sectors of use, types of products) and available toxicological data. The survey applies to volumes over 1kg.²⁶⁰
- The Dutch Parliament has called on the government to introduce mandatory reporting for the use of nanomaterials.²⁶¹

And in what appears to be a move in the direction of actual regulation, the U.S. Environmental Protection Agency intends to propose a rule which would "require companies to generate test data on the health effects of 15 to 20 different nanomaterials, including carbon nanotubes, nanoclays, and nano aluminum, and also on nanomaterials used in aerosol-applied products."²⁶²

"It's a disaster"

The food industry appears to be particularly shy when it comes to nanotech and no one – apart, perhaps, from the industry itself – seems to know what nano foods or packaging are in the marketplace.²⁶³

There was confusion at an EU conference in 2008 with European Food Safety Authority rep stating that there were no nano foods on the market in the EU, while a representative from the Dutch National Institute for Public Health and the Environment stated that nano foods and beverages were indeed on the market. EFSA later clarified that its conclusions were based on information from the industry.²⁶⁴

This ongoing confusion prompted a European Commission official to exclaim: "We are very frustrated when people come out with contradictory messages. It's a disaster. Why would the man in the street have any confidence in the system?"²⁶⁵

Meanwhile, the food industry was not particularly forthcoming during the UK House of Lords investigations into the use of nano in food and food packaging. The Lords' Science Committee urged for a "culture of transparency," proposing that the UK Food Standards Agency maintain a product registry and that the government "work with the food industry to secure more openness and transparency about their research and development."²⁶⁶ Given the government's difficulties in marshalling the nanotech industry to volunteer information thus far, the Lords' vote of confidence seems like wishful thinking.

Codes of Conduct

While voluntary reporting schemes have had a hard landing, codes of conduct developed to guide nanotech activity are finding it difficult to touch down at all. Industry codes – among them the chemical industry’s Responsible Care (now tooled for nano), the Nanocare Initiative and individual corporate schemes such as BASF’s personalized code of conduct – jostle with government and the odd non-governmental or cross-sector schemes in the crowded marketplace of good conduct.

The European Commission’s Code of Conduct for Responsible Nanosciences and Nanotechnologies Research, unveiled in 2008, is a centrepiece of the EU’s nano policy.²⁶⁷ At its base are seven principles so broadly framed that dissenters will be difficult to find.

The Code is wholly focused on nano R&D and proposes getting tough on some activities. Indeed, it proposes a moratorium on funding or conducting certain forms of research. On the chopping block are:

- projects that could involve the violation of fundamental rights or fundamental ethical principles;
- non-therapeutic enhancement of human beings (at least not enhancements that could lead to addiction or come under illicit performance enhancement);
- the deliberate intrusion of nanoparticles, systems or materials in food, feed, cosmetics, toys, or the human body if long-term safety is not known.²⁶⁸

Hear, hear! But the Commission may want to have a word with apparently delinquent member state, the Netherlands, which pumped €12 over four years into the nanofood R&D consortium, Nano4Vitality, beginning in 2007.²⁶⁹ Equally, the powerful and commendable principle that “researchers and research organizations should remain accountable for the social, environmental, and human health impacts that their N[anosciences] & N[anotechnologies] research may impose on present and future generations” is left dangling in the absence of policies to ground it.

It is difficult to see the Code making much of an impression on the rollout of nano. The Commission flung the Code out into the EU without an implementation plan (aside from a biyearly review of its uptake) in the expectation that EU member states (and their science funding agencies), universities, research institutes and the private sector will pick up on it.²⁷⁰

Nevertheless, it was feeling decidedly upbeat about its prospects. At its launch, the EU’s Science and Research Commissioner announced that the Code would “make it very simple to address the legitimate concerns that can arise regarding nanotechnologies.”²⁷¹ That optimism has not been well founded, with one recent EU-funded report describing the response as “tepid.”²⁷² Public consultation in 2009 saw nearly 90% of respondents wanting changes to the Code, and three quarters urging commercial activity be brought under the Code.²⁷³ In January, a multistakeholder dialogue was established and a so-called “CodeMeter” is under development to help nano-operators measure their adherence to the Code.²⁷⁴ Meanwhile, a revised Code, initially planned for release in February 2010, has yet to appear.

The Responsible Nano Code: All Care and No Responsibility?

A high profile code currently in dry dock is the “Responsible Nanocode.” The UK Royal Society investigations that led to their widely cited 2004 report revealed that the industry “was not engaged”²⁷⁵ and so the Royal Society set about rousing a few players: Insight Investment (one of the UK’s largest investment managers), the Nanotechnology Industries Association (NIA) and the Government-sponsored Nanotechnology Knowledge Transfer Network to find a way to bring industry to the table.

The Nanocode targets corporate boardrooms, where ‘the big strategic decisions’ are made. But development of the Code has faltered in the areas of benchmarking and liability – elements that would move it from lofty principles towards saliency. Confirmation that companies want the Code to be all care and no responsibility came when good practice examples were proposed as part of the code proper: A flurry of activity in corporate legal departments of Unilever and Johnson & Johnson, among others, ensued, with lawyers advising that examples of good practice could make companies liable should their company depart from them.²⁷⁶ In the end, the principles and the good practice examples were published separately, “thus likely avoiding any legal implications.”²⁷⁷

However, it is around benchmarking and compliance measures that the process has really ground to a halt. A benchmarking methodology was to be developed to create a mechanism for accountability and performance review of companies. Sufficient funds for this part of the project have not been found and organizers have criticised the UK government for not coming forward with financial support.²⁷⁸

Bottom Line: No Regs = No-show by Cos.

Voluntary approaches are discount governance – a concession that allows developers of technologies to proceed under more lenient terms than might be achieved through regulation. That concession depends on the willing and good-faith participation of technology developers, but the nanotech industry has shown itself to be alternately sheepish and obstinate. Industry’s failure to show deepens the scepticism that many civil society organizations have voiced towards soft options for nanogovernance.²⁷⁹

Even the industry-friendly International Risk Governance Council (IRGC) acknowledges that, at best, voluntary approaches “make a contribution to clarifying and boosting awareness of issues such as safety assurance.” At their worst, they typically result in “a ‘lowest common denominator’ approach.”²⁸⁰

While industry generally opposes regulation, it is hamstrung by wider business unease at the lack of regulatory certainty; though it touts the virtues of self-regulation and voluntary measures, it snubs attempts at either; it pledges to provide relevant information yet hides behind “confidential business information” claims; it is everywhere in announcements about progress in nano R&D for ‘societal benefit,’ and virtually nowhere when it comes to product labeling.

Regulatory Harmony or the Sound of Silence?

Various regional and multilateral forums are exploring regulatory harmonization on nanotech.

Transatlantic Chat Rooms: the EU-US Summit

Known more for discord on a number of trade and policy fronts – GMOs, bovine growth hormone, climate change, etc. – Washington and Brussels have been chatting about nano-regulatory harmony within the frame of the EU-US Summit to create “a level playing field for nanotechnology-based products in the globalised market.”²⁸¹

The industry lobby – the Transatlantic Business Dialogue (TABD) – is certainly for harmonization, hoping to avoid regulatory barriers down the line.²⁸² The Transatlantic Consumer Dialogue (TACD), on the other hand, fears the two regions may harmoniously agree to do nothing, and has called for regulatory systems that actively manage nano, including mandatory reporting, consumer product inventories, mandatory labeling, and clear manufacturer liability.²⁸³

...Chat Rooms on Cosmetics

Each year, Canada, the EU, Japan and the U.S. meet under the umbrella of the International Cooperation on Cosmetic Regulation (ICCR) to talk cosmetics, including nanotech products.²⁸⁴

Governments describe the ICCR as a “voluntary international group of cosmetics regulatory authorities” which “can enter into a constructive dialogue with their relevant cosmetics’ industry trade associations.”²⁸⁵ Cosmetics industry reps sit around the table with regulators for one day of the three-day meeting.²⁸⁶ Civil society has been tossed a bone: according to its terms of reference, the forum is to dialogue with industry “and potentially other stakeholders.” Thus far, however, efforts to introduce civil society participation by groups such as the U.S. Environmental Working Group have failed.²⁸⁷

The quest for harmonization will have doubtless suffered a setback with the EU’s albeit timid foray into nano cosmetics regulation. Even coming to a common definition of nano could be a problem: the FDA does not intend to create regulatory definitions of nano, while the EU adopted a definition with the passing of the new cosmetics directive. A recent statement by an FDA official does not intone harmony: “We have a lot to learn from working together, but we will not let the EU run the show.”²⁸⁸

More broadly, moves by the European Parliament to introduce specific regulation for nanofoods in the EU, including labeling, could, according to one commentary, “open up a gap between the regulatory approaches taken in the EU and those in the U.S., with far-reaching consequences for international trade in nano-enabled products.”²⁸⁹

Part 7. Intergovernmental Policy Frameworks

While the international circuit abounds with regional forums and workshops to promote nanoscale technologies – ASEAN, APEC, the Asia Nanoforum, the EU/Latin American Nanoformula, the Asian/Eurasian ECO-Nanotechnology Network – intergovernmental policy discussions are generally rare and rarified.

International Dialogue on Responsible Research and Development of Nanotechnology

The International Dialogue has, until now, been the jewel in the crown of intergovernmental small talk. Initiated by U.S. National Science Foundation Senior Advisor for Nanotechnology Mihail Roco, the custom-built, biennial dialogue is an invite-only, non-binding event where government representatives from around the world participate in their individual capacities.²⁹⁰

There is a strong dose of mythologising around the International Dialogue: participants seem to have convinced themselves that it represents the “broadest space” available,²⁹¹ even that it is “the only really inclusive place available to address topics of common interest at the level of governments and policy makers.”²⁹² Thus far, dialoguers have talked their way from Alexandria (USA) in 2004, to Tokyo in 2006 and Brussels in 2008, but it is difficult to determine what the Dialogue has achieved as it remains a closed shop. (Notably, it need not have been that way. A report of the first Dialogue reveals an interest by many delegates to widen the circle to include the global South and civil society.²⁹³) One recent assessment states that there are no tangible results from the Dialogue, but generously attributes this “to its inclusive nature and broad scope.”²⁹⁴

While the international circuit abounds with regional forums and workshops to promote nano-scale technologies, intergovernmental policy discussions are generally rare and rarified

The Picnic’s Over: Time for IPNiC?

Talking, of course, can be good, as are information-exchanges and forums where governments can be candid with one another. The problem with the Dialogue – aside from its lack of transparency, its exclusivity and the extent to which it is dominated by NanoNations – is contextual: the absence of a more democratic, representative forum that can subject nanotech activities to disinterested governance and bring accountability.

It may be dawning on Dialoguers that the summer of free love is drawing to a close. At the Brussels event, French government official and vice-chair of the OECD Working Party on Nanotechnology, Françoise Roure, informed participants that the picnic was over. “Informal cooperation only,” she noted, “is no more an acceptable option.” Social unrest, loss of trust in public institutions, legal uncertainty and economic losses were likely to result from continuing down that path.²⁹⁵ Nano

governance – and the Dialogue itself – needed beefing up in the form of an inclusive, intergovernmental panel of experts on nanotechnology-induced change (IPNiC) that would serve the Dialogue.

That concept still seeks to entrench discussions outside more democratic intergovernmental institutions (e.g., the United Nations) and is grounded on the assumption that the technology should be driven forward. Nevertheless, it is the first significant sign of understanding that closed dialogue is the wrong approach. As plans for a 4th meeting in Russia in the first half of 2010 fell through, it’s not yet clear whether the International Dialogue has seen the light or has gone dark. Rumours are that European Union moves to regulate nanotech (see above) have dulled the U.S.’s desire for dialogue.

United Nations' Nano Presence

Governments have assiduously avoided the United Nations in all things nano, and, until very recently, the UN itself has largely side-stepped the issue with a few exceptions:

UNIDO's program to promote nanotech capacity in the global South and the odd UNEP report that reiterates well-characterized knowledge gaps and regulatory challenges.²⁹⁶

UN University researchers have roundly criticized the UN as having "failed to comprehensively grasp the full range of regulatory challenges posed by nanotechnology across all sectors," with efforts to date "at best rudimentary and fragmented" and the analysis "cursory."²⁹⁷

Last sighted, UNESCO's World Commission on the Ethics of Scientific Knowledge and Technology (COMEST) called for a discussion of the precautionary principle's applicability to nanotechnology development and concluded that scientific uncertainty is no reason to delay debate.²⁹⁸

COMEST also recommended the development of voluntary guidelines that could "inspire national regulations."²⁹⁹ The UN's Food and Agriculture Organization is slowly grinding into gear, with a joint FAO/WHO Expert Meeting in 2009 and, in June 2010, a nano food safety workshop and a conference on "beneficial" nano applications for food and agriculture.³⁰⁰ With all its weaknesses, the UN is still the only place where every member of the global community has a voice, and it must begin to actively track and govern nano development.

The OECD Working Parties

At present, the Organisation for Economic Co-operation and Development (OECD) is the central hub for coordination and cooperation among NanoNations.

The OECD's forays into nano began in earnest with the formation of the Working Party on Manufactured Nanomaterials in 2006. Outputs since then include a database of global safety research and a preliminary analysis of occupational exposure to nanomaterials.³⁰¹ A second posse – the Working Party on Nanotechnology – was formed in 2007 to scout broader policy issues. (An envisioned Network on Nanoscale Pesticides and Biocides seems to have fallen by the wayside.³⁰²)

The OECD apparently enjoys "broad legitimacy," at least according to its members and the industry. It is described (by one member country) as bringing together "the right parties,"³⁰³ and the industry deems it "the most effective multi-stakeholder forum within which to explore the right policies."³⁰⁴

That enthusiastic appraisal may not be widely agreed outside the gates of OECD. OECD members consist of 19 EU member states, NAFTA countries and some Asia and Pacific countries (e.g., Japan and Korea).³⁰⁵ (Other countries may be invited to observe, and Brazil, China, Singapore, South Africa, Thailand and the Russian Federation participate in the Working Party on Manufactured Nanomaterials in that capacity.) While NGO and trade union participation is theoretically possible, the cost of participation is a considerable barrier.³⁰⁶

The OECD has recently been urged in a London School of Economics study to develop "greater transparency and inclusiveness" in its work; however the authors acknowledged that the OECD structure and culture would make this a "serious challenge."³⁰⁷

The point of departure for OECD nano working groups is that adoption of nano is a given and that governments should facilitate the nano industrial revolution while keeping casualties along the way to a minimum. Certainly, governments and industry expect the OECD to help smooth nano's path to market.³⁰⁸ The Deputy Director of the OECD Environment Directorate has made clear, for example, that the OECD's work on nano's environmental health and safety is "not an attempt to 'put the brakes' on."³⁰⁹

Indeed, even though economics is the OECD's game, there has been no serious analysis to size up the costs of the nano enterprise or to assess the relative merits of nano against other technologies, systems or approaches. The scope of socio-economic impacts in a recently published statistical analysis is confined to industrialist country preoccupations – including forecasts of windfalls in dollars, jobs and products – leaving unconsidered any potential negative fallout, such as nano's impact on existing or potential industries, technologies, labour or vulnerable populations.³¹⁰

No one, according to the research by the London School of Economics, saw the OECD as the forum for creating a comprehensive international regulatory framework for nanomaterials.³¹¹ Nevertheless, the organization has a track record of disseminating its initiatives to non-OECD countries³¹² – particularly in the absence of initiatives from other, more democratic intergovernmental institutions, such as the UN.

OECD: Industry's PR Department

While favouring the OECD as the forum for coordinated global action, the industry recently saw fit to underline the OECD's duties to business. In a grandiosely titled 'vision document,' BIAC (the Business and Industry Advisory Committee) argues for self-governance, advising OECD countries to look to business-led initiatives when considering regulatory responses.³¹³ OECD countries are also reminded of industry's expectation that governments defend intellectual property while, for its part, the industry pledges to "continue to share relevant information throughout value chains."³¹⁴ Finally, BIAC expects the OECD to become a PR department for nano by developing "thorough case studies that demonstrate the important contributions of nanotechnology towards addressing selected global challenges."³¹⁵

The OECD appears to be obliging, with the conference on the "Potential Environmental Benefits of Nanotechnology: Fostering Safe Innovation-Led Growth" held in Paris, July 2009.³¹⁶ Officials from at least one country wrestled with OECD staff to achieve a less promotional position in the background documents and opening address to the conference. However, calls to frame nanotech as one of a range of competing technologies went largely unheard.

One product of the Paris meeting is a new subgroup to the Working Party on Manufactured Nanomaterials, Cooperation on the Environmentally Sustainable Use of Nanotechnology, to be led by the U.S. and the EU. Some member countries and sections of the European Commission have voiced concerns that the project's budget is insufficient and that it could degenerate into a nano promotional program. A draft operational plan has been circulated that suggests that the latter concerns have yet to be addressed.³¹⁷ The desire to "enhance the knowledge base about life cycle aspects of manufactured nanomaterials" may be worthwhile, but the open-endedness of this enquiry risks falling servant to the aim of promoting nanotechnologies by way of 'exemplary' applications. First task on the work programme is to identify "nano-enabled applications that demonstrate potential to reduce environmental, health, and safety impacts as a basis for selecting cases for further study."³¹⁸

The International Conference on Chemicals Management

The Strategic Approach to International Chemicals Management (SAICM) is a policy framework dedicated to achieving the target agreed at the 2002 World Summit on Sustainable Development: to minimize, by 2020, significant adverse impacts on the environment and human health arising from chemical production and use. Explicit in SAICM's approach: a fundamental change in chemicals management is required; some communities (e.g., children, pregnant women, elderly) are particularly vulnerable to chemical pollution and inclusiveness is needed to realize its mandate.

In 2008, the International Forum on Chemical Safety (IFCS) – the forum from which SAICM sprung – issued an unexpectedly strong resolution on nanotechnologies. At a meeting in Dakar, Senegal, country delegations, civil society and even industry unanimously affirmed the right of countries to accept or reject nanomaterials. It emphasized the absence of a global policy framework and urged application of the precautionary principle.³¹⁹ It also urged that further action be considered at the Second Session of the International Conference on Chemicals Management (ICCM-2), the conference that reviews progress of SAICM.

The Dakar statement clearly irked some NanoNations, most notably the U.S., which had not been present at the Dakar forum. The U.S. stepped up at ICCM-2 in Geneva (May 2009) to bring the politics back into line. A draft background paper and plan of action, prepared by the U.S. and Switzerland, jettisoned significant elements of the position taken in Dakar.³²⁰

Discussions at ICCM-2 were heated and pushed into the eleventh hour. A bid to further sideline the UN by endorsing the OECD and the International Organization for Standardization (ISO) as international HQ for nano matters was rejected, however, and the plenary affirmed the need for a more global, open and transparent process.³²¹ Nevertheless, the US/Swiss correctional effort succeeded insofar as the resolution that emerged from Geneva was a muted affair. By and large, the action points adopted – consultations, information-sharing, regional awareness-raising workshops, a report to the conference's Third Session in 2012 (ICCM-3), cooperation on nano safety – are non-controversial for those seeking to stay the course with the OECD at the helm.

However, African countries haven't abandoned the resolve of the Dakar Statement. In a resolution adopted at the African regional awareness-raising workshop early in 2010, African countries called for a report to ICCM-3 to consider "the critical role of the precautionary principle;" the "no data, no market" principle; product labeling; the right of countries to reject nanomaterials and products; the involvement of workers in occupational safety arrangements and life-cycle appraisal, among others.³²² A resolution by Latin American and Caribbean countries at a subsequent regional workshop, while less bold, includes similar recommendations.³²³

The proposed report to ICCM-3 provides a significant opportunity for a broad analysis of the implications of the technologies for the global South, and is a first at the international/ intergovernmental level.

However, the quality of its contribution will depend on the reporting process. The African and Latin American and Caribbean resolutions called for financial support and a multi-stakeholder group to develop the report.³²⁴ Both understaffing at SAICM's Secretariat and a lack of resources are dimming the prospects of a strong follow-through from the regional workshops.

The mandate of SAICM is limited; nevertheless, it has provided the closest thing to a genuine international dialogue on nanotechnology thus far – a fact underscored by Sweden, which during its tenure of the EU Presidency, cast its vote for SAICM as a prime nano-forum "to reconcile policies and secure a level playing field."³²⁵

Part 8. Gone-a-Courtin': Engaging the Public

Since ETC Group's first nanogeopolitics report, public dialogues, stakeholder forums, opinion polls and online public consultations run by governments, universities and industry abound. In raw numbers, it would appear that, in some countries at least, the citizen-consumer has been thoroughly engaged.

By early 2008, French researchers catalogued around 70 government and non-government exercises (including routine policy consultation processes) related to nanotech. Europeans are talking the most, with 47 dialogue exercises; North Americans apparently less (12 events), with a handful shared between Latin America and Australasia.³²⁶ Meanwhile, India and South Africa are not engaging in public discourse.³²⁷

Given the extent to which governments are dipping into the public purse to finance the technology, including the wider community in decision-making should be obvious. The emphasis on engaging the public suggests that "the engagers" (governments or businesses) seek a mandate to operate, that governments and/or industry agendas are not fully formed, and that the wider community's input will set the agenda. But most government and industry dialogues are monologues in disguise: sessions used "to ensure that technologies are not 'held back' by public skepticism."³²⁸

Because governments have yet to lift their oars out of the water in their race to commercialization, engagement, for all its "upstream" pretensions, has largely been a downstream affair.

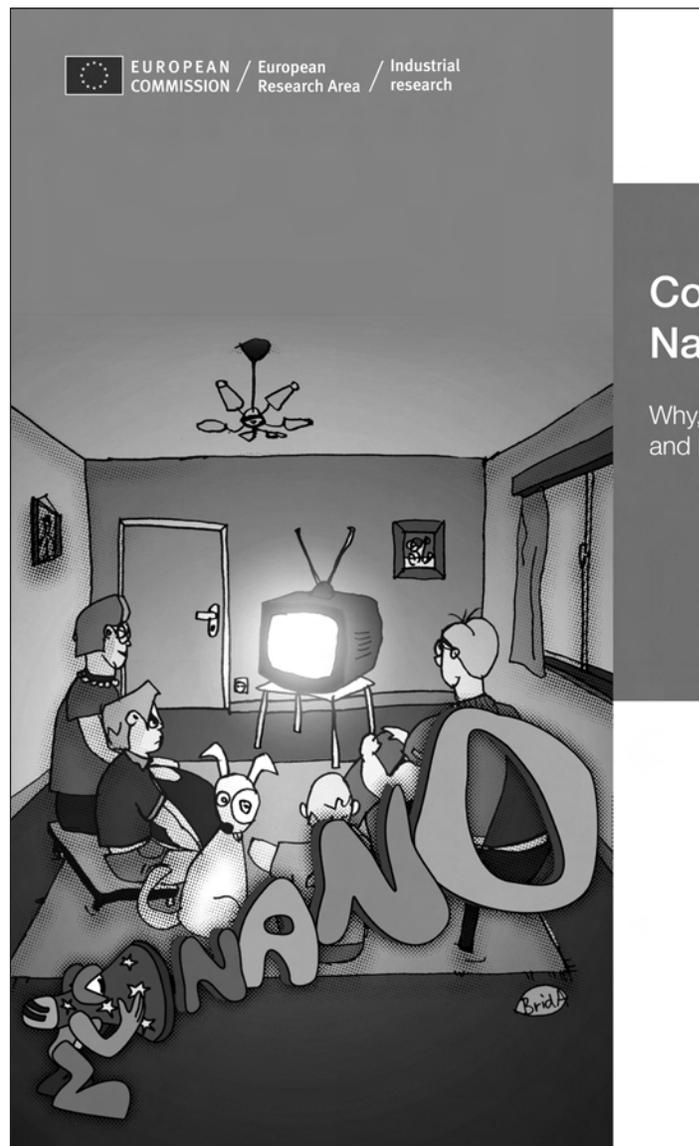
Engagement exercises thus far have rarely been plugged into decision-making.³²⁹ Efforts by the UK government, which has made ambitious commitments to public engagement,³³⁰ are no exception. The country's Royal Commission on Environmental Pollution – which was given the axe in late 2010, ostensibly due to budget cuts – declared that genuine openness to public involvement in early decisions about technology and governance has been "elusive" and that techno-enthusiasm has outstripped political commitment or capacity to do anything with the results, "especially if the latter raise fundamental questions about the direction and development of innovation."³³¹ The Commissioners called for an end to one-off public engagement exercises and urged the government to embark upon a political process by which "civil society can engage with the social, political and ethical dimensions of science-based technologies, and democratize their 'license to operate.'"³³²

The Government's initial response was decidedly muted³³³ and the 2010 UK Nanotechnologies Strategy document suggests that the Commission's assessment (and, for that matter, previous assessments of state efforts to engage) has had little effect on the government's approach. Deficit-model thinking runs throughout the strategy (e.g., "We will engage with the public to make sure they are informed and confident about nanotechnologies and the products which contain nanomaterials."³³⁴). Further, the new Nanotechnologies Collaboration Group may be a permanent forum that involves government, industry and "stakeholders," but with the project brief being to "facilitate ongoing communication and collaboration between Government, academia and industry," it is difficult to see how this represents an advance.³³⁵

Who's the EU Talking To?

In 2009, the European Commission laid blame for what it perceives as the slow commercialization rate of nanotech products by European enterprises on the public: Europeans' lack of understanding is causing the holdup. A strategy is needed, the Commission said, to address public concerns so as "to avoid delays in introduction of new technologies in the EU."³³⁶

In a review of EU nanotech policy the same year, the Commission took a different tack, acknowledging the need for a more permanent public forum on nanotechnology "in its broad societal context."³³⁷ In 2010, the Commission presented what it describes as an "an open-minded, consistent and even audacious communication roadmap aiming to bring everyone in."³³⁸ (The cover art – presumably not meant to be ironic or condescending – illustrates an experience decidedly less than audacious or inclusive: a cartoon family sits in a living room, apparently struck dumb by the aura of light emanating from a television screen. Only the pet dog has the volition to turn his head and notice the embodied megaphone shouting NANO in the foreground.) The roadmap identifies the core communication challenge as "engaging a public that might have been inadequately informed so far, or perhaps outright misled because of the very complexity of the issue." Admitting that engagement thus far has been "somehow lagging," the roadmap promises future responsiveness on the part of the Commission.



Who's the EU Talking To?
Cover detail from the European Commission's, *Communicating Nanotechnology: Why, to whom, saying what and how?*, 2010

Not So Bon Voyage for Nano?

In France, the recently concluded "Débat Public Nanotechnologies" saw public debates run by the Special Commission for Public Debate (CPDP) in 17 cities. Protesters accompanied most meetings, who argued that genuine debate was not possible because the government had already committed to the technology. In Marseilles and Grenoble, the meetings were shut down, with the presentations transferred to video conferencing and live webcasting.³³⁹ One civil society organization that was to take part in the debates pulled out in protest that the larger questions – military uses, surveillance and privacy – were not being addressed.³⁴⁰

Part 9. The Science of Catching Up: Ums and Ehs

In 2010, *nanosafety* – the science of understanding the impact and interactions of nanomaterials in biological systems, known by the shorthand *environmental, health and safety* (EHS) – lags far behind commercialization.

In the last two years, a volley of reports from public science institutions and programmes – the UK Royal Commission on Environmental Pollution, the U.S. National Research Council (NRC), the EU’s Scientific Committee on Emerging and Newly Identified Health Risks (SCENHIR), the European Food Safety Authority (EFSA), the UK-funded EMERGNANO, the European Commission-sponsored ENRHES (Engineered Nanoparticles: Review of Health and Environmental Safety) and the Council of Canadian Academies – all confirm that the nanosafety ‘to-do list’ is long.³⁴¹

Almost nothing is known about nanomaterials in the environment. Safe exposure levels for humans and ecosystems are not known and, at present, there is not even a theory that can be used to predict concentrations of nanomaterials in the ambient environment. In 2008, the Royal Commission on Environmental Pollution concluded that determining whether nanomaterials are safe is “extremely difficult [...] because of our complete ignorance about so many aspects of their fate and toxicology.”³⁴²

In addition to methodological hurdles, the EMERGNANO review of global nanosafety research noted that there is insufficient information for the risk assessment of titanium dioxide particles, quantum dots, carbon nanotubes, iron oxide, cerium oxide, zinc oxide, carbon black, gold nanoparticles, silver nanoparticles, silica nanoparticles, aluminum oxide, nickel or nanoclays.³⁴³ And that takes into account only first generation nanomaterials already in commercial circulation or nearing the market. For those nanomaterials already in products, in the environment, and in the workplace, methods for detection and monitoring either do not exist or are not widely available.³⁴⁴

The European Food Safety Authority (EFSA), likewise, warns that any attempt to assess the safety of nano foods will be subject to a “high degree of scientific uncertainty” and that “it may be very difficult to provide fully satisfactory conclusions.”³⁴⁵

New governance arrangements are necessary to deal with ignorance and uncertainty...We strongly recommend a more directed, more co-coordinated and larger response led by the Research Councils to address the critical research needs.

– UK Royal Commission on Environmental Pollution, *Novel Materials in the Environment: The Case of Nanotechnology*, 2008.

However, there are sufficient results from early research into carbon nanotubes to send the insurance industry into a tailspin (see below). Similarly, research on titanium dioxide and nanosilver has led the EMERGNANO reviewers to recommend that a precautionary approach be taken. The UK Royal Commission on Environmental Pollution declared that a moratorium on certain nanomaterials would be appropriate, but chose not to identify candidates for such action. Judging from commentary elsewhere in its *Novel Materials* report, fullerenes, carbon nanotubes and nanosilver are likely in the running.³⁴⁶

Up for Grabs

In an effort to start filling the gaps in nanosafety knowledge, countries in the OECD Working Group on Manufactured Nanomaterials have put together a work programme that includes an online database of global nanosafety research, a review of existing risk assessment methodologies to determine whether these are up to the task for nanoparticles, and a sponsorship program to test some nanomaterials.³⁴⁷ The sponsorship program invites countries and companies to lead or support targeted nanosafety research on select nanomaterials.

The line-up looks ambitious with about a dozen nanomaterials having been “adopted,” but given the range of nanomaterials in R&D and on the market, the selection is tiny.³⁴⁸ A swathe of nanomaterials currently in commercial production and for which wide-ranging uses are foreseen – including quantum dots, boron nanotubes, gold nanoparticles and cadmium telluride, among many others – are still looking for sponsors.

One third of the nanomaterials listed – aluminium oxide, carbon black, dendrimers, nanoclays and polystyrene – have no lead sponsor.³⁴⁹ Moreover, of the nanomaterials selected, just one or two forms are being investigated though there are many existing and potential forms and a range of factors that determine the safety of a nanomaterial, including shape, surface chemistry and size within the nanoscale.³⁵⁰ Consider that there could be up to 50,000 different types of single-walled carbon nanotubes, each version with potentially different chemical and physical properties;³⁵¹ or that while France is investigating five forms of nanoscale titanium dioxide, there are 200 different forms of TiO₂ reportedly in circulation and that the risk profile of any one of these could be different if the particles are modified with coatings.³⁵² Other gaps include the omission of soluble nanomaterials/particles, which increasingly are being used in foods, cosmetics, pharmaceuticals and agrochemicals.³⁵³

United States EHS Research Effort Gets an ‘F’

U.S. federal agencies have found it difficult to focus on the positive in the wake of the National Research Council (NRC) assessment of the combined agencies’ research effort into the environmental, health and safety implications of nanotech under the National Nanotechnology Initiative (NNI).³⁵⁴

According to the review, the federal strategy for nano-related EHS research lacks a vision, a clear set of goals, a plan of action for achieving those goals, mechanisms to review and evaluate progress made in addressing uncertainty or risk, as well as accountability and input from the wider community. The NRC found that the federal program was grounded on a flawed analysis and that it “substantially overestimates” the level of research actually focused on environment, health and safety, with few projects making any direct contribution to nanosafety or decision-making. It would even appear that some of the funds tagged for safety research found their way into product development: more than 50% of the funds in one research category were being used to develop products instead.

The NRC concluded that the U.S. government’s research path for nano will not lead to public and environmental protection. It recommends a division of labour between the promotion of nanotechnologies and safety research – currently both run under the NNI – in order to give proper priority to the public health mission. Developing a nanosafety research strategy “should have high priority for the nation” and should begin immediately.

As expected, the NNI hit back, claiming a number of errors and false assumptions in the review. The report failed, according to the NNI, “to appreciate the breadth and depth of the NNI commitment to EHS research.”³⁵⁵ Further, in a hair-splitting exercise, the NNI argued that it was never intended to be a strategy but was a strategic plan for nanosafety research, which is apparently something quite different; and the fact that the document at the center of discussion is called the *National Nanotechnology Initiative EHS Strategy* is, apparently, missing the point.³⁵⁶

The NNI can protest the criticisms leveled by the National Research Council, but this is not the sole review to reach such conclusions. An assessment by the Government Accountability Office – the U.S. Congress’s investigative arm – drew similar conclusions when it looked at the 2006 nanosafety activity under the NNI. For example, 20 of 119 projects – almost one-fifth in budget terms – were incorrectly classed as nanosafety research.³⁵⁷ Other reviews of 2006 estimated the portion of nanosafety research to be as low as 1%.³⁵⁸

The Generation Gap

The state of nanosafety research is not surprising given its historic underfunding relative to other preoccupations of state nano funding. The OECD reports that just over 5% of government nano budgets is earmarked for health and safety research in ten countries that offered information.³⁵⁹ Those figures are likely to be generous. As of 2009, the EU was spending a paltry 4% (€28 million of a total €600 million) on safety research, a figure that has seen the European Parliament Environment Committee call for a “major stepping up of the funding.”³⁶⁰ South Africa has had a national R&D initiative on nano running since late 2005, but has reportedly not invested any funds into nanosafety research thus far.³⁶¹

U.S. federal funds earmarked for nanosafety research have come well under 5%, with actual spending considered to be less again. Nanosafety funding has received a boost under the Obama Administration, however, from around 5% in 2010, and a proposed budget for 2011 is \$117 million or 6.6% of the total NNI funds for 2011.³⁶²

These minor increases are unlikely to make a major dent in the lengthy timeframes projected for nanosafety research to begin informing risk assessments. U.S. researchers recently crunched some numbers to get an idea of how far out the safety research effort is. They estimated that if U.S. companies were to spend around 1% of their (R&D) budget on researching the safety of their products, it could take between 35 and 53 years to properly assess the safety of nanomaterials *currently on the market*.³⁶³ While the exercise does not account for government investment, it nevertheless helps put in perspective the scale of the required effort.

In its 2008 report, the Royal Commission on Environmental Pollution was equally pessimistic. Even under ideal-case scenarios, where better risk assessment procedures are adopted in the next 2-3 years, the Commission believed it could be decades before the toxicology of many nanomaterials can be determined. As for the comparatively small number of nanomaterials currently on the market, unless there is a marked increase in safety research funding, it may be “many years” before toxicity information is available.

Meanwhile, the nanomaterials incorporated into products may well be finding their way into waterways and ecosystems. Swiss researchers have estimated that up to 95% of the nanoparticles used in commercial products such as cosmetics, paints, coatings and cleaners are most likely to end up in water treatment plants during manufacture, use and disposal.³⁶⁴

“A war worth fighting”?

Until recently, carbon nanotubes have tended to hog the headlines. Now the industry is getting nervous about the attention nanosilver is getting. The warning has gone out that the battle of nanosilver could be the industry’s Waterloo and potentially influence the regulatory and commercial fate of nanomaterials in general.

Nanosilver appears to be the nanomaterial most widely used in consumer products currently – at least on the basis of the products known to contain nanomaterials. Used mostly for its anti-bacterial/microbial properties, this nanoscale metal has found its way into socks, trousers, kitchen appliances, and more.

A legal petition filed with the U.S. Environmental Protection Agency by the International Center for Technology Assessment (ICTA)³⁶⁵ pushes for all nanosilver products to be regulated as pesticides, and that products be taken off the market until their safety is demonstrated. The EPA is currently reviewing the petition and its attendant thousand or so comments.

In a stirring call to arms, one U.S. law firm is calling on the industry to stand its ground, asserting that nanosilver is the most well-regulated and understood nanomaterial. (The competition is not exactly stiff.) Both the UK Royal Commission on Environmental Pollution and the EU-funded EMERGNANO review, however, put nanosilver in another category: the most worrisome of nanomaterials, along with carbon nanotubes, fullerenes and nanoscale titanium dioxide.³⁶⁶ The German Federal Ministry for the Environment would appear to agree. Recently, it recommended that use of nanosilver in commercial products be avoided until more is known about the fate of nanoscale metal.³⁶⁷

Part 10. Insuring the Invisible

In the five years since ETC's first nanogeopolitics report, little appears to have changed in the insurance world; by and large, the industry remains ambivalent towards nanotechnology. Companies want a piece of the nanotech action, but are fearful of signing on the dotted line. The industry, it is delicately explained, "is in a study and analysis phase."³⁶⁸

Since Swiss Re (the world's second largest reinsurer) first diagnosed the problems for the industry in 2004, Lloyd's of London has weighed in, ranking nano as one of the key emerging risks for the insurance industry.³⁶⁹ The spectre of 'the next asbestos' looms large – not surprisingly, as the insurance industries have allegedly paid out \$135 billion in claims for asbestos-related harm.³⁷⁰ "Most insurance companies," legal commentators report, "find themselves in the same position as the rest of us: what to do in the absence of regulation?"³⁷¹

For the time being, some members of the insurance industry and civil society share similar concerns: Lloyd's warns of a stampede to commercialize products before the risks have been properly assessed and considers the regulatory vacuum a particular risk for the insurance industry, urging fellow insurers to lobby for nano-specific laws. As rapid commercialization increases levels of exposure for workers and the environment, calls to make nano products liable as part of a regulatory regime have been issued by the European Trade Union Confederation (ETUC) and the European Parliament's Committee on Employment and Social Affairs, among others.³⁷²

Will They, Won't They?

How far nanotech activity is currently insured is unclear. Swiss Re says that nano is currently covered but that insurance companies are limiting their exposures by way of "careful selection."³⁷³ Lloyd's has a different take: it told the UK House of Lords that "at least one U.S. company has excluded all aspects of nanotechnology; others are actively avoiding providing direct cover to this industry."³⁷⁴

The company is likely Continental Western Group, which announced it would not cover nanotubes and nanotechnology.³⁷⁵ Following the news that (multi-walled) carbon nanotubes act like asbestos fibres, the company decided "it would not be prudent [...] to knowingly provide coverage for risks that are, as of yet, unknown and

unquantifiable."³⁷⁶ The announcement initially caused fears of a domino effect, as limited or no insurance coverage has all kinds of upstream effects, most notably on investor confidence. It obviously ruffled the nanotech lobby: the Brussels-based Nanotechnology Industries Association (NIA) filed a complaint with the Iowa Insurance Commissioner recommending that the company either clarify or retract the policy.³⁷⁷ Soon after, Continental removed documentation related to the exclusion from its website.³⁷⁸

The nano industry may be finding it difficult to capture insurance company confidence,³⁷⁹ but some industry advisors believe that offering short-term coverage is the best approach in case demonstrable public health or environmental harm from nano products emerges down the line.³⁸⁰ Lloyd's, however, is cautious about using exclusions as a way for the industry to get a slice of the pie. Creating bulletproof exclusions, it says, will be difficult given the current lack of definition and regulation.³⁸¹ One company, Lexington Insurance Company, sells LexNanoShield – nano-specific liability coverage and "risk management services" for companies manufacturing, distributing, or using nanomaterials.³⁸²

Outclauses

Law firms are jumping at the chance to advise nano companies how to protect themselves from liability. The advice from the legal fraternity: admit nothing. Companies responding to California's carbon nanotubes reporting requirements, for example, have been advised against confirming that the nanomaterials they use "constitute a hazardous waste under California Health & Safety Code provisions."³⁸³ Posting safety warnings on products is also a way to divert responsibility from manufacturers to consumers, according to a U.S. law firm that claims to have dodged liability with this "sophisticated consumer" defense.³⁸⁴

"When you think that part of the reason behind the turmoil in our financial markets was the blithe acceptance of complex products that many didn't understand, the importance of getting to grips with and quantifying complex sources of risk has never been more obvious."

– Lloyd's, *Nanotechnology: Balancing Risk and Opportunity*,
March 2009

Another recommended strategy is for the nano industry to begin “crafting careful responses to foreseeable inquiries from employees, stockholders, and the media as coverage about nanotechnology’s supposed dangers builds.”³⁸⁵ Apart from helping win the battle for public opinion, such responses can increase the chances of a “fair shake” in the jury system in the event of court action.³⁸⁶ Responses may be a little too crafted. A review of Securities Exchange Commission (SEC) filings in the U.S. by the Investor Environmental Health Network (whose member companies managed some \$41 billion in assets in 2008³⁸⁷) identified a failure by some companies to clearly flag to investors the use of nanomaterials or the lack of scientific knowledge of their risks. Although some companies are providing some information, the investor network found that many do not signal the use of nanomaterials or, if they do, “rely on vague boilerplate comments” and “are consequently failing to inform investors of the actual state of a company’s preparedness on risks to finances.”³⁸⁸ According to another recent review of the U.S. nano industry, few companies can answer safety questions or are proactively collecting data.

Management is good at talking benefits, the author observed, but often takes little substantive action on nanosafety.³⁸⁹

But why would they? It is generally accepted that, for the foreseeable future, legal action is unlikely to succeed. According to a joint report by the OECD and insurance company Allianz, both the challenge of proving causation and the potentially long latency periods before harm manifests are major impediments to enforcing liability.³⁹⁰ The UK’s Royal Commission on Environmental Pollution has been pessimistic about liability providing redress. Informed by the American Chemical Association that it is not possible to tag and trace nanoparticles back to a particular manufacturer, the Commission concluded that the public – not those responsible for manufacturing nanoparticles – will pick up the tab should harm arise.³⁹¹ Further, it is possible that manufacturers may duck liability if they are able to demonstrate that risks were genuinely unknown and that they had followed accepted current best practice.³⁹²

Part 11. Nano Standards: Private Codes

Metrology has been handmaiden to all industrial revolutions,³⁹³ and a primary goal of nano-standards development is to move from the current, Babel-like confusion to a nano-Esperanto clarity in order to facilitate nano-commerce. Safety is also a focus and, in that respect, standards are viewed as a necessary precondition for public acceptance of new technologies.

Since “whoever develops the controlling standard controls what the world does,”³⁹⁴ it is no surprise that big money is thrown into standards development. Industry and governments are the big players; trade union and civil society participation remains rare. The U.S., for example, is investing \$84.3 million in 2010 in the area of instrumentation, metrology and standards development and is proposing \$76.9 million for the 2011 fiscal year.³⁹⁵

The Contenders

NanoNations are hedging their bets and backing several horses at once – national, regional and global standards institutions. At the national level, China has developed around thirteen nano-specific standards since 2002, ranging from general terminology, test methods and product specifications (for nanoscale zinc oxide, calcium carbonate, titanium dioxide and nickel),³⁹⁶ and a further 20 standards are understood to be in the pipeline. Meanwhile the British Standards Institute (BSI) has published nine documents for nano terminology and guidance. As the BSI holds the Chair for the ISO [International Standards Organisation] Nanotechnology technical committees, its guidelines are being used as a first draft for ISO standards.³⁹⁷

International standards, however, are where the action is, and several institutions – including ISO, the International Electrotechnical Commission (IEC), the International Telecommunication Union (ITU) and the Institute of Electrical and Electronics Engineers (IEEE) – are in the business of bringing order to the nanoworld.

However, ISO is generally seen as the forum for most global standards on nano.³⁹⁸ Its Technical Committee on Nanotechnology (TC229) consists of thirty-two countries involved in four Working Groups³⁹⁹ – on terminology and nomenclature; measurement and characterization; health, safety and environmental aspects of nanotechnologies; and material specification standards for particular nanomaterials.

Governments are Jockeying Hard at ISO: in the United States, officials are nostalgic for the days when U.S. standards were accepted as *de facto* international standards.⁴⁰⁰ In an attempt to keep the upper hand, the U.S. has its own Technical Advisory Groups (TAGs) – working groups mirroring ISO's – to formulate the U.S. positions on standards and feed them to the U.S. delegates at ISO. The tag-teams are convened by the American National Standards Institute (ANSI) and are led by a mix of corporate, research, and government figures.⁴⁰¹ "American industry has a rare opportunity to shape the content of these very early stage working draft standards and influence the strategic direction," says one corporate representative in the U.S. team active at ISO.⁴⁰² ANSI, meanwhile, portrays a meeting of standards institutions as "a lot of intelligent people around the table working together to meet the needs of the industry."⁴⁰³

The Europeans are also taking ISO seriously. The European Committee on Standardisation (CEN) technical committee (TC 352 Nanotechnologies) has been directed to develop EU standards in cooperation with ISO.⁴⁰⁴

Other Players in the Standards Arena

The work program of the American Society for Testing and Materials (ASTM) International E56 Committee on Nanotechnology covers terminology and nomenclature; characterization; environmental and occupational health and safety; international law and intellectual property; liaison and international cooperation; and risk management and product stewardship. Twelve countries are currently on the E56 membership roster and the Committee, which is apparently driven by one or two key individuals,⁴⁰⁵ has partnership agreements with the Institute of Electrical and Electronics Engineers (known as "I triple E"), the Japanese National Institute of Advanced Industrial Science and Technology, Semiconductor Equipment and Materials International (SEMI) and other American organizations.⁴⁰⁶ Standards released to date include terminology, test methods, and a safety guide for handling free nanoparticles in the workplace.

The International Electrotechnical Commission (IEC) is working on standards in nanoelectronics, multimedia and telecommunications, electroacoustics, and in energy applications (direct conversion into electrical power in fuel cells, photovoltaic devices, storage of electrical energy). The nanotech standards initiative of IEEE, an international electronics industry and research association, is designed to identify "technologies likely to generate products and services with high commercial and/or societal value" and "areas where new standards can aid rapid commercialization, technology transfer and market diffusion." The first standard issued by IEEE covered test methods for measurement of electrical properties of carbon nanotubes (IEEE 1650-2005). A host of further standards are in the works and arise from IEEE's 2007 "Nanoelectronics Standards Roadmap," designed to accelerate standards development in the sector by identifying "a small set of near-term standards to jump start Nanoelectronics standards development" and so "[b]uild momentum within the industry by creating a few quick wins."⁴⁰⁷

Another political beast on the standard's landscape is the Versailles Project on Advanced Materials and Standards (VAMAS). VAMAS was established in 1982 to accelerate trade in "high tech" products by producing the technical basis for codes of practice and specifications for advanced materials. While it is billed as a technical agency, it is clearly intended to set agendas and credits itself with the establishment of several ISO committees. It has special status at ISO and IEC, which have agreed under a Memorandum of Understanding (MOU) to publish Technology Trend Assessments (TTAs) based on VAMAS's work. The original membership of Canada, France, Germany, Italy, Japan, the UK and the USA grew in 2008 to include the EU, South Korea, Australia, Brazil, Chinese Taipei, India, Mexico and South Africa.

Engines of EU standards development funded under the 7th Framework Programme (FP7) include Nanostrand (Standardization Related to R&D for Nanotechnologies), whose goal is to develop roadmaps for European standardization and associated research. NanoSafe, also funded by FP7, is undertaking standards related work including detection and characterization techniques, health hazard assessment and development of secure industrial production systems.

The plethora of organizations active in developing nano standards gave ISO, IEC, the OECD and the U.S. National Institute of Standards and Technology (NIST) cause to agree upon the need for greater communication and coordination and for a "nanotechnologies liaison coordination group."⁴⁰⁸

Nevertheless, tensions between ISO and the OECD working party emerged at a meeting in October 2009. The two organizations do have an MOU to coordinate and avoid duplication, but this apparently hasn't been sufficient to prevent what some OECD member countries saw as ISO stepping on OECD turf. The EU and some member states expressed concern about ISO's forays into testing methodologies and safety assessment – OECD specialties. ISO was told to stick to its specialty – characterization and sample preparation.

Progress: Baby's First Words

Relative to the pace of innovation and commercialization, standards development – like nanosafety research and regulation – is an underachiever. Despite an early focus on standards, as of 2007, there was no international agreement on definitions for nanotech; there were no protocols for toxicity testing of nanoparticles; no standardized environmental impact assessment protocols; and virtually no measuring equipment or internationally validated test methods for nanoparticle detection.⁴⁰⁹ A 2008 gathering of international standards bodies added a few things to the list of needs: experts to support standards development and detailed consideration of instruments for nanosafety.⁴¹⁰ (At an NNI workshop in July 2010, participants noted that the same nanoparticle being tested for toxicity in 3 different labs in the U.S. would likely produce 3 different results.)

In 2008, ISO broke the silence with the issue of its first finalized document: a technical specification on nano terminology – a yield of 12 terms since 2005.⁴¹¹ (While the document is colloquially referred to as a standard, it is a technical specification [TS] – a reference document lower on the hierarchy than a standard.) A guidance document on measures to increase occupational safety followed on the heels of the terminology document.⁴¹² Then, in May 2010, a third technical specification – codifying a common language for talking about carbon nano-objects – was published.⁴¹³

ISO's 2007 opinion that standards will be “developed ahead of the technology” and “will guide the market” was fantasy.⁴¹⁴ ISO is now pledging to step up the pace, with 10-15 documents to be released in the next year.⁴¹⁵ Nevertheless, the Council of Canadian Academies believes that ISO's efforts “will not yield rapid solutions to immediate regulatory challenges.”⁴¹⁶ Although ISO has put a five-year deadline for each standard, many may take longer as some of the basic tools that underpin standards development do not yet exist.

I Came, ISO, I Conquered: The Globalization of Private Standards

Two-thirds of the countries developing nanostandards at ISO are OECD countries; a further five are the BRIC states (all with ambitious state nano programs); with Argentina, Israel, Kenya, Singapore making up the remainder. A further eight countries are observing (Egypt, Estonia, Hong Kong China, Ireland, Morocco, Slovakia, Thailand, Venezuela). ISO's exclusiveness does not come about the same way as the OECD's: technically, the organization is open to all-comers. However, resourcing participation is an issue for a number of countries, particularly those of the global South. The European Commission sees ISO as “facilitat[ing] a global convergence in standards for the implementation of regulation.”⁴¹⁷ It is expected that the OECD, among others, will shepherd countries to adopt ISO standards. (The International Risk Governance Council is also urging countries and the industry to accept the recently-adopted ISO terminology and definitions.⁴¹⁸) Plain old cost-cutting may further drive the globalization of ISO standards. Many countries will simply adopt those standards due to the cost of DIY standards development:⁴¹⁹ some EU member states are citing concern about duplication as grounds for following ISO outcomes at the EU level.⁴²⁰

ISO also has a rather persuasive friend in the form of the WTO. The Agreement on Sanitary and Phytosanitary Measures (SPS), for one, will make it difficult to deviate from existing international nano standards.⁴²¹ Indeed, SPS signatories have a duty to participate (wherever possible) in international standards development, to avoid duplication with international activities, and to use these as a basis for any national standards.⁴²² So while ISO is at pains to emphasize that the standards developed under its roof are voluntary⁴²³ and that adoption of its standards is a sovereign decision of a sovereign nation, this is somewhat of a political fiction.

Part 12. Codes of Monopoly: Nanotech Intellectual Property

While government agencies have held up scientific uncertainty as the reason for delaying nanomaterial regulation, colleagues in patent offices have not been similarly sheepish. Patent examiners have managed to negotiate their way around the absence of global definitions of nano, as well as the characterization and standardization methodologies that would support them, and have largely ignored its cross-sectoral, multidisciplinary nature as well as the biggest risk tiny tech poses: the potential reach of exclusive monopoly to the fundamental building blocks of all of nature.

Although the number of nanotech patents is reportedly a tiny part of all patent activity (less than 1% of all applications at the European Patent Office [EPO]),⁴²⁴ some accounts have it that more than twelve thousand nanotech patents have been granted over three decades (1976-2006) by the three offices responsible for most of the world's nanotech patenting – the U.S. Patent & Trademark Office (USPTO), EPO and Japan Patent Office (JPO).⁴²⁵ As of March 2010, close to 6,000 patents for nano have been awarded by the USPTO and a further 5,184 applications are waiting in the queue.⁴²⁶

According to World Intellectual Property Office (WIPO) statistics, nanotech patenting is showing some recession-resistance: while in 2009 patent activity as a whole dropped 4.5% from the previous year, nano patenting grew – a 10.2% increase.⁴²⁷

Governments are keeping a keen eye on the patent stats. An OECD review of the 1995-2005 period attributes 84% of all nano patents to the U.S., Japan and the EU, with Japan leading in nanoelectronics, optoelectronics and energy, and the U.S. ahead in nanomaterials and metrology.⁴²⁸ U.S. commentators estimate that the U.S. accounts for more than 60% of nano patents,⁴²⁹ while another review puts the U.S. at 45%.⁴³⁰

Looking forward, however, a different picture emerges, as the President's Advisory Committee on Science and Technology (PCAST) recently identified: China led patent application filings for the 2005-2008 period by a healthy margin (over one-third more than the U.S.), interpreted as another indication of the "overall declining dominance the U.S. has enjoyed."⁴³¹ European leaders are also licking their wounds, with the Commission and the Parliament both displeased at trailing the U.S., Japan and, by some accounts, Korea in recent nano patent activity.⁴³²

The extent of government funding of nanotech R&D investment is not reflected in the distribution of IP. The private sector reportedly holds 61% of all nano patents awarded between 1995 and 2005,⁴³³ with universities holding just 20% of the pie. At the EPO, 87% of all nano patents over the last two decades (1986-2006) were awarded to commercial enterprises and individuals, with the remaining 13% going to public institutions.⁴³⁴

Pledges that tiny tech will benefit, in particular, the peoples of the global South are hard to reconcile in the face of such robust privatization activity.

The past decades of political debate around intellectual property's effect on agriculture, medicine and economic justice appear to have made little impression on

governments navigating this latest frontier. At any rate, rallying cries to economic competitiveness and technological domination have overwhelmed the voices calling for economic justice. As one commentator cautions, Northern countries arriving early in the field of nano medicine have been granted 20-year monopolies "during a critical time window of innovation," and the barriers to accessing pharmaceuticals developed by Northern-based multinational drug companies are likely to persist for any potentially useful nano medicines that may be developed.⁴³⁵ Further, patenting by Southern countries does not of itself guarantee access for vulnerable populations.

*Pledges
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activity.*

And while WIPO continues to work out its “development agenda” – the goal of which is to somehow make intellectual property fair (45 recommendations have been approved and a Committee on Development and Intellectual Property for their implementation established)⁴³⁶ – no such considerations have figured in the trilateral meetings of the USPTO, EPO and JPO. Their political resolve has been to establish a common classification scheme to be used within the International Patent Convention that will further facilitate nano patenting.⁴³⁷

The Morning After Hangover

Patent offices may come to regret their headlong rush into nanotechnology. In certain fields – particularly carbon nanotubes and nanobiotechnology – a legal mess is in the making and patent attorneys are gearing up for intense litigation because of broad and overlapping claims. The USPTO, for example, has been “generous”⁴³⁸ in dishing out patents on carbon nanotube technology.

Patent Pending . . . Reforms at the USPTO

In 2009, the USPTO was facing a backlog of nearly 800,000 applications. By that time, the Office had been under protracted fire for the length of time required to process a patent application. Reasons identified for the sluggish performance include “questionable examination practices... inadequate search capabilities, rising attrition, poor employee morale and a skyrocketing application backlog.”⁴³⁹ With revenue projected to fall with a predicted drop in patent filings due to the global financial downturn, the Office told Congress in 2009 that it might not be able to deliver on its mission.⁴⁴⁰ The increase proposed in the federal budget for the 2011 fiscal year aims to help the PTO climb out of the hole.⁴⁴¹

“Green technology” is now to be put in the fast lane as part of a reform plan at the USPTO. Technologies to combat climate change and foster job creation in the green tech sector will be given “accelerated status” and the Patent Office is pledging to shave a year off the average pendency period for these applications.⁴⁴²

However, this fast-track policy is likely to exacerbate tensions between the global South and Northern countries over energy-related IP, with access to new energy technology generation an ongoing source of disagreement at negotiations for a post-Kyoto era.⁴⁴³

Class of 2008: Nano Patent Activity at the USPTO

For a snapshot of life at the nano IP frontier, ETC Group reviewed application filings and patents awarded under Class 977 at the USPTO over the 2008 calendar year.

This profile comes with caveats:

- The USPTO’s Class 977 – the tag for nano patents – can be unstable (i.e., search returns can differ from day to day)
- Application filings are included because they provide a more current indication of where the focus of research is; however, because an application may not be granted, or granted in part only, they do not provide a definitive measure of technology-capture
- Due to the lag-time between application filing and publication (generally 18 months after the earliest filing date), the final tally of applications filed in the 2008 calendar year will change
- Class 977 operates on the NNI’s 1-100 nm definition of nano and therefore does not capture all nanoscale patenting activity
- U.S. players have home-court advantage, as they are more likely to file at the USPTO than players outside the U.S.
- A single year may not be representative.

Given the preceding caveats, 429 nano patents were awarded and 684 applications published under Class 977 for the year 2008:

- Approximately one-quarter of all applications and one-third of all patents granted by the USPTO in 2008 are within the broad field of electronics.
- Nanomaterial manufacturing (processes for making nanomaterials) account for around one-quarter of patents awarded in 2008 and around 18% of applications.
- Medical/pharmaceutical account for 16% of applications filed with the USPTO in 2008. One-quarter of these represent drug delivery systems.
- Energy related R&D (e.g., fuel cells, photovoltaics and battery technologies) accounts for 57 applications (8%) filed.

The private sector holds 42% of applications and almost two-thirds of patents awarded; universities 16% of applications and 21% of patents; and despite its massive investment in nano R&D, the U.S. government has rights to just 17% of patents awarded in 2008 (see below).

In 2008, the home team certainly dominated the field in both applications and patents, with around 60% of applications and patents awarded to U.S. individuals and institutions.⁴⁴⁴

Top 5 Countries by Patent Activity at USPTO*

December 31 2007 - December 31 2008

	Awarded	%	Applications	%
Total	429		606	
US	273	63%	403	59%
Korea	30	7%	77	11%
Japan	67	16%	61	9%
Taiwan	13	3%	73	11%
China	7	2%	52	8%

* These country tallies include patents assigned to and applications filed by individuals. In the case of a filing with three inventors and three different nationalities, the filing is assigned to the three countries and therefore counted three times.

USPTO Nano Patents 1976 to 2008

Chen, Roco et al. USPTO top 10 assignees	Patents 1976-2006	Patents 2000-2008	Applications 2000-2008
IBM	209	123	42
University of California	184	69	46
US Navy	99	23	4
Eastman Kodak	90	15	10
MIT	76	35	6
Micron Technology	75	36	16
Hewlett-Packard	67	89	0
Xerox Corporation	62	10	6
3M Corporation	59	25	17
Rice University	51	53	24

Not in Chen, Roco et al.

Samsung	48	76	113
Hon Hai Precision Co (aka Foxconn)	9	21	96
Tsinghua University	5	11	82
FujiFilm (incl. Fuji Xerox)	10	17	19
Fujitsu Corporation	13	13	26
Sony Corporation	31	32	14
Mitsubishi	31	7	9

NanoNations are feeling the heat from emerging economies in the IP arena (as well as in government spending on nano R&D). In 2008, Tsinghua University (Beijing) and Hon Hai Precision Co., Ltd. (owned by Taiwan-based multinational Foxconn) inundated the USPTO with 42 patent applications, virtually all related to carbon nanotubes (around half in touch screen panels – a product of the Tsinghua-Foxconn Nanotechnology Research Center in Beijing). Foxconn, manufacturer of electronics (including iPhones) and computer components, had \$61.8 billion in revenues in 2008 and operates its own patent office staffed by IP experts who help guide research strategy on the basis of patentability. The office is said to have filed 1000 applications so far, and has won 300 patents.⁴⁴⁵

The Miracle Molecule: Carbon Nanotubes at the USPTO in 2008

Legal commentators caution that fundamental issues such as patentability, prior art, adequate disclosure and non-obviousness have not been properly addressed by the USPTO in early IP awards for CNTs,⁴⁴⁶ turning the CNT patent landscape not just into a thicket but a minefield. The extent of the problem created by the Patent Office's 'generosity' has yet to become clear as CNTs are still, by and large, on the hunt for commercial applications. Anecdotally, the situation seems to have left some larger companies and investors queasy about getting into the CNT game⁴⁴⁷ and has been cited as one of the "most acute challenges for those wishing to commercialize nano applications."⁴⁴⁸ Perhaps as a result, one assessment found that many companies and academic researchers outside the U.S. are now looking to "tight nondisclosure policies to protect their trade secrets rather than rely on patent filings and IP positioning."⁴⁴⁹ Elaborate fixes such as nanotube patent forums are now being concocted to navigate out of the confusion created by early IP awards.

Industry consultant Lux Research may be on the mark with its assessment that interest in CNTs has taken a downturn and that nanosilicon is the new darling,⁴⁵⁰ but the R&D shift to silicon has yet to make itself felt in patenting activity at the USPTO. There, the nanotube feeding frenzy continues in both patents and applications, with carbon nanotubes featuring prominently in 40% of all applications.

Carbon Nanotube Patents Awarded in 2008

- Cryovac, Inc., a division of multinational Sealed Air Corp., is offering to wrap meat, pizzas, toys, paper products, etc. in single-walled nanotube-packaging (7,335,327: Method of shrinking a film).
- University of North Texas has been awarded a patent for using CNTs to combat climate change: in particular, to assist in converting greenhouse gases to hydrogen fuel. The process itself, according to the inventors, "is substantially free from carbon contaminants and carbon dioxide production" (7,468,097: Method and apparatus for hydrogen production from greenhouse gas saturated carbon nanotubes and synthesis of carbon nanostructures therefrom).

- Seldon Technologies (Vermont, USA) has been awarded patent # 7,419,601 (Nanomesh article and method of using the same for purifying fluids), which describes using CNT nanomesh membranes for bioremediation, including removing a range of biological agents (among them anthrax, cholera, typhus and nanobacteria) and hazardous chemicals (including industrial agricultural pesticides, fertilisers) from water. Apparently, the technology will also work with blood; food products such as oils, wine, juice; and in pharmaceutical production.
- With funding from the National Science Foundation and Nanoscale Science and Engineering Center, the Rensselaer Polytechnic Institute (New York, USA) has scored fairly extensive IP on CNT foams, their production method, and a range of uses, including filters; flexible membranes; acoustic damping material; fabric; electrochemical storage; cell growth matrix; and a therapeutic agent delivery system (7,473,411: Carbon nanotube foam and method of making and using thereof).

Carbon Nanotube Patent Applications Filed in 2008

In addition to Foxconn and Tsinghua University's 42 patent applications for CNT-based technology, IP is being claimed for using CNTs in almost everything that moves and doesn't move:

- French multinational Arkema describes using food crops (or biomass) to manufacture CNTs. "Vegetable matter," according to the applicant, "has the advantage of being able to be cultivated in large quantities throughout most of the world, and of being renewable." Beet, sugar cane, cereals (corn, wheat, barley and sorghum) and potatoes are being targeted as the feedstock for the ethanols it plans to manufacture nanotubes from... a recipe to place food production under even more pressure from competing, non-food uses of crops (20090008610: Process for producing carbon nanotubes from renewable materials).
- Battelle Memorial Institute (Ohio, USA), meanwhile, proposes bringing together carbon nanotubes and seed enzymes (from soybeans and horseradish, among others) to manufacture biocatalysts for use in biofuel cells, biosensors, labs-on-chips, and for bioremediation. The U.S. Department of Energy has funded this research and has rights to the IP (20080318294: Biomolecular hybrid material and process for preparing same and uses for same).

- Los Alamos National Security Laboratory (New Mexico, USA) has visions of sending Department of Energy-funded CNT fibres to Mars, as well as having them used in laminates, woven textiles for aircraft armor, missiles, space stations, space shuttles, and other high strength articles (20090208742: Carbon nanotube fiber spun from wetted ribbon).
- U.S. researchers propose a union of carbon nanotubes and nuclear power generation to wean civilization off hydrocarbon fuels and to tread lightly on the earth. According to the applicants, bringing CNT and hydrogen isotopes together would provide a new means of meeting “current and future energy needs in an environmentally friendly way” (20090147906: Methods of generating energetic particles using nanotubes and articles thereof).
- The same researchers recommend using CNTs in spray-on cleaning products for home and work to remove anything from anthrax spores and radioactive waste to food stains. Nanobacteria are a potential further ingredient to assist in removal of certain contaminants. Under the envisaged use, CNTs will be components in a hi-tech kitchen wipe – surfaces can be wiped and the materials picked up will be flushed down drains (20090196909: Carbon nanotube containing materials for the capture and removal of contaminants from a surface).
- Canadian researchers describe using CNT-fibres in tissue regeneration. The applicants note that, as CNTs are generally not biodegradable, “the release of carbon nanotubes as nanosized particles in biological systems may potentially be undesirable.” The application proposes coating CNTs with biological materials to make them biocompatible (20090169594: Carbon nanotube-based fibres, uses thereof and process for making same).
- University of South Florida scientists describe a hybrid nanoparticle made of CNTs and chitosan (derived from chitin, found in the exoskeletons of crustaceans) to deliver drugs and to form a biosensor. The researchers acknowledge that CNTs may be harmful but suggest that coating with chitosan may fix the problem and hope to use CNTs “to fabricate nanomotors, which can enter inside the cells to treat diseases” (20080214494: Method of drug delivery by carbon nanotube-chitosan nanocomplexes).

U.S. Government: Largest Patent Patron for 2008

U.S. federal agencies funded research that resulted in 92 patent applications and nearly one-fifth (72) of nanotech patents awarded in 2008. The financial support gives the government “certain rights in the invention.” Technically, that makes the U.S. government the largest patent-holder of 2008, although the extent of federal IP rights is not specified.

U.S. Government-funded R&D Leading to Nano Patents and Applications, 2008

Federal Agency	Applications	Patents Awarded
National Science Foundation (NSF)	92 of 684 (13%)	72 of total 429 (17%)
Department of Energy (DOE)	28 (17*)	24 (12)
Defense Advanced Research Projects Agency (DARPA)	22 (17)	18 (12)
NASA	5 (4)	8 (2)
Navy (including Office of Naval Research [ONR])	13 (10)	7 (3)
Air Force; including Office of Scientific Research (AFOSR)	8 (7)	13 (2)
National Institutes of Health (NIH)	8 (3)	8 (2)
US Army (ARO) (Including Army Research Laboratory and Natick Soldier Systems Center)	12 (9)	6 (2)
Department of Defense (DOD)	2 (1)	5 (2)
NIST	3 (2)	2
National Cancer Institute		3 (2)
National Human Genome Research Institute	2	1
Food and Drug Administration	1	
Special Operations Command	1	
Unspecified Government Agency	4	4

* Numbers in parentheses are the number of patents or applications where the agency is the sole federal funder.

By number of applications and patents, the National Science Foundation's support has resulted in the most IP, followed by the Department of Energy, whose sponsorship extends beyond energy to biomedical R&D. Military agencies account for one-fifth of federally funded applications and 40% of patents awarded for federally-funded research in 2008.

The Prior Art of War: Military and Defense Applications

U.S. military interest in tiny tech ranges from DNA analysis to optoelectronic applications, from nanomaterial manufacturing and tissue engineering to solar cells, as made evident in patents and patent applications awarded/filed in 2008 and resulting from funding by military agencies:

- Detecting biological or chemical warfare agents is the focus of several patents resulting from research funded by the military.⁴⁵¹ If this Air Force Office of Scientific Research product sees the light of day, public spaces could be riddled with “a broad network of sensors” that would provide early warning of a biological or chemical warfare attack. As a second home, the ‘interferometers’ could be used in semiconductor production by ferreting out impurities or in detecting contaminants in water (20090257057: Common-path interferometer rendering amplitude and phase of scattered light).
- Massachusetts-based Icet Inc. used an SBIR (Small Business Innovation Research) grant funded by the Army to develop textiles that protect soldiers/combatants against biological and chemical warfare. The textiles contain biocidal and catalytic nanoparticles (copper and/or silver) that will apparently automatically “deactivate” and destroy biological and chemical agents in the field. Further, ubiquitous civilian use is envisioned, including coating surfaces such as vehicles, buildings, walls, wallpaper, furniture and carpets in public places (20090130161: Material compositions for microbial and chemical protection).
- Science Applications International Corporation (SAIC), a U.S. Fortune 500 company, has been awarded a patent on nanopolymer smart-textile fibres that will cater to electronics and information technology, chemical and biological detection, and health monitoring in a range of products including uniforms, blankets, tents, parachutes. According to the company, the flexible electronic textiles will spawn “information technology from previously unrecognized sources” (7,410,697: Methods for material fabrication utilizing the polymerization of nanoparticles).
- To clean up after a chemical or biological attack, Georgia, USA-based Nanomist Systems has invented a biocidal mist (from hydrogen peroxide) for sterilizing/decontaminating buildings or sites exposed to anthrax (7,326,382: Apparatus and method for fine mist sterilization or sanitation using a biocide). Civilian uses include odour control, neutralising phenols, pesticides, solvents, among others. (The patent refers to “nanoscale droplets less than one micron.” One micron is 1000 nm.)
- Texas-based Quantum Logic Devices has been awarded patent 7,338,711, which describes an explosive or propellant coating for nanoparticles (such as TNT, Tetryl, RDX, and PETN) for use in fuels, propellants and explosives (Enhanced nanocomposite combustion accelerant and methods for making the same).
- Cubic Corporation, headquartered in California, has apparently found a way for friends to communicate and for identifying enemies in the combat zone using nano-optical tagging devices as “combat identification systems” (20090116850: Resonant quantum well modulator driver).



Academia Boosts the Nano-War Effort

Universities are proving to be important partners in realizing the U.S. military's nanotech ambitions.

Since 2000, U.S. military institutions (the Army Research Office, the Office of Naval Research, the Department of Defense, the Navy and the Air Force Office of Scientific Research) have hauled in around 195 nanotechnology patents, with a further 151 applications pending.⁴⁵² R&D at universities accounts for seventy percent of the patents awarded (135).

Rice University is the preeminent nano-warfare research institution, holding 22 patents that it shares with the military; followed by Harvard University (18); Northwestern University (12); California Institute of Technology (12); University of California (12) and Boston College, Cornell and Stanford (6) and MIT (5). IBM and Hewlett Packard are the most active corporate researchers for the military as judged by patents (with 8 and 7 nano patents respectively since 2000).

Rice University's Richard E. Smalley Institute for Nanoscale Science and Technology has a healthy portfolio of 68 U.S. patents relating to nanoscale carbon (fullerenes and nanotubes). Half of those holdings are generated by federally-funded research. Just under one-third are sponsored by the military (predominantly the Office of Naval Research, mostly in conjunction with other federal agencies such as NASA and the National Science Foundation).⁴⁵³

The Institute is not only fraternizing with state military institutions but has also teamed up with arms manufacturer Lockheed Martin to form the Lockheed Martin Advanced Nanotechnology Center of Excellence (LANCER) to pursue "new technologies for materials, electronics, energy, security, and defense," including "neuromorphic" computers that are structured like mammalian brains" and stealth materials.⁴⁵⁴ Lockheed is looking to exploit the Smalley Institute's expertise in the field of CNTs and fullerenes, among others. Its own patent, #7,025,840 (Energetic/explosive fullerenes), describes carbon nanotube or fullerene explosives in the form of "bullets, artillery rounds, tank rounds, packaging materials, missiles, fuselages, nano-scale ordnance, micro-scale ordnance, and shell casing."

Given that MIT is home to the Institute for Soldier Nanotechnologies (ISN), its patent haul appears paltry by comparison with other military-funded universities. The Institute, with its 60 MIT staff and 100 students, has received two federal five-year grants of \$50 million since 2002.⁴⁵⁵ Its ultimate goal is to create a 21st century battle suit. Co-founding members DuPont, Raytheon and Partners Healthcare (Massachusetts General Hospital, Brigham and Women's Hospital, and the Center for the Integration of Medicine) are actively involved in research and have royalty-free (but not exclusive) access to Institute IP.⁴⁵⁶

In total, ten of MIT's nano patents involve federal military agency funding.⁴⁵⁷ The sole patent attributed to funding from the Institute for Soldier Nanotechnologies describes genetically engineered viruses to produce prototype lithium ion batteries. The engineered viruses coat themselves with iron phosphate nanowires and then latch on to conductive carbon nanotubes.⁴⁵⁸ The trick, as the lead scientists noted in earlier experiments, is to force nature to work with "materials that evolution has ignored." According to the researchers, the production process is benign because "no harmful or toxic materials are used."⁴⁵⁹ The small matter of the potential effects of a prime ingredient, carbon nanotubes, is left unaddressed.

The dearth of patent activity from the ISN should not, however, be confused with lack of activity: as patents require some level of disclosure, it is quite possible that the military has decided not to pursue that path in order to keep its R&D below the radar. (See Appendix for more on nano-patenting backed by the military.)

Appendix:

Class of 2008 – Awarded Patents and Filed Applications of Note at the USPTO

Nanobiotechnology

DNA is growing in popularity as a workhorse for the electronics industry, as the following patents illustrate.

Patent 7,374,649: Dispersion of carbon nanotubes by nucleic acids

DuPont (Delaware, USA) is using DNA to separate CNTs for use in electronic devices. The DNA is used to sort metallic CNTs from semiconducting CNTs as well as sorting tubes by diameter size.

Patent 7,326,954: Scaffold-organized metal, alloy, semiconductor and/or magnetic clusters and electronic devices made using such clusters

The University of Oregon – funded by the Department of Defense, Office of Naval Research, and the National Science Foundation – has been awarded IP rights over nanobio clusters for use in electronics and high-density memory storage.

Patent 7,393,699: NANO-electronics

Five different viruses can apparently churn out memory devices, computer assisted drawing, pacemakers, insulin production systems, and energy storage, at least as described by a U.S. researcher. Assembly of the pacemaker involves injecting the virus “near the heart to build a pacemaker that supplements the pacing done by the human heart pacing cells.” The proposed virally-generated medical implants will apparently sidestep immuno-suppression responses that have plagued other forms of implantation.

Patent 7,416,911: Electrochemical method for attaching molecular and biomolecular structures to semiconductor microstructures and nanostructures

Researchers from the California Institute of Technology have invented a method for coating silicon nanowires in either chemical or biological material for electronic devices in screening and pharmaceutical applications but that could also be used in all kinds of biochemical, electronics, chemical, medical, petrochemical, security, and business applications.

Patent 7,449,445: Conductive peptide nanofiber and method of manufacture of the same

To make microelectronic structures smaller than 20 nm, Japan’s Panasonic Corp. and the National University Corporation Kobe University are harnessing protein power, in particular, the spontaneous formation of structures (known as amyloid fibres) associated with prions and diseases such as Alzheimer’s disease and BSE. The patent-holders claim that “no adverse influence on the environment is exerted,” specifying that, because the conductive peptide nanofibres are biodegradable, they are healthier for the environment.

Application 20090194317: Electrical conductors and devices from prion-like proteins

Researchers from the University of Chicago and the Whitehead Institute for Biomedical Research (affiliated with MIT) also propose using prions for the self-assembly of electronic components, funded by the U.S. National Institutes of Health. According to the researchers, little attention has been paid to the economic benefits of prions, with the focus until now being on “the immediate medical implications of diagnosing, treating, and preventing spongiform encephalopathies and other amyloid diseases.” Prion-like proteins found in yeast are preferred. The electronics industry would not appear to be the sole sector the researchers intend to service. Genetic engineering of plants, animals, microorganisms or fungi using chemically or genetically engineered prion proteins is also part of the plan. Particular emphasis is given to engineering life forms to be “climate ready” (e.g., able to survive in drought conditions, saline soils, etc.), for use in bioremediation, or to modify pigments in plants and animal fibres.

Application 20090258355: Nanoscale clusters and methods of making same DNA

Brookhaven Science Associates/ Brookhaven National Library (New York, USA) researchers want to manufacture nanoparticles by way of self-assembly using bio-encoded nano building blocks (with gold, silver, copper, platinum or palladium the favourites). Nanobio sensors and catalyst dispensers are hoped-for products of this research funded by the U.S. Department of Energy.

Agriculture and Food

Nanobio agricultural and food applications are scarce in 2008 filings (perhaps due, in part, to the sub-100 nm working definition of nano used by the USPTO, which may be too small to capture nanobio activities).⁴⁶⁰ Among those that do feature in the Class of 2008 are the following.

Application 20090104700: Methods for transferring molecular substances into plant cells

Researchers at Dow AgroSciences reveal their latest recipe for plant engineering – the technology appears to be in pursuit of pesticide and herbicide resistance, of which glyphosate-resistance is offered as an example. The coverage sought is broad: the method of introducing foreign genetic material into a plant cell by way of nanoparticles, where the type of foreign genetic material and the nanoparticles are numerous (gold nanoparticles are favoured as the medium). The invention appears to be a kinder, gentler “gene gun” – the cell wall and the nanoparticle simply have to come in contact and the cell takes up the nanoparticle on its own, “non-invasively.” Dow makes a particular play for use of the technology in “tobacco, carrot, maize, canola, rapeseed, cotton, palm, peanut, soybean, *Oryza sp.*, *Arabidopsis sp.*, *Ricinus sp.*, and sugarcane, cells.”

Application 20090105738: Device for transfecting cells using shock waves generated by the ignition of nanoenergetic materials

Electric shock treatment takes on new meaning with the University of Missouri’s plans to shock bacteria, plants, animals and fungi into behaving differently. A miniature device that produces shock waves will apparently assist in introducing pharmaceutical compounds and genetic material into cells and tissues. The description focuses largely on pharmaceuticals; however, the breadth of life forms – bacteria, animals, plants, fungi – suggests the possibilities extend well beyond human therapeutics.

Patent 7,459,283: Nanoparticulate compositions having lysozyme as a surface stabilizer

Elan Pharma International proposes using lysozyme – an enzyme found in tears, nasal mucus, milk, saliva, blood serum of vertebrates and invertebrates, as well as egg white, some molds, and in the latex of different plants – as a bioadhesive. The company has secured claims on the composition, method of manufacture and use for an extremely wide range of active agents including drugs, herbs, cosmetics and sunscreens, herbicides, germicides, plant-growth regulating agents and all manner of pharmaceutical agents and biological material. Agricultural applications are in the company’s sights: bioadhesiveness is proposed for better application of pesticides, fungicides and herbicides. According to the patent description, “all plants, such as grass, trees, commercial farm crops (such as corn, soybeans, cotton, vegetables, fruit, etc.), weeds, etc. are encompassed by the scope of this invention.”

Application 20090227784: Processing method for nano-miniaturizing chitosan of modifying property

Taiwanese company, Acelon Chemical and Fiber Corporation, describes making nanoscale chitosan for use in “cosmetics, medical treatment, hygiene, health care, biomedicine, agriculture, textile, food.” Chitosan, made from the shells of crustaceans (crabs, shrimps, etc.), is used in organic agriculture as a biocontrol agent and in biomedicine for its antiseptic properties.

Application 20090149426: Process for synthesizing silver-silica particles and applications

Medical Tool & Technology, LLC (Florida, USA) is proposing its silica-silver nanoclusters be put to use as a spray-on fungicide for plants. The company suggests that the silver-silicon blend will not pose the same environmental risks that the use of nanosilver may.

Medicine and Pharmaceutical

Medical and pharmaceutical patent activity accounts for almost one-fifth of applications, compared to around one-twentieth of nano patents awarded by the USPTO in 2008. Targeted drug delivery is an overwhelming preoccupation of applications filed that year, with one-third focused on exploiting nanoscale properties to get drugs to specific sites and cells. Medical implants and tissue engineering are also of great interest.

Application 20090117087: Methods and compositions for printing biologically compatible nanotube composites of autologous tissue

The Air Force Office of Scientific Research funded Wake Forest University (North Carolina, USA) to work on 3D tissue scaffolds to generate tissue taken from one part of the body to replace damaged tissue elsewhere in the body ('autologous transplants'). The process involves taking samples from the patient and using biocompatible "inks" to print the collected cells into tissue scaffolds. The nanoparticles range from carbon nanotubes to metals (silver and gold). Fullerenes that chew through free radicals are also foreseen.

Application 20090117045: Soy or lentil stabilized gold nanoparticles and method for making same

The University of Missouri is using soy and lentils to generate biocompatible gold nanoparticles for use in medical applications (as well as electronics and in sensors). Gold salts exposed to the plant material are said to react by forming biocompatible gold particles. (The prospects of increased profits for the GM soybean industry are not looking good, however, as the researchers describe buying organic soybeans from a local grocer.)

Application 20080268060: Methods and apparatus for producing nanoscale particles

Philip Morris (Virginia, USA) is using its vast commercial experience in inhalation-based products (i.e., cigarettes) for an aerosol drug delivery system. Treatment methods other than aerosol – oral (tablets, capsules) and injection – are also included, and the company wants the Patent Office to give it monopoly over a wide range of drugs administered via the method it describes. Meanwhile, the company has not abandoned its traditional 'inhalation technology' and has been working on inserting nanofibrils into cigarettes to reduce carbon monoxide in smoke. A useful technology according to the company, as "reduction of carbon monoxide and/or nitric oxide in smoke is desirable."

Philip Morris already has one patent to show for it (7,509,961: Cigarettes and cigarette components containing nanostructured fibril materials); and has applied for two others describing nanocatalysts that may do a similar job for vehicle exhaust (20060289024: Catalysts for low temperature oxidation of carbon monoxide and 20070014711: Method for forming activated copper oxide catalysts).

Patent 7,391,018: Nanostructured thin films and their uses
Nanosys's (California, USA) aluminium/alumina thin film technology is destined for medical implants and tissue grafting as well as catalysis, electronics, sensors and the like. Funded by the National Human Genome Research Institute, Department of Health and Human Services and the NIH, the technology is said to be useful in reducing bio-fouling that can occur on medical implants – attributes that also apparently make it ideal for public hygiene in the form of surface coatings for ATM and gambling machines, among others.

Patent 7,329,638: Drug delivery compositions

The University of Michigan (with financial help from NIH) says it has worked out how to get pharmaceutical compounds across biological barriers – including the blood-brain barrier – with the stated benefit of reducing potential toxic side effects on non-targeted cells and tissues. This patent is broad and covers delivery of a wide range of pharmaceuticals, a wide range of cancer types, diabetes, HIV, depressions, infections, and uses a range of administration schedules, etc.

Patent 7,404,969: Lipid nanoparticle based compositions and methods for the delivery of biologically active molecules

Sirna Therapeutics (California, USA) describes new forms of genetic engineering and gene therapy using nanoparticles that help effect RNA-mediated gene silencing. This includes "methods of use for the study, diagnosis, and treatment of traits, diseases and conditions that respond to the modulation of gene expression and/or activity in a subject or organism." A particular preoccupation is "facilitating transport across cellular membranes." There is considerable emphasis on treating medical conditions and disease (including preventing organ transplant rejection) but the claims and description do not limit the application of the technology to humans, as the overarching purpose is described "to prevent, inhibit, or treat diseases, conditions, or traits in a cell, subject or organism."

Patent 7,332,586: Nanoparticle delivery vehicle

North Carolina State University has been awarded a patent on a nanoparticle delivery system for inserting DNA or RNA into cells/a cell nucleus for gene therapy. In this NSF-funded approach, the nanoparticles provide a scaffold that the DNA can attach to.

Cosmetics

Application 20080214670: Therapeutic malonic acid/acetic acid C60 tri-adducts of Buckminsterfullerene and methods related thereto

Washington University (Missouri, USA) researchers' recipe for a long life is to down fullerene derivatives on a daily basis. The researchers explain that compounds "such as Gingko, Ginseng, Vitamin C, have been proposed to improve survival, but controlled and statistically significant survival studies reporting the benefit for these compounds are unknown." Whether or not that it is the case, the scientific literature is not teeming with data about fullerenes or their safety (on the contrary, they have a tendency to show up on the 'most worrying nanomaterials' ratings⁴⁶¹). Nevertheless the researchers appear upbeat about the life-enhancing effects of the fullerene derivatives prescribed here, which will apparently work their wonders by treating neuronal injury.

Application 20090104291: Water-dispersible nanoparticle which contains blood circulation promoter

Those who associate FujiFilm (Tokyo, Japan) with the family photo album may be surprised to find the company seeking to have a hand in their cosmetics and dietary supplements. In a cluster of three applications apparently spun from the same research, the corporation proposes nanoemulsions to promote blood circulation in cosmetics, functional foods, dietary supplements, "quasi-drug" components and pharmaceuticals.

The blood circulation promoters are to be made from a range of materials including extracts from plants such as ginger, cayenne, peppermint and garlic. A second application proposes water-soluble emulsions such as microbicides in cosmetics, foods and pharmaceuticals (20090130159: Water-dispersible nanoparticle containing microbicide). The company has also developed a recipe for an anti-acne skin cream that uses protein nanoparticles (e.g., collagen, gelatin, acid-treated gelatin, albumin), which apparently results in a "highly safe" product (20080299159: Anti-acne skin agent for external use).

Application 20080112909: Compositions for providing color to animate objects and related methods

PPG Industries Ohio is concerned with the all-important business of getting the colour right for various products, whether it is hair spray or mouthwash, or a fungicide for plants. The application describes polymer-encapsulated nanoparticle dyes or colorants for personal care products, tattoos, food additives and agricultural chemicals (fertilizers, fungicides, insecticides, herbicides and bactericides).

Application 20090193595: Coloring composition comprising at least one pigment and at least one electrophilic cyanoacrylate monomer

Quantum dots are among the "special-effect pigments" incorporated in L'Oreal's new hair dye recipe.

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ETC Group

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ETC Group is an international civil society organization. We address the global socioeconomic and ecological issues surrounding new technologies with special concern for their impact on indigenous peoples, rural communities and biodiversity. We investigate ecological erosion (including the erosion of cultures and human rights), the development of new technologies and we monitor global governance issues including corporate concentration and trade in technologies.

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In 2008, ETC Group and its partners convened an international meeting of civil society activists in Montpellier, France under the title, BANG – signifying the convergence of technologies at the nanoscale – specifically, Bits, Atoms, Neurons and Genes. At the meeting, ETC Group agreed to prepare a series of background documents on major new technologies, which could assist our partners and governments in the global South in understanding these developments and responding to them. This report is one of the studies.

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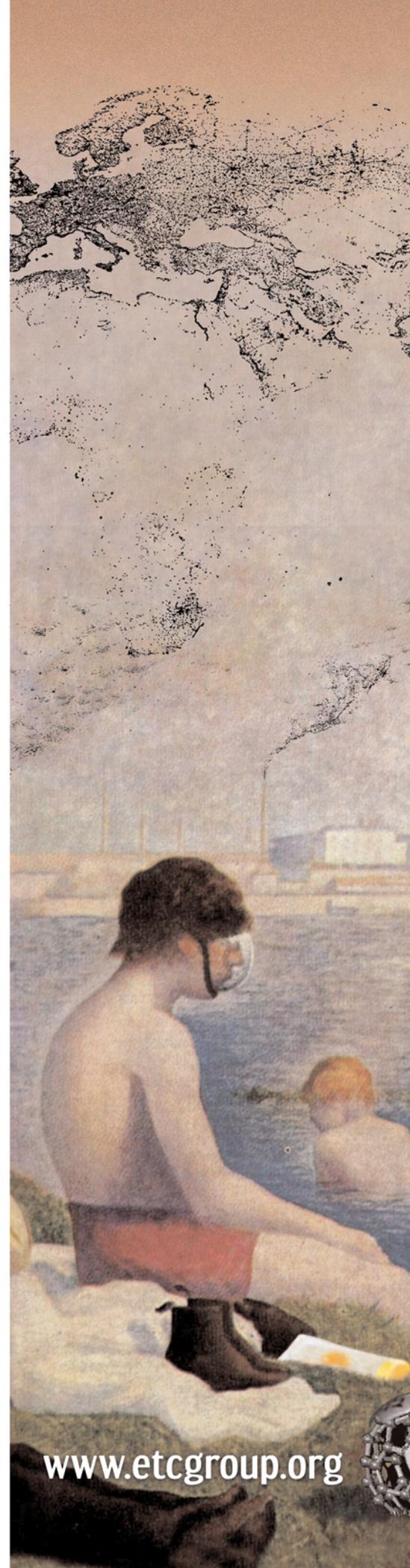
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