July 2009
ETC Group
www.etcgroup.org

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Nanogeopolitics 2009: The Second Survey

Issue: Technology in general, and the nanotechnology industry in particular, presents itself as the clean, green solution to all our compounding crises – food, fuel, financial, and Fahrenheit. Big investments in nanotech, we are told, will yield big payoffs in energy-savings and climate change mitigation. But even as the over-hyped technology is rolling out, nano seems neither squeaky clean nor green. Over the past weeks and months a succession of heavy-hitting government and scientific studies have issued increasingly alarmed warnings that nano comes with a host of unseen risks. More than ever before, nanotechnology looks like it is at a tipping point. In an effort to provide some critical context for the OECD conference touting the "environmental benefits" of nano, ETC Group is providing a draft preview of our second Nanogeopolitics Survey.

At stake: This year, the world will add almost $10 billion to the more than $40 billion spent on nanotech research over the past decade. Although the estimates are that nano's current commercial market runs somewhere between a boring $12 billion and a bloated $150 billion – and the worldwide recession hasn't helped – OECD governments and countries are bullish that little nano is still the next big thing.

Actors: Since ETC Group first surveyed the nanogeopolitical landscape in 2005, the actors have both changed and shifted positions. In cash terms, Russia now leads the research charge although the EU (with 27 member states) spends more collectively. The old leaders (USA and Japan) are now laggards and Asia is moving up fast. While China spends only 10% of the world's nanotech research budget, its EU competitors are cognizant that Chinese research is about 1/20th the cost of European research. In real terms, China could be out in front.

Fora: For more than five years now, OECD states have delicately wrung their hands through a succession of national and collective dialogues, voluntary guidelines and codes of conduct, while twittering over the need for inclusive participatory processes. However neither civil society nor developing countries are true participants in this OECD's ambitious nano agenda, lacking both the invitation and the financial means to participate in the dialogue on an equal footing. In the meantime, the modest conclusions reached in May 2009 at the Second International Conference on Chemicals Management, notably the resolution calling for a process to examine the impacts of nano on developing countries, are liable to be ignored by the nano nations in Paris.

Policies: The nanotech debate needs to be firmly entrenched in the UN system where all nations can have a say about the technology and where the so-called nano-nations will come clean with everybody else about what they are doing to the economy and the environment. The potential environmental and economic benefits of nanotechnology can only be responsibly discussed if equal attention is paid their risks, and if attention is focused on addressing the enormous gaps in our knowledge regarding their long-term effects on human health and the environment as well as the deepening divide between technological have and have-not nations.

Pat Mooney, Executive Director of ETC Group, is attending the Paris meeting.

"Human kind is increasingly developing technologies with greater potential impact...and the 'wait and see' approach is increasingly becoming a dangerous way to determine the risks of these technologies. This is because if the risks are miscalculated the negative consequences can be on a grand scale." – Lloyd's, *Nanotechnology: Recent Developments*, Lloyd's Emerging Risks Team Report, 2007

"New governance arrangements are necessary to deal with ignorance and uncertainty...We strongly recommend a more directed, more co-ordinated 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

"Informal cooperation only is no more an acceptable option....we shall face political and societal unrest with a loss of trust in the ability of public institutions to provide appropriate nanotechnology governance, as well as legal uncertainty, both with deep, long lasting and, unfortunately, predictable consequences on the market side." – Françoise Roure, Economic Ministry (France) and vice-chair of the OECD Working Party on Nanotechnology, 2008

"Federal regulatory agencies already suffer from under-funding and bureaucratic ossification, but they will require more than just increased funding and minor rule changes to deal adequately with the potential adverse effects of the new technologies. New thinking, new laws and new organizational forms are necessary..." – J. Clarence Davies, *Oversight of Next Generation Nanotechnology,* the Project on Emerging Nanotechnologies, The Woodrow Wilson International Center for Scholars / Pew Charitable Trusts, 2009

"In many respects we are ill-equipped to live with nanotechnologies. We do not understand the nature and properties of most nanomaterials. We have yet to develop methods and tools to measure and detect nanoparticles. Most importantly, we know little about how nanoparticles might affect human health and our environment." – Phil Woolas, Minister for the Environment (UK) in a letter to industry, expressing his disappointment in the low level of participation in the UK's voluntary reporting scheme, 2008

You can't say we didn't warn you... Going on seven years now, governments and industry have been using one hand to pat themselves on the back for being pro-active and the other hand to wave away red flags raised by some scientists and civil society organizations. When ETC Group called for a moratorium on the commercialisation of new nano-products back in 2002, for example, the response bordered on hysteria. The nanotech industry's U.S. trade journal, *SmallTimes*, featured several articles attacking 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] Has the tide begun to turn?

Markets and Players

The most quoted and – possibly, most disputed figure – related to the nanotechnology market was published by the National Science Foundation (NSF) in 2001 estimating the world market for nano-based products would reach $1 trillion in 2015. Since then, others have forecast a $150

billion market in 2010 (Mitsubishi Institute, 2002) and $2.6 trillion worth of products incorporating nano in 2014 (Lux Research, 2004). There's more than a sniff of hype in these figures: They may be accurate for the value of the total product, but the role of nano may vary widely across the product range: It may be truly nano for some and micro for others. The cost of finding out, however, is not so small, with more detailed analysis being proprietary to some industry reports that are so expensive that even some regulators rely on the free summaries. But even in hindsight, the measure of the nano's market varies wildly, from $11.6 billion in 2007 (BCC research)[2] to $147 billion[3] for the same year (Lux Research). Lux's $147 billion is made up of $97 billion materials and manufacturing, $35 billion from electronics and $15 billion from healthcare.

The most widely cited database of products, the Project on Emerging Nanotechnologies' product inventory,[4] estimates that around 807 product lines are on the market, which translates into millions of actual products in circulation. The most recent analysis states that the U.S. market is responsible for more than just over half (428) of the nanoproducts, while Asia accounts for just under 30% (228) and Europe 13% (106 products).

Governments have been bankrolling nano – to the tune of $40 billion over the last decade. According to nano-consultancy Cientifica, the global government investment in 2009 is $9.75 billion:

Government Investment 2009	% of total
EU (27 members + FP7)	27%
Russia	23%
U.S.A	19%
Japan	12%
China	10%
Korea	4%
Taiwan	1%
India	(<1%)
Rest of world	4%

Since the inception of the interagency National Nanotechnology Initiative in 2000 (credited with launching the global/intergovernmental nano-race), the U.S. has invested around $10 billion dollars of public funds[5] and the EU has invested €5.1 billion through its Framework Programme. (This does not include additional investments by individual EU countries.[6] The U.S. budgeted $1.5 billion in 2009, with the Department of Defense getting the lion's share – $431 million.

In 2008, corporate R+D investment nudged ahead of government investment, according to Lux Research. By 2010, Cientifica predicts corporations will command 83% of the nano R+D investment.[7] Academic institutions are a considerable player: Lux reported in 2007 that interviews with executives at 31 global corporations revealed they all collaborate with academic institutions.[8] Around 35,000 people worldwide are engaged in nanotech research.[9]

Russia's tiny war: According to Cientifica, Russia's government is now supporting nanotech at a higher level than the U.S. Russia came late to the nano-party, but arrived with a bang – a $5.1 billion investment and the detonation of the world's first nanobomb[10] – a fuel air explosive with nano features capable of flattening nine city blocks all at once.[11] Russia's nano-bomb is significantly more powerful than its US macro counterpart – already endearingly dubbed the Mother Of All Bombs (making the Russian's nano-version the "Nanny Of All Bombs?"). The Kremlin, which was quick to reassure the international community that the bomb is environmentally friendly and does not breach any international conventions,[12] sees nano as "the locomotive of science and technology strategy"[13] and the basis of an economic resurgence.

The global nano-race has thus far been staged under the banner of 'responsible nano,' with pledges to transparency, dialogue, openness and stewardship. Early ambassador for nano- and converging-technologies, the U.S. National Science Foundation's Mihail Roco describes this new approach governments have adopted as a departure from traditional regulatory approaches: "the replacement of traditional 'powers over' with 'powers to.'"[14] His formulation is a feel-good *apologia* for self-regulation: Instead of governments restricting what can and can't be done (through regulation), governments are empowering "the social ecosystem" to behave in such a way as to produce "desired outcomes."[15] Other commentators note – correctly – that governance is 'broader than regulation.' For them, it includes foresight and public deliberation, but it also includes 'soft-law,' voluntary regulation and codes of conduct.[16] Thus far, however, governments have not gone for the full package deal but have opted for regulation-lite.

Governance, Or What Governments Have Been Doing Instead of Governing:

A. Hand-wringing

Without exception, a wave of reports from public science institutions show that the scientific understanding of how nanomaterials will affect workers, citizens, other species and ecosystems is seriously wanting. Since September last year, the Council of Canadian Academies, the UK's Royal Commission on Environmental Pollution, the U.S. National Research Council, the EU's Scientific Committees on Emerging and Newly Identified Health Risks, the European Food Safety Authority and, most recently, the EMERGNANO review of safety research have all weighed in with assessments that confirm that the nanosafety 'to-do list' is enormous. In a now familiar chorus, these reports chant a list of urgent research and methodological needs. The collective view is that while existing risk assessment frameworks are broadly appropriate, specific risk assessment procedures do not yet exist because of ignorance or uncertainty in critical areas.

Safety First? Conservative estimates put scientific understanding of the risks at least a generation behind the development and commercialisation of the technology.[17] This is not surprising given the investment in product development versus investment in ecological and health effects research. Under FP7, the EU is investing a paltry 4% – €28 million of a total €600 million – on safety research. This has sparked criticism from the European Parliament Environment Committee, which is calling for a "major stepping up of the funding."[18] Official accounts for the U.S. are worse: The Bush administration claimed $37.7 million of $1.5 billion nano R+D budget in 2006 was dedicated to safety research – just 2.5% – but other reviews place this number at around 1%.[19]

For nanosafety alone, U.S. researchers have estimated that costs for testing *existing* nanoparticles range from $249 million for optimistic assumptions about nanoparticle hazards (i.e., they are primarily safe and mainly require simpler screening assays) to $1.18 billion for a more comprehensive precautionary approach (i.e., all nanomaterials require long-term *in vivo* testing).[20]

At present, says the Royal Commission on Environmental Pollution, determining how safe nanomaterials are is "extremely difficult [...] because of our complete ignorance about so many aspects of their fate and toxicology."[21] Almost nothing is known about nanomaterials in the environment, particularly over their lifetime, it says. Safe exposure levels for humans and ecosystems are not known. No long-term exposure studies have been done. Methods for detecting and monitoring nanomaterials once manufactured or incorporated in products are also required. Currently, there is not even a theory that can be used to predict concentrations of nanomaterials in the ambient environment. The to-do list, it says, is "potentially overwhelming,"[22] and speculates that even against optimistic scenarios where better risk assessment procedures are adopted in the next 2-3 years, "it will be several more years, **possibly decades**, before the toxicology and ecotoxicology of significant numbers of nanomaterials can be properly evaluated."[23]

B. Dialoguing

Dialogue is *de rigueur.* A number of international dialogues have sprung up to discuss nanotechnology's "challenges" and "opportunities," which is the conventional, fair and balanced formulation.

(1) The International Dialogue on Responsible Research and Development on Nanotechnology One of the primary vehicles for the new-look global governance fora is the custom-made International Dialogue on Responsible Research and Development of Nanotechnology. Initiated by NSF's Mihail Roco, the "International Dialogue" was launched in 2004 in Alexandria (U.S.A), and has subsequently continued in Tokyo (2006) and Brussels (2008).

The International Dialogue is billed as the "broadest space to analyse progress, share experience and benchmark initiatives, explore synergies between different stakeholders and foster cooperation to define what can be done better at international level."[24] This is an overstatement as involvement of the global South has been extremely limited, although a greater attempt was made in Brussels to drum up greater representation, with scientists and government officials from Big South countries in attendance.[25]

The International Dialogue does provide safe space for nanonations to discuss issues without the need to account for or be bound by outcomes. With little transparency in its operations beyond the release of meeting reports, it is difficult to gauge the contribution that the Dialogue has made. However conveners suggest that the first meeting of the International Dialogue provided the impetus for OECD and ISO activities on nano, the Global Dialogue on Nanotechnology and the Poor and the International Risk Governance Council's nano-activities (see below).[26]

The picnic's over: IPNiC In Brussels, where nanotechnology governance, bridging the nano-divide, societal engagement and "enabling means" were the focal points, Françoise Roure, of the French Economic Ministry and vice-chair of the OECD Working Party on Nanotechnology, signaled that the picnic was over. "Informal cooperation," she noted, "is no longer an option."[27] Continuing on the same path, she warned, would lead to social unrest, loss of trust in public institutions, legal uncertainty and economic losses.[28] Her proposal was for an intergovernmental, inclusive panel of experts on nanotechnology-induced change (IPNiC), which would report to the International Dialogue and help guide the international community towards necessary nano-governance. The concept is wanting in that it still seeks to base discussions outside democratic institutions and advances on the unquestioned assumption that the technology should be driven forward. Nevertheless, it is the first significant sign of understanding within that forum that current arrangements are unacceptable. Whether other participant countries are willing to move in will be revealed at the next event, rumoured to be in South Africa in 2010.

(2) The Global Dialogue on Nanotechnology and the Poor (R.I.P.)

A further vehicle for nano dialogue across borders was the Global Dialogue on Nanotechnology and the Poor (GDNP). Initial funding for the forum, which ran from 2005-2008, was provided by the Rockefeller Foundation, the UK Department for International Development and the Canadian International Development Research Centre. During its brief lifetime, the GDNP considered nano and water purification and the potential impact on the economies of commodity dependent-countries of nano-substitutes for commodities.

However, after a brief flirtation with considering the ways in which nanotechnologies might negatively impact upon the economies and well-being of the communities of the global South, funding has dried up. Nanonations – including the EU – appear to have reverted to domestic or regional R+D funding and focusing on technology transfer, apparently with the view that this is the best way to close the nanodivide between North and South. While the GDNP was no substitute for UN-based assessment and resolution, it was the sole forum considering the potential impact of nano on the global South and its demise demonstrates a lack of interest by governments to engage with broad-based issues that may not serve their own interests or imply curtailing the roll-out of nanotech.

(3) Transatlantic chatrooms: U.S., EU to get cosy on nanotech regulation?

Regulation of nanotech will be on the table at the 2010 EU-U.S. Summit on transatlantic methods for handling global challenges.[29] This follows earlier cooperation agreements, including the Framework for Advancing Economic Integration adopted in 2007 by then-President of the EU, Angela Merkel, and George W. Bush. There the EU and U.S. agreed to sponsor joint workshops and conferences to foster exchange of information on nanotechnology; to exchange views on policy options and explore common research actions "paving the way to a level playing field for nanotechnology-based products in the globalised market."[30] The London School of Economics, Chatham House and the Woodrow Wilson International Center for Scholars/Pew Project on Emerging Technologies are working on the half-million dollar project, which, in addition to international events in capitals around Europe and the U.S. in 2009, will feed into the 2010 EU-U.S. Summit.[31]

Some nanonations have placed the precautionary principle at the heart of their 'responsible nano' policies. However, squaring precaution with the commercialisation of hundreds of product lines in the absence of risk assessment proved a challenge for government PR staffers. To get the right fit, the Principle has undergone an extreme makeover. Clearly, the feature of the Precautionary Principle most overhauled has been the burden of proof. The new-look precaution is that though there are enormous gaps in scientific understanding and an absence of methodologies to assess the risks of nanomaterials already in circulation, preventing the release or commercialisation of nanoproducts is not justified.

A further defense for throwing precaution to the wind (the exception being the newly introduced EU cosmetics directive, see below) is that nano is nothing new – drawing on a time-honoured tradition of technology introduction: Just as the nuclear industry argued that there is background radiation everywhere (hence, by association, nuclear power is natural), and the plant biotech industry states that humans have been modifying plants for millennia, the nano industry is making us aware of the natural nanoworld all around us. According to the European food industry alliance (CIAAA), for example, "naturally occurring nanoparticles have always been present in food such as milk and fruit juice."[32] At last year's International Forum on Chemical Safety meeting in Senegal, a representative of the chemical giant DSM traced the history of nanotechnology back to ancient Egypt and China prompting one participant to ask if that meant DSM was on the cutting edge of the Bronze Age.

(4) Public engagement (or is it a shotgun wedding?)

Four years ago, ETC Group identified 15 public engagement exercises on nano. Dialogues have continued apace as part of the 'responsible nano' programme, although Canada and the U.S. have largely side-stepped such exercises.[33] The UK seems to have called a time-out on dialogues, after having sponsored the NanoDialogues and the Nanotechnology Engagement Group, both two-year projects (2005-2007).[34] Germany is about to go into round two of a national dialogue, and a new EU dialogue called FramingNano has just launched this year.

(Open, transparent and accountable government has always been a goal for civil society, so the concept of dialogue is in principle positive and preferable to monologues. But the trouble with talking is that there are few, if any, assessments available that identify the extent to which governments, research institutions or industry have acted upon the concerns and recommendations of dialogue participants.)

C. Asking for volunteers

Voluntary schemes are increasingly favoured by governments to avoid stepping on industry's toes – their most influential constituency – and to give the appearance of action. Despite assurances from governments and industry that voluntary measures are not intended to substitute or delay mandatory approaches,[35] self-regulation dominates what passes for nano governance.

Voluntary reporting is one type of scheme intended to capture some information – that is, if industry is willing to offer it up – on the manufacturing, processing and use of nanomaterials. That way, at least, governments may begin to identify what nano-manufacturing and processing take place within their borders and related safety issues.

So far, however, such reporting schemes have been dismal failures, leaving governments shamefaced at being unable to secure industry participation even on such favourable terms. The UK Department for Environment, Food and Rural Affairs (DEFRA) launched a voluntary reporting scheme in 2006. Despite efforts to simplify the forms and despite the Nanotechnology Industry Association (NIA) professing strong support for the scheme, after two years, just eleven submissions (nine from industry and two from academia) had been filed.[36] In a letter to the nano-industry trying to drum up participation, the UK Environment Minister expressed his disappointment in the low turn-out and admitted that, "In many respects we are ill-equipped to live with nanotechnologies."[37]

Not surprisingly, the industry blamed its no-show on concern that the reporting requirements would put commercially sensitive information at risk.[38] The scheme has been pronounced a failure, most recently by the chair of the Royal Commission on Environmental Pollution who reportedly labelled the scheme "pathetic"[39] and called for mandatory reporting.[40]

Watching a train wreck in Brownian motion: Nano-manufacturers across the Atlantic have been similarly resistant to providing information voluntarily. Last year, the U.S. Environmental Protection Agency launched its two-year Nanoscale Materials Stewardship Program (NMSP). At roughly the halfway mark, 29 companies had signed up to a basic reporting program and just 4 companies to the in-depth program, a paltry turnout given the level of research and commercial activity in the country. In its interim report, the EPA tried to sound positive, but was forced to observe that the poor response to involvement in the in-depth program "suggests that most companies are not inclined to voluntarily test their nanoscale materials."[41]

This performance may be the grounds for recent trailers that Canada and France are moving to make reporting mandatory. Canada indicated that it will introduce a mandatory scheme, requiring identification of nanomaterials in or soon to enter the Canadian market; use (volumes, sectors of use, types of products); and available toxicological data.[42] The French government introduced a bill in January this year, which may place mandatory information requirements including the identity, volume and uses of nanoparticles in commercialised products and could require manufacturers to provide toxicological data on request.[43]

D. Codifying Conduct

Voluntary codes of conduct have been a further gap-plugging exercise.

The centrepiece of the **European Commission's Code of Conduct for nanotechnology research and development** – unveiled in 2008 – is seven principles so broadly framed that dissenters will be difficult to find.[44] (In Europe, that is. The Commission sought support for the Code outside the EU borders but, it reported "there has not been unanimous worldwide agreement on the Commission's proposals."[45]) The EU Code does, however, propose getting tough on some nano R+D. In fact, it effectively proposes a moratorium on certain forms of research: recommending no funding for projects that could involve the violation of fundamental rights or fundamental ethical principles; no support for research on non-therapeutic enhancement of human beings and no research involving the deliberate intrusion of nano-particles, systems or materials in food, feed, cosmetics toys or the human body if long-term safety is not known.[46]

The Commission expects the Code to be adopted throughout the EU member states (and their science funding agencies), universities, research institutes and the private sector. In a flush of optimism, the Commission has flung the Code into the EU without an implementation plan (aside from a two-yearly review of its uptake).[47]

Meanwhile the **UK's Responsible Nanocode,** developed by the Royal Society, Insight Investment (one of the UK's largest investment managers), the Nanotechnologies Industry Association (NIA) and the UK government-sponsored Nanotechnology Knowledge Transfer Network, is a principles-based approach targeting corporate boardrooms. The Nanocode includes seven very generic principles (board accountability; stakeholder involvement; worker health and safety; public health, safety and environmental risks; wider social, environmental, health and ethical implications and impacts; engaging with business partners; and transparency and disclosure). There are, however, no clear, auditable standards and although a benchmarking process is intended to create a mechanism for accountability, this is currently behind schedule due to a lack of funds to run the process.[48] Examples of good practice – intended to be in the main body of the code – scared the horses and now appear as a separate document. These make clear that members of the Code are expected to "support the development of effective regulatory frameworks and be responsible, transparent and consistent in [their] external statements and public policy lobbying."[49] With co-founder Nanotechnology Industries Association's opposition to mandatory reporting of nanomaterials, it's difficult to see how the Code will work in practice if one of its authors can't abide by it.

E. Producing Standards

Definition is everything.[50] Standards – globally agreed definitions, characterizations, testing and measuring methods, safe exposure levels and the like – will determine the scale of the international economic nano-enterprise, how accountable governments and industry will be and the level of risk that people and the wider environment are subjected to.

Metrology has been the handmaiden to all industrial revolutions.[51] And while standards to protect human health and the environment are on the table, these are secondary to the primary attraction, which is to free up the way for nanocommerce. The European Commission is blunt: Standards are needed for the "rapid development of the technology."[52]

Despite the sales pitch, standards development is by no means a purely technical exercise. Big questions – what is nano? what levels of exposure to nanomaterials are acceptable? how do we measure nanoparticles entering waterways? and how much nano is too much? – are being determined in fora in which the risk-bearers (e.g., countries in the global South, social movements and civil society) cannot participate.

The Organisation for Economic Cooperation and Development (OECD) is one forum where nanonations are doing more than talking. OECD forays on nano began following a 2005 workshop, leading to the formation of the **Working Party on Manufactured Nanomaterials** in 2006. The working party has eight projects: a recently launched online database on safety research (led by Australia); development of a nanosafety research strategy (led by Germany); review of existing test guidelines for relevance to nanomaterials (U.S. and EU); safety testing of a representative set of nanomaterials (EU and U.S.); cooperation on voluntary schemes and

regulation (Canada); cooperation on risk assessment (UK); and a review of alternative methods in nanotoxicology and exposure measurement and exposure mitigation (U.S.).[53]

To plug up some of the gaps, countries involved in the Working Party have developed a work programme that includes a database of research into safety risks and reviewing existing risk assessment methodologies to determine whether these are up to the job for nanoparticles. An online database of research into nanosafety research around the world was launched in April.[54] The OECD has also launched a sponsorship programme to test a representative set of nanomaterials: fullerenes, single and multiwalled carbon nanotubes, silver and iron nanoparticles, carbon black, titanium dioxide, aluminum oxide, cerium oxide, zinc oxide, silicon dioxide, polystyrene, dendrimers and nanoclays.[55] Some OECD countries are picking up the tab to do the research, and industry lobby associations (BIAC, CEFIC and the Nanotech Industry Association) have pledged to drum up support from within their ranks.[56]

A second posse – **the Working Party on Nanotechnology** – was formed in 2007 to scout broader policy issues under six programmes that include statistics and measurement; nanobusiness needs; international research collaboration; outreach and public engagement; and nano water purification strategies. And as of this April, the newly convened OECD Network on Nanoscale Pesticides and Biocides is also in motion.

The OECD working parties assume that governments' role is to facilitate the nanorevolution while minimizing casualties along the way. Certainly, governments are looking to the OECD to help smooth nano's path to market.[57] But this is not the sole problem with the OECD being *de facto* HQ for intergovernmental coordination on nano. The OECD is not exactly a broad church and the industry view that it is "the most effective multi-stakeholder forum within which to explore the right policies"[58] is not likely to be widely shared outside its membership, which consists of 19 EU member states, NAFTA countries and some Asia (Japan and Korea) and Pacific countries. Argentina, Brazil, China, India, Israel, Russia and Thailand have joined the Working Party on Manufactured Nanomaterials as observers but thus far, no countries of the African continent have participated in the coordinated international initiatives. And despite technically being open to all-comers, the cost of participation in OECD working party and nanopolicy development has thus far prevented consistent trade union and NGO participation, as the OECD admits.[59]

Industry's vision: business as usual

While favouring the OECD as the forum for coordinated global action, the industry recently saw fit to remind the OECD and member countries of their proper role. In a grandiosely titled 'vision document,' BIAC (the Business and Industry Advisory Committee) baldly argues for self-governance, advising OECD countries to "look at business led initiatives when considering regulatory responses" as these will be "particularly essential in cases where regulation may currently be unsuitable or simply lacking in certain jurisdictions."[60] OECD countries are also reminded of industry's expectation that governments defend strong intellectual property protection, while for its part, the industry pledges (through gritted teeth) to "continue to share *relevant* information through the value chains" (emphasis added). 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."[61]

The **International Standards Organisation** (ISO) – widely viewed to be the international arbiter of nano standards – pitches itself as a forum where governments and industry forge a broad societal consensus. There's a snag to this political fable. With government investment in and commitment to the technology, government and industry are all but indistinct.[62] Trade unions and civil society are not on the guest list to the ISO nano-programmes, and few countries from the global South are currently participating.[63] This might not be a problem were it not for small matter of the WTO Agreement on Technical Barriers to Trade and other such mechanisms that enshrine international standards as the basis for any national standards, with potential high hurdles to clear before a country can part company with the international community.[64]

Baby steps ISO has issued its first standard: a yield of 12 terms since 2005. Following hot on the heels of the 12 terms was a guidance document on measures to increase occupational safety. As nano is just learning to talk while commercialization is already running, ISO's view that its work is "developed ahead of the technology" and "will guide the market" is optimistic.[65] It is certainly not widely shared. The Council of Canadian Academies observed that ISO's efforts "will not yield rapid solutions to immediate regulatory challenges."[66] Although ISO has given a five-year deadline for each of its programmes, many standards may be some time away as some of the basic tools that underpin standards remain a twinkle in nanoindustry eyes.

The plethora of organisations active in developing nanostandards gave the 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."[67] Some of the **OECD Working Party** forays are venturing into territory being explored by ISO – such as the work to harmonize testing and risk assessment – and has led the two organisations to sign a Memorandum of Understanding to make sure wires aren't crossed.

Nano gets bigger

For most of the last decade, the received wisdom has been that the nano realm is less than 100nm as it is at that size or under that the quantum changes that are of commercial interest occur.

That working definition has been international currency, although there is some divergence. In its 2005 standard, the British Standards Institute (BSI) defined nanoscale as one or more dimensions <100nm.[68] For the purposes of its voluntary reporting scheme, the UK Department of Environment, Food and Rural Affairs defined nano as having two or more dimensions up to 200nm.[69] Across the Atlantic, the federal National Nanotechnology Initiative also subscribes to the sub-100 definition. Across town, the FDA chose not to place size limits on nano at all in its 2007 agency review, although this may reflect its laissez-faire regulatory approach rather than an enlightened, scientific openness.[70]

Recent research has challenged the relevance of the sub-100 threshold by documenting quantum changes and novel properties occurring above 100 nm. Contrary to assertions by German chemical giant Evonik and others that all quantum effects are confined to sub-100 nanomaterials and that the 100nm threshold is 'generous,'[71] these findings indicate that a hard and fast 100nm or less definition is arbitrary and not scientifically warranted. Indeed, adhering to earlier working definitions would leave unregulated a potentially wide range of nanomaterials and exposures to biological communities and ecosystems. It would also create an incentive for developers to favour use of nanomaterials above the legislated threshold in order to duck regulatory scrutiny.

Trade unions and civil society organisations have called for official definitions to reflect the science. The UK Soil Association has called for 200nm; Friends of the Earth believes that scrutiny of anything smaller than 300 nm is required for a precautionary approach.[72] Size is not the only determining factor. Other defining aspects of nano's effects include shape/morphology, chemical composition, solubility, surface area and particle concentration, the presence of impurities such as residual catalyst, biodegradability and biopersistence.[73]

In some jurisdictions, nanoparticles that form aggregates (collections of strongly bound particles) or agglomerates (collections of weakly bound particles) larger than 100nm have been deemed not to be nanomaterials. That view is losing ground. Recently, the EU's scientific committee on emerging and newly identified health risks (SCENIHR) stated that "the majority of nanoparticles may be in the form of agglomerates/ aggregates and warned against the "misinterpretation" that they were therefore no longer therefore 'nano.'[74] SCENIHR also urged the food and cosmetics industry to accept ISO's definition, which includes agglomerates and aggregates.

F. Facilitating Privatisation

Governance of intellectual property happens farther under the radar but it's crucial nonetheless. Nanonations make assurances that nanotech will benefit people living in the developing world while ignoring the realities of technology transfer and the effects of privatization. With nanotechnology, the reach of exclusive monopoly extends beyond life to the fundamental building blocks of all of nature. By some counts, more than twelve thousand nanotech patents have been granted over the last three decades (1976-2006) by the three patent offices responsible for most of the world's nanotech patenting – the US Patent & Trademark Office (USPTO), the European Patent Office (EPO) and the Japan Patent Office (JPO).[75] The U.S. accounts for more that 60% of the total.

While government regulators have defended their inaction to-date by claiming that the level of scientific uncertainty has made taking action impossible, their colleagues in the patent office do not appear to suffer from the same angst. They have managed to define nanotechnology and to move quickly to address the biggest challenge it poses for patent examiners – its cross-sectoral, multidisciplinary nature. The USPTO, the EPO and the JPO have each established a system for classifying nanotech patents, intended to assist patent examiners searching for prior art. Still,

patent attorneys are gearing up for intense litigation because of broad and overlapping claims.

While the World Intellectual Property Organization continues to work out its "development agenda" (so far 45 recommendations have been approved), nano-nation patent offices are deciding who will gain exclusive monopoly over a technology expected to bring profound changes in demand for raw materials and manufacturing around the globe.

The State of Regulations

Barring a newly introduced regulation that will apply to some nanocosmetics in the EU (see below), there are no national nano-specific regulations in place anywhere in the world. In a rather bizarre admission of ignorance, governments tend to cite lack of information about the technology to allow for its products to be unregulated.[76] No regulatory agency currently possesses effective methods to monitor engineered nanoparticle exposure risks and no health regulator currently specifies safe exposure levels that nanoparticle manufacturers must meet – despite that the technology has at least 800 commercialised products to its name, and a raft of others coming to market.

But it shouldn't be as a surprise, since regulators in under-resourced agencies in Northern countries are struggling to get on top of risk assessing and regulating *existing* chemicals. To date, the EU has managed to get through 3,000 of the 30,000 bulk chemicals in common use.[77] It is estimated that by the mid-1990s, the U.S. EPA had managed to review the risks of about 1200 (2%) of the 62,000 "1979 existing chemicals."[78] Already, regulators are swamped by the task of dealing with the current wave of nanotechnology particles and products and do not have the capacity to begin to address new applications on the horizon.[79]

The EU: Is nano in or out of REACH? Despite an apparently progressive array of attempts to do science differently, the EU has been giving the nanotech industry a free pass. Are things about to change?

The primary regulation for nanomaterials is the recently introduced REACH directive. In spirit, the directive is commendable: It shifts the burden of proof to demonstrate the safety of chemicals on industry. Its basic operating principle is "no data, no market."

However, nanomaterials will not necessarily be captured by REACH. Firstly, there are no nanospecific provisions in the directive, despite a last ditch effort by the European Parliament's Environment Committee.[80] As a result, the directive does not distinguish between bulk and nanoscale forms of the same chemical.[81] Further, REACH regulatory scrutiny is volume-triggered with registration and risk assessment requirements becoming live above one metric tonne. The volume-based rule is rather irrelevant in the case of nanomaterials as a there are far more nanoparticles to the tonne than in the manufacture of larger particles, and volume is not a guide to hazard. REACH is therefore expected to wave through a significant amount of nanomaterial manufacture, which at least at present is coming in under one tonne.

The European Chemicals Agency (ECHA), which administers the directive, does have some discretion to regulate nanomaterials, as it can class nanomaterials as substances of high concern based on scientific uncertainties around their safety. The extent to which ECHA will see fit to

give regulatory life to REACH on nanomaterials is unknown given that the 849-page directive entered into force in 2007 and the agency has a mammoth task ahead of it.[82]

The Commission's view that the situation can be monitored[83] did not wash with the European Parliament. At the end of March, the European Parliament issued the Commission with marching orders.[84] In an overwhelming majority, the Parliament roundly criticised the Commission's view that current legislation is sufficient to address nanorisks and warned that responsible nano is not possible in the absence of necessary risk assessment data. MEPs gave the Commission two years to establish an official register of nanoproducts, complete with safety assessments, and a labelling regime. (That it is not required to act upon Parliament resolutions will come as a relief to the Commission, which would be hard-pressed to meet those deadlines.)

That's not all. The Parliament voted in near unanimity (658 votes of 684) just days later for what amounts to a moratorium on commercialisation of nanofoods.[85] In a set of amendments adopted by the Parliament to the Commission's proposed review of the Novel Foods Directive, the Parliament agreed that ethical review of nanofoods and labelling were required. Most significantly, however, it concluded that nano-specific risk assessment methods are needed and that nanofoods should not be allowed on the market until these methods are finalised and products have been cleared as safe according to those standards.[86] According to the European Food Safety Authority's Scientific Committee, those methodologies are not in place. In a report released a month before the Parliament vote, the Committee concluded that "the risk assessment processes are still under development with respect to characterisation and analysis of [engineered nanomaterials] in food and feed."[87]

The European Parliament was also behind the inclusion of some nanocosmetics in a recently adopted directive on cosmetics. According to insiders, the industry's failure to come to the party with information in part drove parliamentarians to bring nanocosmetics to regulatory scrutiny (around 5% of all cosmetics on the market in Europe in 2006[88]). Still, MEPS have extended the industry holiday for a further three years (the directive will come into force in 2012) and have not cast a wide net on nanomaterials – only those that are biopersistant or insoluble are covered, and only if they are used as colorants, UV filters or preservatives, which will also have to be labelled. All other types and uses of nanomaterials in beauty products will not be visible to the eye of the beholder. Some CSOs – such as the European Consumers Union – have cautiously greeted the new legislation as a first step.[89] However, the tortured, slow progress to regulate a narrow range of nanocosmetics suggests that the cosmetics industry may be allowed to free wheel for some time to come.

The United States – investment giant, nanoscale regulator Across the Atlantic, the U.S. has also resolved that current laws are broadly up to the task of managing the risks of nanotechnology.

However, recent assessments of the country's nanoreadiness reveal a regulatory system that is "weak and inadequate" and that will "more often than not, fail to protect the public,"[90] as well as a regulatory culture that has been neutered by decades of anti-regulatory sentiment expressed in under-funding, successive legislative reviews that have shifted the burden of proof onto regulators while crippling their ability to act and court rulings that have further undercut the

regulatory mandate.

The primary legislation for regulating nanomaterials – the **Toxic Substances Control Act (TSCA)** – is not up to the task on several fronts. Although responsible for reviewing every chemical, the EPA is only able to require the chemical structure profile from producers to base its assessment on.[91] The agency can only require safety data from producers if it can prove that there is "an unreasonable risk" to humans or the environment[92] or that the chemicals will be produced in large quantities. Significant legal obstacles to regulating chemicals have been placed in the EPA's way (such as the requirement to demonstrate that the regulation is the least burdensome option for risk management and heavy evidential requirements to justify the rule) that make regulation practically impossible.[93] While the Act does allow the EPA to define all nanomaterials as new uses, the Agency has decided that, in general, nanoscale versions of chemicals will be considered the same as their bulk form, *even if their chemical and physical properties differ.*[94] This effectively means that nano does not exist as a category under the Act. TSCA is currently up for review, with the House of Representatives considering "critical gaps in the statute and explore how these gaps hinder effectively chemical safety policy in the United States." Whether this will lead to nano-specific provisions is as yet unclear.

Meanwhile dietary supplements and cosmetics are effectively unregulated, as the **Food and Drug Administration (FDA)** has little or no authority over them. Even when dietary supplements are on the market, the FDA has no authority to require monitoring or testing and no authority to require a recall of unsafe products. As with other agencies, the burden of proof for demonstrating potential harm lies with the FDA and the agency relies on voluntary industry compliance.[95] By the agency's own assessment, where new technologies are concerned, 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."[96] Nevertheless, the **FDA** has rejected labeling of nanoproducts under its jurisdiction (on the basis that not all nanomaterials will be hazardous[97]) and has recently confirmed that it does not intend to strengthen its regulatory scrutiny of nanoproducts.[98]

Across town, budget cuts and regulatory reviews by successive administrations have effectively neutered **the Consumer Product Safety Commission** (CPSC).[99] Sister agency to the FDA, the CPSC is responsible for all non-food and drug consumer products, which account for around half of the 800+ products currently known to be on the market. Due to its narrow legislative mandate and lack of resourcing, the CPSC relies upon industry to come to the party, and tends to arrive late. A report by Public Citizen found that over the period 2002-2007, it took companies an average 993 days to notify the Commission of known product defects.[100] (This is 992 days longer than required by law). Against this background, the prospects for vigorous regulatory scrutiny of nanoproducts look slim. In addition to being desperately understaffed, in 2007, the Commission was able to allocate just $20,000 to its regulatory oversight of nanoproducts.[101]

Regulatory inaction at the federal level may trigger state action California is the one of several U.S. states beginning to take legislative action on nano in response to a lack of regulatory stamina at the federal level. The state government considered such action necessary because "government is not doing a good job regulating these materials."[102] Since 2006, nanomaterials have been classed as hazardous materials under the city of Berkeley's hazardous material

reporting, and nano-manufacturers are required to provide information on the toxicity of the materials they use and to detail their safety handling and reporting procedures.[103] In January the California's state government put carbon nanotube manufacturers and processors on notice. The industry has one year to provide information on their use of CNTs, workplace and environmental monitoring procedures, any known data on ecotoxicity over the lifecycle, occupational safety of CNTs, as well as waste-handling and disposal procedures.

Workers are on the front line

This year, the European Agency for Safety and Health at Work (EU-OSHA) expert panel identified nanoparticles and ultrafine particles as the top emerging workplace risk.[104]

There are no official data as to the number of workers exposed to nanomaterials. An international survey in 2004 estimated around 24,388 workers (including admin and management staff) employed in companies using nanomaterials. Projections range from two million workers globally by 2015[105] to as much as 10 million jobs in nanomaterial/product manufacture by 2014.[106]

Currently, there are no nano-specific regulations for worker safety in place. Nano-nations claim that existing occupational safety legislation applies. However the Council of Canadian Academies does not believe that worker safety can be effectively monitored in the absence of monitoring tools and standards specific to nanomaterials.[107] Last year, the OECD also noted the "[l]ack of national or international consensus standards on measurement techniques for nanoparticles in the workplace" and detailed a long list of research needs *before* meaningful standards could be reached. It is generally accepted that it will be some time before the OECD work programmes yield results.[108] A preliminary analysis on exposure measurement and exposure mitigations released by the OECD this year does little more than describe the content of other reports and make recommendations to itself for further work.[109] Meanwhile the chair of the ISO Technical Committee developing contamination control for cleanrooms (ISO/TC 209) noted that it is in catch-up mode because of the time required to develop standards.[110]

A number of guidelines have been issued. Yet as there are no known safe exposure levels, these can only set out protection measures (e.g, 'wear gloves'). In its 2008 guidelines, where the ISO breathlessly notes that "the potential applications of nanomaterials seem to be only limited by the imagination," it cautions that while many of the controls it recommends might be effective (even very effective), "to date there is only limited evidence regarding the effectiveness of the control methods."[111] Indeed, in the current conditions of ignorance, the 'best practice' guidelines may provide the greatest protection to employers determined to use nanomaterials, by shielding them from law suits if harm to workers results, while leaving workers little or no recourse under the law.

Workers are understandably worried. It is estimated that asbestos – another wonder material gone wrong – will be responsible for 1 million deaths worldwide by 2035.[112]

In 2007, the **International Union of Food, Farm and Hotel Workers (IUF)** called for a moratorium on the commercialisation of nanofoods and nano agricultural products until their

safety is proven and a full regulatory regime is in place.[113] The **European Trade Union Confederation** (ETUC), representing 60 million workers in 36 countries, decried the manufacture and commercialization of nanoproducts in the EU in the absence of scientific understanding of their safety and called for the 'no data no market' principle underlying EU law (REACH) to be applied to nanomaterials and for manufacturers to be required to take precautionary measures.[114] The **Dutch trade union FNV** is seeking immediate action from the Dutch government to protect workers.[115] There are no mandatory protections in place in the Netherlands and voluntary workplace protection measures have largely failed, the Union noted, as employers are citing confidentiality.

The **Australian Council of Trade Unions** (ACTU) has recently called for urgent nano-specific regulations to protect workers by the end of 2009; for nanomaterials to be regulated as new chemicals and for a register of nanomaterials imported, manufactured or used in Australia.[116] The government says it has no plans to take any regulatory action, and will continue to monitor the debate.[117]

Beyond these frontline health and safety concerns lie questions about how nanotechnologies will change the nature and geographies of work that are rarely, if at all, a topic of consideration by governments. Nano-applications that break down the commercial implications of geophysical distances – such as food packaging for longer shelf-life and nanosensors used in monitoring – will allow for remote control of industrial activity, continue replacement of human skilled labour by machines and further delocalization of production and processing.

Governance: ways forward

There is still time at the top: Fifty years ago, Nobel Prize-winning physicist, Richard Feynman introduced the concept of nanotechnology in his now-famous speech, "There's Plenty of Room at the Bottom." OECD regulators seem to have misunderstood. They have turned their responsibility for socio-economic, health and environmental safety into a search for the lowest common denominator – a race to the bureaucratic bottom. There is still time to reach for loftier goals.

The case of nanotechnology underscores the international community's need for global coordination and national capacity-building with respect to the monitoring and evaluation of rapidly-emerging technologies. Nanotechnology also exposes the urgent need for a permanent international forum wherein governments, scientists, civil society organizations and social movements, and industry can meet together to consider new technologies. The enormous power of these new technologies makes it clear that post-hoc technology assessments are no longer acceptable.

Nanotechnology could play a part in moving us away from the unsustainable techno-cultures that have been piloted and patented by OECD states. However, civil society will not sign away technological responsibility on some (quantum) dotted line. The ecological history of the twentieth century can be characterized by the adoption of platform technologies with little understanding of how these might shape human activity or form entrenched economic/consumption systems that are difficult to alter. Fossil fuels – a technological

breakthrough made in the 19th century that went on to become the engine of the 20th century and the potential nemesis of the 21st – together with nuclear power are the greatest threats ever to humankind .

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