EJLT European Journal of Law and Technology

The Regulation of Nano-particles under the European Biocidal Products Directive: Challenges for Effective Civil Society Participation

Michael T. Reinsborough [1], Gavin Sullivan [2]

Cite as: Reinsborough, M. T., Sullivan, G., 'The Regulation of Nano-particles under the European Biocidal Prodcuts Directive: Challenges for Effective Civil Society Participation' European Journal of Law and Technology, Vol. 2, No.3, 2011

ABSTRACT

This article considers factors that limit or exclude civil society involvement in the regulatory process for nanotechnologies by critically examining an attempt to mount a public-interest legal challenge against the UK Health and Safety Executive for failing to properly enforce the European *Biocidal Products Directive* in relation to nanosilver consumer products. The temporal gap between innovation research, knowledge of implications, and regulatory action can often be decades (Owen 2011). Often key stakeholders within civil society are positioned to identify certain relevant problems earlier than governance, regulatory, and investment actors. They might thus limit a *dilemma of control*(Collinridge, 1984) - where technology at an early stage of development provides opportunities for control but insufficient evidence of impacts to justify or direct control, whereas greater maturity in the development process provides sufficient evidence of impacts but the technology has become 'locked in' after widespread application. One form of intervention in the regulatory process by civil society is litigation. This article critically reflects on the limitations encountered in pursuing a judicial review challenge in the UK between 2008 and 2010. This account highlights some of the structural conditions underlying the contemporary regulatory balance of forces which limit civil society participation (access to legal expertise, resources, scientific knowledge, public awareness, and the regulatory process itself). We also suggest that individuals and civil society organisations thus limited (without meaningful access) may legitimately turn to more explicitly political forms of engagement with nanotechnology. Direct action (as opposed to mediated) is a plausible alternative to regulatory participation and litigation.

1. WHAT IS NANOTECHNOLOGY, WHO IS CONCERNED AND WHY?

'Nanotechnology' as a word is understood in multiple ways by different professional communities. The ability to manipulate matter at or close to the nanometer (1x10-9m) is now a scientific, industrial, and commercial reality. At this scale matter can behave very differently by acting with quantum properties (Royal Society 2004). For research scientists, industrial engineers and chemists 'nanotechnology' is the possibility of creating new material properties useful for designing products (Royal Society 2004). [3] For the corporate boardroom it is the possibility of gaining competitive advantage because a product is cheaper, or can do something unique that other products cannot. For a government economic policy planner 'nanotechnology' is the elusive potential for a competitive regional economy in an increasingly competition driven global economy (Wullweber, 2007, 2009). For the labour or environmental movement it is a poorly articulated risk that follows more than a century of industrial and environmental hazards, many of which have resulted in deaths and ecological destruction followed by conflict, protest, litigation, and even industrial action (Plows & Reinsborough, 2011). For the legal and regulatory professionals however, the many meanings of the word 'nanotechnology' make it legally difficult to define.(ETUI 2010, ObservatoryNano 2011, ETC 2010, Hodge, Bowman, & Maynard 2010). [4] Regulators and law-makers struggle with effectively articulating what, if anything at all, is to be regulated. Furthermore, as this article points out, there is a relative incoherence to the existing regulatory frameworks at play.

Despite (or perhaps because of) this multiplicity, 'nanotechnology' has functioned as an effective organising principle in the recomposition of the physical and life sciences. [5] A variety of already existing scientific disciplines at the nanoscale - each with its own literature, traditions, and scientific victories - have been subsumed under the term 'nanotechnology' (Toumey 2010, Jones 2010). Changes in university scientific research organization (particularly an emphasis on exploiting intellectual property), long term changes in the organization of innovation economics (the post-fordist rearrangement resulting in the loss of the centralized corporate research lab), and a greater emphasis on economic applications rather than basic science have also facilitated the expansion nanotechnology research and development within and beyond the university (Jones 2010). At the same time, national competiveness discourses have taken hold in government science policy and success in 'nanotechnology' has emerged as a key indicator of this elusive competitiveness (Wullweber 2007, 2009, for an example see PCAST 2010, p20). Government policy literature is cluttered with comparative analysis of national research and market position in nanotechnology and at least 60 countries have national nanotechnology initiatives (ETC, 2010, p.iii). Consequently, recent economic forecasts of the sector's growth are impressive. The U.S. National Science Foundation (NSF, 2001), for example, estimated that by 2015 the market value of nano-based products will be at least one trillion US dollars. [6]

As might be expected, the nanotech sector has yet to live up to the most imaginative claims about its economic and scientific potential. Methods for estimating present economic impact vary. [7] Initial hopes for molecular scale machines with working parts have proven elusive (Guchet and Bensaude-Vincent, 2008, Jones 2004). There are also concerns that nano-particles will have significant environmental and human health issues (Royal Society 2004, Bowman & Fitzharris 2007, Cheng et al. 2007, Griffitt et al. 2008, Seaton et al. 2009; Aitken et al. 2009a, Aitken et al. 2009b, ObservatoryNano 2010, European Commission 2011). Several civil society organisations suggest that nanotechnology will even turn out to be socially regressive (ETC 2010, 2005b, 2003, Miller and Scrinis 2010). By concentrating greater economic and technical capability in the hands of the large corporations and wealthy nations which sponsor the research, successful nanotechnologies could exacerbate income and political power disparities (both within countries and between countries) - for example, by synthesizing raw materials more cheaply than they can be sourced from the developing countries that rely on their natural resources to participate in the global economy (ETC 2005b). Current intellectual property laws tend to exacerbate economic imbalances by supporting monopoly control of technology applications. Civil society groups initially raised concerns that the basic building blocks of matter could potentially become private property (ETC 2010, p36). Further concerns have been expressed that nanotechnology could also increase surveillance capabilities and military power of states and security bodies (ETC 2010, pp.41-42), thus consolidating the power of the existing assemblages of governance.

There are, therefore, a wide range of social, economic, and political concerns that are at stake in the development and expansion of the nanotechnology sector. Yet, in our view, few of these core impacts are being adequately engaged with or taken into account within the context of the current European regulatory debate.

2. TECHNOLOGY ASSESSMENT AND TEMPORAL GAP

The introduction of any particular technology is only later followed by a full understanding of all its social, economic, environmental and health effects. It is usually when communities experience over time the impacts of a particular technology they can consider how it might be regulated or redesigned to better match their needs. However, during the period of experience the use of a particular technology may create dependencies when other systems of production or social interaction are lined up in coordination with it. There are higher costs (social/economic) to removing established technologies than there are to removing relatively new introductions (Rosenburg 1994, Arthur 1994, David 1997). [8] The temporal gap between innovation research, knowledge of implications, and regulatory action can often be decades (Owen 2011).

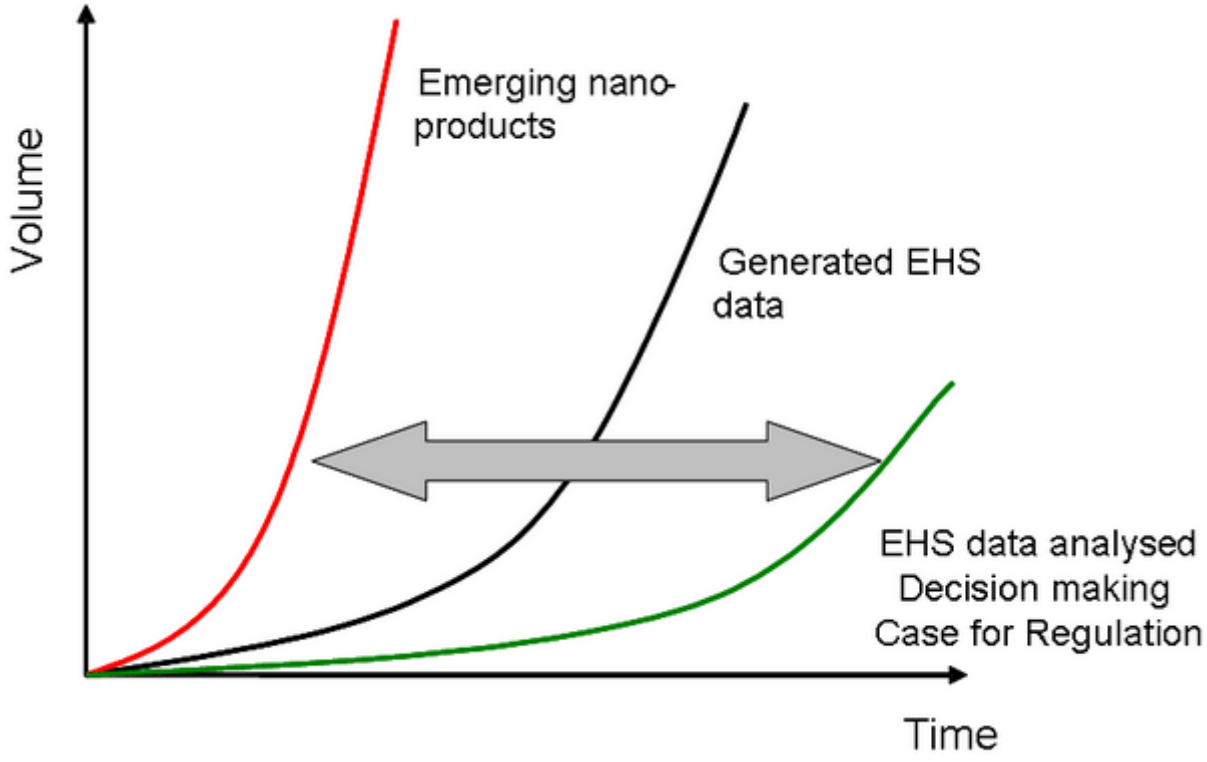

Figure 1 Source: (Owens 2011)

Specifically, with nanoscience, it has been shown that the publication of health and safety research, as well as the cross-referencing of this research within other publications (uptake and distribution of the knowledge), lags the original innovation research (Youtie, 2010). [9] These types of gaps often lead to a dilemma of control (Collinridge, 1980) where technology at an early stage of development provides opportunities for control but insufficient evidence of impacts to justify or direct control, whereas greater maturity in the development process provides sufficient evidence of impacts but the technology has become 'locked in' after widespread application has increased the cost of changing the existing arrangements.

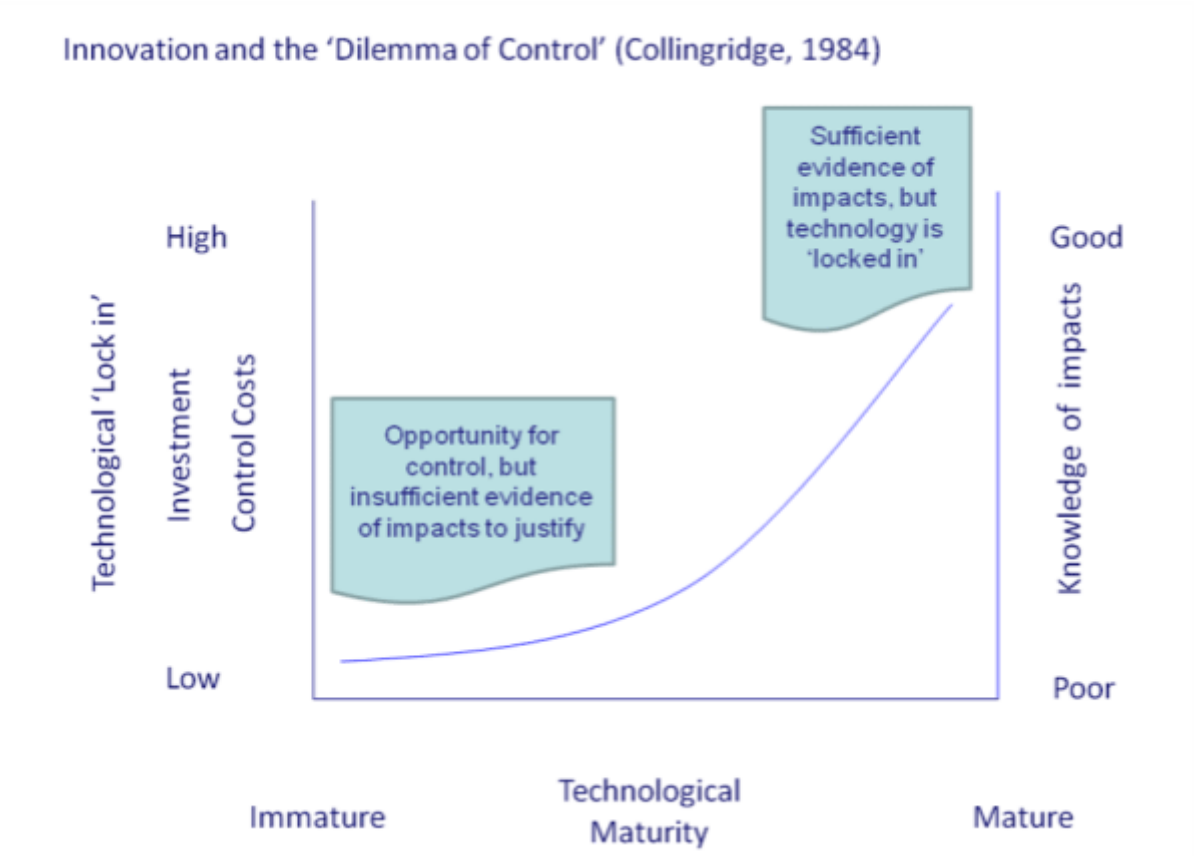

Figure 2 Source: (Owens 2011)

The emphasis on early commercialization of products without consideration of precautionary health and safety research exacerbates the problem. [10] If we analyse the history of asbestos, [11] for example, it is apparent that broadening the pool of decision-makers concerned with device introduction to include those directly affected by the risks of particular technologies (such as workers or other sections of civil society) might be an important strategy for resolving this dilemma. Stakeholders within civil society are often better positioned to identify certain types of relevant problems earlier than governance, regulatory, and investment actors, because they are more directly affected. Early civil society influence upon technology development and regulation could thus be a way of avoiding or limiting the dilemma of control and limiting the consequent accrual of significant costs when forced to reverse or undo established technological systems.

3. UNREGULATED INTRODUCTION OF NANOTECHNOLOGY

In our view, the rapid growth and circulation within Europe of products enabled by nanotechnology threatens in future such a dilemma of control. These introductions have taken place within a relative regulatory vacuum where no nano-specific regulation of these products has been proposed. [12] The European Commission and other key Member States (such as the United Kingdom) argued that 'current legislation is enough to cover issues related to nanotechnologies, nanosciences and the potential risk for health and the environment'(ETUI p.14, Brekelmans 2009, sl.5, European Commission 2008). [13]

The European Parliament (2009) disagreed with the Commission, pointing out that there was a significant lack of definite information on risks, but clear evidence of concerns:

> 'Nanotechnology entails new toxicological risks which are vaguely defined and difficult to test, a field in which our knowledge about immune defence response - if it is able to react at all in any given situation - is poor. Carbon nanotubes have proved to give rise to exactly the same type of damage as asbestos, carbon nanoclusters in low concentrations have caused brain damage in fish and sterilising nano silver from socks has leaked into waste water with unknown risks to treatment plants. When we know that nanoparticles are capable of penetrating the blood-brain barrier, how can we allow sun creams on to the market when we

> cannot guarantee that they have been tested to explore the possible differences in behaviour they may exhibit compared with previous creams? Moreover, the fact that different tests performed on the same nanomaterial can produce different results in toxicological investigations and that chemically identical nanomaterial produced by different manufacturers or manufacturing processes can have different properties also requires a better understanding. The experience gained with nanoparticles produced by combustion in engines, etc. is discouraging.'

A diverse range of civil society organizations have also disagreed with the official approach, arguing (for a number of different reasons) that existing regulations are neither appropriate nor effective for regulating nanotechnologies. [14]For example, size specific properties mean nanoparticles are effectively a different chemical and deserve to be regulated as such. Thus carbon nanotubes and bulk graphite, while they are both forms of carbon, have very different properties and deserve to be regulated as separate chemicals. *The Registration, Evaluation and Authorisation of Chemicals (REACH) Regulation* [15], for example, does not require registration for substances produced or imported in volumes of less than one ton. Thus many nanomaterials (inherently small, sometimes a few kilograms is all that is needed for manufacture of products) are likely to be exempt from the legislation. The European Trade Union Institute (ETUI 2010, p.19) has argued that 'volume threshold and testing methodology should be revised, and nanomaterials should have a unique risk assessment in order to be safe in use.'

The regulatory framework for nanomaterials in the United Kingdom is similarly *ad hoc* and has been the subject of a number of key government-commissioned reports. [16] A 2005 report commissioned by the UK Department for Environment, Food and Rural Affairs (DEFRA), for example, had identified within the UK context:

> ' ... regulatory gaps ... deriv[ing] from thresholds or exemptions under relevant legislation; or from the lack of information or uncertainties over clear definition(s); current scientific knowledge and understanding of hazards and risks; reliable and validated methods for monitoring exposure and potential impacts of NMs [nanomaterials] on human and environmental health.(Chaundry et al., p.5).'

This DEFRA report concluded that:

> '.... A substantial body of work will be required to reduce these uncertainties. There is ... an urgent need for setting clear, authoritative definitions for nanotechnologies and NMs, and achieving a scientific consensus to categorise different types of NMs into new or existing substances, as this will have a major bearing on the appropriateness and applicability of current and future legislation.(Chaundry *et al*). '

Rather than using primary legislation to engage with the specific challenges posed by nanomaterials, the UK government has instead followed the approach of the European Commission and sought to meet regulatory requirements through the application of a patchwork of diverse (and overlapping) legislative and policy documents - principally from the fields of environmental control, chemicals regulation, health and safety, consumer protection and product liability - with each legislative element covering a discrete part of the nanomaterial product cycle. [17] As this article further demonstrates, regardless of whether or not the existing regulation is specifically adequate to nanotechnology, *the existing regulation is not actually being enforced*. In fact, as outlined below, the U.K. government engaged legal resources specifically to defend its right to not enforce E.U. legislation that requires action be taken on nano-silver consumer product biocides.

4. PUBLIC- INTEREST NANOTECHNOLOGY LITIGATION

Although the authors of this article had had been discussing strategies for opening a broader public debate around the problems associated with nano-regulatory failures for some time, it was not until 2008 that we first began thinking about using public-interest litigation to achieve this end. Our original impetus for attempting to use the law strategically in this way within the United Kingdom actually came from the United States. On 1 May 2008 the Washington-DC based *International Center for Technology Assessment* (ICTA) - together with a broad coalition of 13 other non-government organizations active within the health, consumer and environmental field - filed a statutory review application against the US Environmental Protection Agency (EPA) for failing to properly regulate nanomaterials. [18] The ICTA petition claimed *inter alia* that nanosilver functioned as an 'active ingredient' within nanomaterial consumer products aimed at destroying bacteria. Given that bacteria was expressly identified as a pest under the US *Federal Insecticide, Fungicide and Rodenticide Act* (FIFRA), [19] it was therefore claimed that nanosilver products - which ordinarily highlighted antibacterial qualities in their marketing claims [20] - fell within the statutory definition of either a 'pesticide' and/or an 'active ingredient' of a pesticide. [21]

Inspired by these US efforts, in 2008 we began to think creatively about the possibility of initiating a similar public-interest legal challenge in the United Kingdom. As discussed in Part 4 above, the regulatory framework for nanomaterials in the United Kingdom at that time was (as with the US) [22] similarly incoherent and had been the subject of numerous government-commissioned reports. [23] After reviewing this regulatory patchwork in some detail in light of the principles underpinning the ICTA challenge and its primary focus upon extending the scope of pesticide regulation to cover nanomaterials, we took the initial strategic decision to focus our attention on two key European legislative documents -

the *Biocidal Products Directive* (98/8/EC, hereafter the 'Directive') and the *Biocidal Products Regulations* 2001 (hereafter the 'Regulations') that transposed this European directive into UK law.

4.1 Biocidal Products Directive and the basis of legal challenge

Nanosilver products as Biocidal products

The Biocidal Products Directive 98/8/EC (the Directive) came into force within Europe on 14 May 2000. [24] The Directive aims, *inter alia*, to harmonise the European market for biocidal products and their active substances and to provide a framework for the protection of people and the environment. The Directive essentially sought to achieve these aims by setting up a 10-year review program (that expired on 14 May 2010, but was extended shortly after until 14 March 2014) to evaluate both new and existing active substances. [25] After this time, it was envisaged that all biocidal products would require specific authorisation prior to being placed on the EU market.

Under Article 2(1)(a) of the Directive, 'Biocidal products' are defined as:

> 'Active substances and preparations containing one or more active substances, put up in the form in which they are supplied to the user, intended to destroy, deter, render harmless, prevent the action of or otherwise exert a controlling effect on any harmful organism by chemical or biological means.' [26]

An 'active substance' is defined in Article 2(1)(d) as 'a substance or micro-organism having a general or specific action on or against harmful organisms'. A 'harmful organism' is defined in Article 2(1)(f) as 'an organism which has an unwanted presence or a detrimental effect for humans, their activities or the products they use or produce, or for animals or the environment'. [27]

Given the similarities between the legislative definitions of 'pesticides' under applicable US law and 'biocides' within the European legal order we decided to undertake further investigations to consider whether (and in what ways) nanosilver products could be considered as biocidal products for the purposes of the Directive. Upon a brief analyses of the relevant policy documents, we found that this applicability issue had been directly addressed by the European Commission in their *Manual of Decisions for Implementation of Directive 98/8/EC concerning the Placing on the Market of Biocidal Products* (hereafter, 'the Manual'). [28] In the Manual (p.67, para. 3.2), for example, the Commission stated the following:

'3.2 Tooth brushes, nappies and dummies

> Question: A company places tooth-brushes, nappies and dummies on the market which contain nano-particles of silver in order to prevent micro-organisms from growing on their surface. Are these products within the scope of the BPD [*Biocidal Products Directive*]?
>
> Answer(as agreed in June 2003): According to the relevant guidance document, the combination of an article and an active substance, if the active substance is placed on the market as an inseparable ingredient of a product, shall be regarded as being under the scope of the Directive if it is intended that the biocidal active substance is released from the treated article to control harmful organisms outside the treated article (external effect) or if it is intended to only control organisms that are not harmful to the treated article itself. When the combination of the article with the biocidal active substance is intended to control organisms harmful to the treated article/material itself (on the surface or outside) then the article shall not be considered as a biocidal product (internal effect).
>
> In this case, although there is most probably only very limited release of the active substance and the intended control effect is merely on the surface of the treated product, it is obvious that the intended effect of the biocidal substance is not to protect the articles (tooth brushes, nappies, dummies), but humans, i.e. outside the treated article. Hence the treated articles are biocidal products.' [29]

Crucially, the applicability of the Directive itself was residual - that is, it did not apply to biocidal products whose use was already regulated under other European legislation. The relevant legislation, which is listed in full in Article 1 of the Directive, operates to exclude, *inter alia*, the following types of products from regulation:

- Veterinary Medical Products (Directive 81/851/EEC)
- Medicinal Products (Directive 65/65/EEC, 92/72/EEC, 92/74/EEC)
- Medical Devices (Directive 90/385/EEC, 93/42/EEC)
- Food Additives and Food Containers (Directive 89/107/EEC, 89/109/EEC)
- Milk, Egg and Fish Products (Directive 92/46/EEC, 89/437/EEC, 91/493/EEC)
- Cosmetics (Directive 76/768/EEC)

•Plant Protection Products (Directive 91/414/EEC)

Therefore, subject to satisfying the test of *external effect* and falling outside the exclusions listed in Article 1 above, we concluded that nanosilver products therefore nominally came within the scope of the *Biocidal Products Directive*and transposing UK Regulations as biocidal products.

Biocidal Product Directive: Review Process

There were, in effect, two consequential stages to the review process set up under the Directive - identification and notification. The *identification* stage of review was intended to enable the Commission to identify existing active substances of biocidal products. [30] Producers and formulators of biocidal products were required to submit information about the active substances of their biocides to the European Chemicals Bureau before 28 March 2002. This provided the baseline information for the Commission to compile an exhaustive list of existing active substances of biocidal products on the market as of 14 May 2000. The identification procedure also aimed to enable the Commission to specify which active substances should be included within Annex 1, Annex 1A and Annex IB of the Directive. Inclusion of an active substance into one of these annexes was a necessary (but not sufficient) condition for the biocidal product containing it to be authorised and placed on the market whilst the Commission's 10-year review was being carried out.

The *notification* requirements [31] created a mechanism whereby producers could effectively apply to the Commission to have the existing active substances contained within their biocidal products reviewed for inclusion in Annex I or Annex IA to the Directive during the second phase of the review programme established by Commission Regulation (EC) 2032/2003. Under the notification procedures, producers were required to specify the particular biocidal product types of the existing active substances they were seeking to have reviewed by the Commission. Notification, therefore, consists of two essential elements: *existing active substance and product type*. Crucially for the purposes of our challenge, we discovered that active substances were only supported for review in relation to the product types in which they have been notified [32] and that any products containing active substances that *were not* notified in the appropriate product type were to have been withdrawn from the market by 1 September 2006. [33] This review process initiated at the European level under the Directive was paralleled by an authorisation and registration process within the United Kingdom under the *Biocidal Products Regulations* 2001. [34] The Regulations essentially set up a scheme prohibiting the circulation of unauthorised biocidal products and providing the executive with discretionary powers to remove such products from the UK market.

Foundations of the Challenge

The effects of notification under the Directive, therefore, were significant. If an active substance *had* been notified, then products in the notified product type containing it could be placed on the market until the review of that active substance had been completed. If an active substance *had not* been notified, then the product ought to have been withdrawn from the market until the substance had been evaluated and a positive recommendation for inclusion in Annex 1 had been made.

Silver - in addition to a variety of silver compounds such as silver oxide, silver carbonate and silver chloride - had been included in Annex 1 to Regulation 2032/2003 as an 'existing active substance'. However, at the time we were preparing our challenge in 2008, the EC Regulation that listed existing active substances [35] and product types included in the review programme stated that only the following product types containing silver were supported for review:

•PT02 (Private Area and Public Health Area Disinfectants and other Biocidal products)
•PT04 (Food and feed-area Disinfectants)
•PT09 (Fibre, leather, rubber and polymerised materials preservatives)
•PT 11 (Preservatives for liquid cooling and processing)

Other product-types containing nanosilver as an active substance were not supported in this review process:

'An active substance listed in Annex II shall not be included in Annex I, IA or IB to Directive 98/8/EC within the framework of the review programme in relation to any product type not specified in Annex II in conjunction with that substance. [36]

> The date with effect from which Member States shall ... ensure that such biocidal products are not placed on the market in their territory shall be 1 September 2006. In the case of an active substance listed in Annex II, the first subparagraph shall also apply to that substance *in relation to any product type for which no notification has been accepted.* '(emphasis added). [37]

After analysing the regulatory framework in this way, the foundations for our public-interest legal challenge began to emerge. We observed that whilst silver was supported for review in relation to four specific sets of biocidal product types - namely, Private Area and Public Health Area Disinfectants (PT02); Food and feed-area Disinfectants (PT04); Fibre, leather, rubber and polymerised materials preservatives (PT09) and Preservatives for liquid cooling and processing

(PT11) - *it was not supported* in relation to other biocidal product types specified under the Directive. We therefore built an initial argument that nanosilver products:

1.which came within the scope of the Biocidal Products Directive (satisfying the test of *external effect* and avoiding the exclusions contained within Article 1 of the Directive);
2.contained an active substance of silver (rather than another silver compound); and
3.fell outside the product types listed above (PT02, PT04, PT09 and PT11)

should have properly been withdrawn from the EU market before 1 September 2006. [38]

Following our initial analysis of the emerging nanosilver consumer market in the United Kingdom we found that this category of unauthorised nanosilver products was potentially quite broad. It extended to include all nanosilver products classified under the Directive as *human hygiene biocidal products* (PT01) - which included, for example, disinfectant soaps, antibacterial cleaning gels, antibacterial clothing items, detergents and cleaning products intended to have a general biocidal activity by controlling bacterial micro-organisms. [39] Accordingly, we formed an argument that the placement of such products on the UK market would *prima facie* constitute a breach of the *Biocidal Products Regulations* 2001 that implemented the Directive into UK law and began the process of seeking expert legal advice on the prospects of bringing a judicial review legal challenge in the High Court against the nominated UK competent authority - the Health and Safety Executive (HSE).

4.2 Practicalities of public-interest litigation and the struggle for funding

The issue of funding is crucially significant to public-interest litigation. Potential claimants need to have access to sufficient funds to pay the costs of their legal team. [40] Whilst lawyers may provide initial advice and support to potential claimants on a *pro bono* basis, they rarely have the resources to litigate the claim in its entirety for free. Furthermore, claimants need either sufficient financial resources to pay the legal costs of the other side should the claim be unsuccessful [41] or have sufficient costs protection in place to ensure that they are not liable to pay such costs in the event that their claim is dismissed. Whilst judicial mechanisms for limiting such costs exposure are becoming increasingly available, [42] it is clear that costs remain the biggest obstacle to accessing justice and that the threat of adverse costs orders are the biggest single deterrent prohibiting claimants and NGO's from more frequently using the UK courts to achieve their objectives.

Public funding - which in the United Kingdom is administered by the Legal Services Commission (LSC) - enables claimants' own lawyers to be paid for their services (albeit at rates markedly less than market rate) whilst providing claimants with protection from adverse costs orders should their claim be unsuccessful. However, its provision is severely restricted by stringent eligibility requirements and is increasingly difficult to obtain for affected claimants seeking to bring environmental challenges against public authorities.

In November 2008 we applied for public funding in order to prepare our judicial review challenge. In doing so, we had to demonstrate *inter alia* that the case had a 'significant wider public interest' (SWPI) - that is, the potential to produce real benefits for individuals other than the client. Given the novelty of the subject matter and the health, safety and environmental concerns associated with the use of nanomaterials we did not think that demonstrating an SWPI in this case would be contentious. However, the LSC took a different view and we spent the ensuing 11 months (that is, until September 2009) in a heated exchange of correspondence with them before initial funding was secured. The LSC sought to adopt a 'hardline position' on the funding of public-interest environmental challenges. At the time the application was filed, the UK Courts were affording executive bodies a wide margin of appreciation in environmental and regulatory matters. Consequently, the success rate of judicial review challenges on environmental cases was quite limited. Furthermore, according to the LSC, environmental challenges tended to turn on competing scientific assessments of risk - bringing a heightened need for expert evidence and disproportionate public cost burden. Such cases, according to the LSC, would rarely meet the 'SWPI' threshold required for public funding. By taking questions such as judicial deference to the executive and governmental resource allocation explicitly into account in this way, the LSC's internal measurement of the 'public interest' became increasingly difficult for potential litigants to either meet or contest.

Given the uncertain prospects of our public funding application, we approached other NGOs concerned about nanomaterials to request help in resourcing our case. In particular, we met with the UK consumer rights body WHICH to ask for support. At that time, WHICH were closely involved with the UK government's Nanotechnology Stakeholder Forum - a network of nanotechnology industry representatives, civil society groups, and scientific experts set up in 2005 that sought 'to ensure that wider concerns and perspectives get built into early policy deliberations, including the formulation of policy and control research objectives and more immediate actions to manage risks' (Sutcliffe 2009 p2). [43] They expressed concerns about being publicly aligned with such a challenge - which was thought to 'work against' rather than 'work with' the UK government. They did not provide support - either 'in-kind', through the use of legal assistants and/or expert counsel; or direct, in terms of financial contributions - to facilitate a challenge. We were offered media assistance should the challenge ever eventuate and encouraged to pursue our concerns through engaging in the government's own Stakeholder Forum (albeit through WHICH).

Given our view that the stakeholder forum was playing a wholly ineffectual role - both limiting the potential of NGOs and other civil society actors to actually influence and shape the emerging discourse of nanomaterial regulation in the UK whilst legitimising the government's strategy of refusing to undertake specific regulation of the nano-industry until a sufficient evidence base demonstrating risk had emerged - we decided to continue in our efforts to develop public-interest litigation. In September 2009 a positive decision was taken by the LSC to grant initial funding, enabling us to finally commence pre-action correspondence with the HSE on the issue.

4.3 Preparing the legal challenge

In September 2009 a pre-action protocol letter was sent to the HSE alleging that they were acting unlawfully by failing to properly withdraw certain nanosilver items from the UK market, as required by the Biocidal Products Directive. In reply (dated 3 November 2009) the HSE argued that there was no basis to our claim because all of the products we mentioned were either excluded from the scope of the Directive or explicitly covered by it. Accordingly, they contended that there was no need for them to take any action to remove nanosilver items from the market. However, they acknowledged that 'establishing whether a specific product is a biocidal product, and then assigning the appropriate PT (product type) is not always straightforward' and invited us to discuss the classification of specific products with them in the future should we still have concerns. On January 2010 another letter was sent to the HSE, challenging their interpretation of the Directive and listing 12 specific nanosilver consumer items - including impregnated socks, hair straighteners and soaps - which we argued ought to be properly classified as PT01 products and accordingly removed from the UK market. In their reply of 8 February 2010 the HSE informed us that they would now need to undertake inquiries with the product suppliers and that they would aim to come back to us as soon as possible.

After months of delay, the HSE finally provided their substantive response to our correspondence on 6 May 2010. Ultimately, they agreed with our argument that active substances were only supported in relation to the product types (PTs) in which they were notified (that is, PT2, PT4, PT9 and PT11) and that silver products could only remain on the market after 1 September 2006 if they fell within those PTs. They therefore agreed with our primary legal contention, radically shifting from their initial position that 'there is no requirement under the BPD on a Member State to remove from the market products containing such active substances'. However, they disagreed with our approach of using the European Commission's Manual of Decisions as the proper starting point for the classification of different nanosilver products because '*operational experience* has shown that it is generally unhelpful to suppliers and others ... when submitting active substance dossiers and applications for product authorisation' (emphasis added). By discounting the MoD in this way, the HSE were able to put forward its own highly contentious (and unsupported) classifications for the products in dispute. One item (a nanosilver-impregnated toothbrush marketed as 'removing five times more bacteria'), for example, was classified by the HSE as PT09 (Fibre, leather, rubber and polymerised materials preservative) rather than the more obvious PT01 (Human hygeine biocidal product) because the company asserted that the nanosilver was there to protect the toothbrush fibres from bacteria rather than the user's mouth. The HSE also asserted that nanosilver socks and stockings were PT09 because 'the presence of the silver is to protect the socks/hosiery themselves (internal effect)' meaning that the products were not biocidal in the terms of the Directive. Whilst they acknowledged that another contested item (a nanosilver hair straightener) *was* likely to be PT01, they stated that because the product website claimed that the nanosilver 'helps release toxins from your hair' no biocidal claims were actually being made and so the product therefore fell outside the scope of the Directive. [44]

HSE Response Letter dated	Responding to letter from	Claim by HSE	Effect
3rd Nov 2009	Sep 2009	No basis for action because too general; However invitation to talk about specific product classifications if we still have concerns	Pre-action legal team must provide specific examples of products illegitimately on the UK market
8th Feb 2010	Jan 2010	HSE requires time to consult with the 12 specific product suppliers	delay
6th May 2010	Jan 2010	Agreement that BPD requires member states to remove products not in compliance; However disagree that MoD should be used for making product classifications and determining compliance Agreement that two products in breach of BPD	HSE gives notice for two nanosilver products to be removed; However tacit endorsement of consumer/user notification model. Pre-action legal team must now write to HSE to clarify proactive steps taken to identify noncompliance with BPD
26th July 2010	Jun 2010	HSE not responsible to 'police biocides on the shelves.' HSE must prioritise limited resources; No explicit evidence of harm from nano-materials therefore resource allocation not justified	Territory of dispute shifted from legal challenge on regulatory compliance to public health and safety contest based on scientific evidence availability

Table 1: Pre-action letter exchange (responses from the Health and Safety Executive)

Of the twelve products that we identified, however, the HSE were forced to remove two elemental silver products (a type of sock and type of soap) from the UK market. These nanosilver products were removed from the market for the precise grounds that we alleged in our claim - that is, breaching the *Biocidal Products Regulations* 2001. Whilst this was certainly a victory for effective nanotechnology regulation - and, so far as we are aware, the first legal action to force such action to be taken in the UK - we were left with insufficiently strong grounds to pursue public interest litigation on the issue in the UK courts and had tacitly endorsed the construction of a regulatory model based upon consumer/user notification rather than broad-based government assessment of risk.

Accordingly, on 15 June 2010 we wrote to the HSE again pointing out that 16% of the products we listed were found to be unlawfully circulating and in breach of the Directive, thus supporting our claim that the HSE were systemically failing to properly implement the regulations and protect public health. Furthermore, in order to shift the onus of responsibility

for identifying unlawful products from consumers to the government (which was a crucially important factor in resourcing a potential challenge) we asked the HSE to identify what pro-active steps they had actually taken to identify non-compliance with the Directive.

In their final reply of 26 July 2010 the HSE asserted that it simply was not their responsibility to 'police biocides on the retail shelves', but that they had 'well established systems' - including a website, factsheets and e-bulletins - for providing information to industry as required. Furthermore, they cited a recent report by the Royal Commission on Environmental Pollution (2008) that found 'no evidence of actual harm [from nanomaterials]' and used this to argue that their failure to pro-actively regulate the sector was ultimately a matter of resource allocation:

> 'Your client expects HSE to take pro-active steps to monitor biocidal products on the market containing nano-silver... As a responsible regulator, HSE has to prioritise allocation of its limited resources, particularly in an environment where Government departments must plan for significant cuts in spending and decreasing resources. HSE bases its prioritisation on known harm and risk.... Taking note of the view of the Royal Commission that there is no evidence of actual harm from nano-materials, the approach taken by HSE is proportionate and reasonable.'

Although such an extra-legal policy justification was considered contestable on the basis of law, it was the view of our legal team that it would be unduly difficult to convince a Court in the current environment of austerity cuts that the HSE were acting disproportionately or unreasonably with respect to their resource-allocation decisions. Accordingly, we took a decision to end the correspondence exchange with the HSE and bring the potential legal challenge to a close.

5. CHALLENGES FOR EFFECTIVE CIVIL SOCIETY PARTICIPATION

From the outset, the process of attempting to use public-interest litigation to contest the legality of the UK government's regulation of nanotechnology had two primary aims. First, and most obviously, we had hoped that such a case would force a more robust regulatory approach to be adopted by the HSE, notwithstanding the relative lack of data conclusively verifying the environmental and health and safety risks posed by nanomaterials. That is, we had hoped such a case might force a more rigorous precautionary principle to be applied to the expansion of the nanotechnology market in the UK. Second, we had hoped that by generating profile on the issue within and across the public domain, such a case might stimulate civil society and broader public engagement with the issue in the UK and open up possibilities for more antagonistic political action that did not exist at the time we began working on the issue.

The case did succeed in forcing the UK government to withdraw a limited number of nanosilver consumer products from the market for the first time. Beyond this very limited success, however, we clearly failed to develop the litigation process in a way that was capable of materialising either of our primary aims and resolving the 'dilemma of control' outlined earlier in this article. This outcome was certainly not inevitable. Indeed, as more scientific evidence providing information on health and environmental impacts becomes publicly available, future legal challenges to enforce regulatory compliance may enjoy much greater prospects of success. However, reflecting on the failure of this procedure is instructive as it highlights a number of organisational, strategic and structural factors that may serve to restrict and problematise civil society participation in broader regulatory debates concerning nanotechnologies.

Forcing the UK government to withdraw certain nanosilver products from the market certainly demonstrated that we were correct in our analysis of the regulatory obligations imposed on competent public authorities by the Biocidal Products Directive. Nevertheless, the HSE managed to effectively ward off the threat posed by the legal challenge through deploying three key strategies.

First, the HSE effectively maintained a position that they were not the responsible public body for enforcing regulatory compliance in relation to the Directive and avowed any responsibility to undertake more systemic analysis and oversight of the emerging nanotechnology consumer market. In so doing, they kept the entire onus of responsibility on consumers to identify potentially unlawful products - a process which, as we discovered, required considerable time, energy and resources to compile and was exacerbated by the lack of support afforded from other civil society organisations which were undoubtedly better resourced and situated to undertake such an exercise. The more time we were forced to expend in identifying individually unlawful products, the more we drew upon our limited public funding resources, thus reducing our capacity to maintain the ongoing support of the LSC and effectively litigate the matter. This question of onus was, therefore, crucially important to the outcome of our specific process.

Second, the HSE ultimately transformed the legal case into a contest over public health and safety risks by relying on the non-availability of clear evidence demonstrating risk. In so doing, they were effectively able to amplify the 'dilemma of control' whilst neutralising capacities that might otherwise serve to address it (such as increased civil society engagement in the nanotechnology regulatory process). Transforming the dispute from a public law challenge based on regulatory compliance into a public health and safety contest based on the evidence availability similarly carried significant resource implications - unlike governments, consumers and civil society actors generally lack the financial

resources to generate independent expert evidence that supports their position and/or engage in complex (and expert-supported) scientific debates concerning the application of new technologies. As outlined earlier, this issue was the LSC's primary concern in funding public-interest environmental litigation. Again, by steering the legal challenge in this direction, the UK government were effectively able to both restrict ongoing claimant access to public funding (which could not fill gaps in or contest existing scientific knowledge) and thus, our concomitant ability to litigate the issue.

Third, by making resource allocation within a context of crisis-driven austerity cuts in public spending a material consideration in the dispute, the HSE severely undermined the public-interest litigation's potential for success. As outlined above, it is well known that UK courts tend to afford public authorities a very wide margin of appreciation in reaching their own resource-allocation decisions, especially in environmental and health and safety matters. Steering the challenge into this public policy direction essentially served to neutralise it. At the same time, it obscured the fact that the HSE were readily prepared to expend significant financial and legal resources in this process in order to defend a regressive position founded on the non-enforcement of regulatory requirements.

Whilst we have considered these three factors as legal and strategic considerations, they are clearly each explicitly extra-legal and policy driven - that is, political. Had they each been identified and contested more vigorously at the outset of the procedure, a different and more robust regulatory outcome could well have emerged from this process. Beyond the specific approach adopted by the UK government in this case, however, there are additional organisational and structural factors that delimit and restrict meaningful civil society engagement in the regulatory process associated with the expansion of the nanotechnology industry.

The regulation process itself is difficult to understand. Yet, as this article demonstrates, access to legal expertise is extremely limited for most individuals and NGOs. Furthermore, in our case the tiered hierarchy of the legal profession (Jones, 2009, sl.20), in part created by the trend for casualisation of junior legal professionals through temporary contracts, created problems of continuity as different junior solicitors had to struggle to understand complicated, new areas of law. As of 2011 the U.K. government has announced serious austerity cuts affecting the availability of legal aid for civil litigation. If implemented, these cuts will undoubtedly exacerbate and compound the difficulties affected individuals face in accessing legal resources.

The problems associated with the professionalised legal character of the regulatory process are compounded by the clear need for scientific expertise in these contests. Few people in the public are aware of the concerns about nanotechnology, or feel confidence in their knowledge of this highly technical field. [45] The amount of time it takes to grasp the broad range of potential social, economic, and HSE effects of nanotechnology is beyond the capacity of the average wage labourer. A host of minoritarian positions opposing patriarchy, racism, or state sovereignty have yet to even articulate how nanotechnology or its regulation might affect them. As exemplified in our case, civil society litigation has only limited access to scientific expertise. Indeed, in our case we strategically sought to steer clear of opening questions of scientific dispute because the costs of data collection and interpretation and acquisition of expert evidence would have been immediately prohibitive. Legal emphasis on scientific expertise, as opposed to other forms of expertise [46] limits early knowledge of the effects of nanotechnologies in a way that is consistent with, and reinforces, the dilemma of control.

Whilst a variety of stakeholders from different social and economic positions might have concerns about the increasing commercialization of nanotechnology and European authorities are opting to nominally pursue a policy of stakeholder engagement alongside expansion of the industry, such processes remain, in our view, severely limited in their capacity to shape the terms of the regulatory debate. Our attempts to proactively engage with the UK consumer group WHICH throughout this process, for example, highlighted a 'consensus-based' culture of engagement. Such a culture, exemplified in arrangements such as the DEFRA-sponsored Nanotechnology Stakeholder Forum, was both materially ineffective in shaping the development of the industry and internally hostile to using law and litigation-strategies to enforce more robust public law obligations upon government decision makers. [47]

Finally, the problems we encountered in attempting to engage with the UK regulatory process through litigation in this case raises broader questions about the role and efficacy of health and safety regulation itself and its role in legitimising new governance structures associated with the expansion of nanotechnology. The immediate role of regulation is apparently the protection of workers, publics, and the environment. But it also serves a crucially important legitimising function to protect the validity of economic transaction systems. Moreover, one needs to keep in mind that even if nanomaterial-specific health and safety regulation existed, was adequate and was properly enforced, it would still not be capable of addressing broader concerns about the social and economic impacts of nanotechnology - indeed, regulation might even exacerbate these concerns by functioning as a protective boundary for large companies (who already have resources and experience in managing regulatory demands) through increasing the entry level costs for smaller firms. Technology regulation does not, therefore, address more fundamental issues of social and economic control and may itself function by bending resistance to that control into a manageable form.

The current balance of forces in technology assessment seems unlikely to close the gap between the introduction of innovation, the generation of EHS data, and use of this data to present just regulation of technologies. A certain amount of technological lock-in is being left in place in an arrangement in which further disparities of power are increased. The general failure of technology assessment, the so-called 'dilemma of control' (Collinridge, 1980), is pertinent to the

environmental, health, safety, social and economic consequences of nanotechnologies. Intervention of some type is required.

The choice of intervention, however, is positional. For government it must mean better policy consideration. For civil society organisations with sufficient access to financial and legal resources, pursuing public-interest litigation (similar to the case outlined in this article) can open public debate and delineate boundaries against corporate interests. Indeed, given the trajectory of technological developments in this field, [48] and the increasing availability of research concerning the adverse health and safety impacts of nanomaterials, we believe that further opportunities for legal action on this issue will continue to emerge and ought to be pursued to open up further possibilities of engagement. However, for those with little access to capital, legal resources and channels of regulatory power - such as workers or ordinary consumers who may collectively find themselves confronted by dangerous nanomaterials in their workplace or household - the most effective intervention possible within the current regulatory environment is likely to be direct action. [49]

One could imagine these three distinct types of positional intervention being able to operate in a complimentary and mutually-reinforcing way. Yet when the regulatory balance of forces limits the power of civil society to act, then policy (which acts always from within the balance of forces) and direct action (which acts always from within civil society) are necessarily opposed.

---

[1] Michael T. Reinsborough is a Doctoral graduate at Queens' University Belfast (History and Anthropology)

[2] Gavin Sullivan is a Solicitor, European Center for Constitutional and Human Rights

[3] Typical scientific definitions have focused on matter with one or more dimensions below a certain scale. For example the Royal Society (2004) defined nanotechnologies (at p.2) as 'the design, characterisation, production and application of structures, devices and systems by controlling shape and size at the .... nanoscale (which we define to be from 100nm down to the size of atoms (approximately 0.2nm)) because it is at this scale that the properties of materials can be very different from those at a larger scale.'

[4] Because of the difficulty of defining complex materials (particularly in relationship to their variable effects within biological systems) some have argued that legal definitions should wait until science led evidence based definitions can be further explored. See Maynard (2011), Maynard et al. (2011). See also Stamm (2011).

[5] Social scientist Joscha Wullweber (2007, 2009), for example, has described ' nanotechnology' as an empty signifier - a buzzword used to compose a set of economic, research and governance practices related to the national competition state.

[6] More recent estimates for 2015 are higher: 1.5 trillion dollars, Cientifica, Ltd., *The Nanotechnology Opportunity Report*, Executive Summary, 3rd edition, 2008; 2.5 trillion dollars, Lux Research press release, 'Economy Blunts Nanotech's Growth,' 24 June 2009. These large value chain estimates somewhat controversially include the original nanomaterials, the intermediates into which they are incorporated, and then the final nano-enabled products.

[7] See previous note for description of value chain estimates.

[8] This is commonly described as 'path dependency' in technology development economics.

[9] These results are not dissimilar to many other fields of innovation where health and safety research often lags innovation research. See also Ludlow, Bowman, and Kirk (2009).

[10] For any particular technology, some of the issues may not be apparent until it begins to have wide spread use. For this reason, even a precautionary approach adopted by states may not resolve the dilemma of control in all circumstances.

[11] The history of asbestos, originally known as the 'magic mineral', shows that early concerns about the material were raised, but they had no influence upon those who were pushing forward industrial applications for asbestos. In 1898, Lucy Deane, one of the first women inspectors of factories in the U.K., recorded asbestos as 'dusty work' on account of 'easily demonstrated danger to the health of workers and because of ascertained cases of injury to bronchial tubes and lungs medically attributed to the employment of the sufferer.'(EEA, 2001, p.53) Regulation thirty years later was never enforced and proper acknowledgement of the catastrophic health consequences of asbestos was not achieved until the end of the century (p.53). Deaths in the European Union for asbestos related cancers are estimated to be between 250,000 and 400,000 over the next 35 years (p.52). Even before 1898 some workers in asbestos mining, which began in 1879 (p.52) would have been in an excellent position to be suspicious of the human health character of asbestos.

[12] Recent actions of the European Parliament (in contrast to the European Commission) suggest that nano-specific legislation will eventually be provided. In Europe the first area to receive nano-specific attention is cosmetics. See Regulation (EC) No 1223/2009 of the European Parliament and of the Council of 30 November 2009 on Cosmetic Products; Official Journal of 22 December 2009; L342/59 (hereafter, the *Cosmetics Regulation*).

[13] Authorities worldwide, including the EU, have first thought to extend existing regulatory regimes, by adding new guidance. The International Standards Organization (I.S.O.) and other organizations have yet to create definitions and metrics appropriate to the specific differences that nanomaterials exhibit relative to traditional chemistry. Various voluntary reporting schemes (as a first step in 'soft regulation') have failed to receive data from businesses (ETC 2010, p.19).

[14] This begs the question of whether existing legislation is effective or enforced for the conventional materials for which it was intended. Trade Union and environmental organizations have been arguing for a number of years that it is not.

[15] Regulation (EC) No 1907/2006 of the European Parliament and of the Council of 18 December 2006 concerning the Registration, Evaluation, Authorisation and Restriction of Chemicals (REACH), establishing a European Chemicals Agency, amending Directive 1999/45/EC and repealing Council Regulation (EEC) No 793/93 and Commission Regulation (EC) No 1488/94 as well as Council Directive 76/769/EEC and Commission Directives 91/155/EEC, 93/67/EEC, 93/105/EC and 2000/21/EC; Official Journal of 30 December 2006; L396/1 (hereafter, REACH).

[16] See, in particular, Chaundry, et al. (2005), & Frater, et al. (2006).

[17] For a succinct overview of the different UK legislation applicable to the nanomaterial sector, see Frater L. et al, supra note 6 (at pp. 78 - 79).

[18] So far as we are aware, the ICTA case was the first legal action brought against environmental authorities for regulatory breaches specifically related to nanotechnology. Full details of the claim can be found at http://www.icta.org/nanoaction/page.cfm?id=244

[19] 7 U.S.C. §§ 136-136y et seq.

[20] See, for example, ICTA petition (pp 15 - 16). Supra note 1.

[21] Ibid, (s.I(B), p. 32). Under § 136(u)(1) FIFRA a 'pesticide' is defined as '(1) any substance or mixture of substances intended for preventing, destroying, repelling, or mitigating any pest'. 'Pest' is then further defined [at § 136(t)] as '(1) any insect, rodent, nematode, fungus, weed, or (2) any other form of terrestrial or aquatic plant or animal life or virus, bacteria, or other micro-organism ... which the Administrator declares to be a Pest' (emphasis added). The 'active ingredient' of a pesticide is defined [at § 136(a)(1)] as 'the ingredient that 'will prevent, destroy, repel, or mitigate' pests.

[22] There was a history of ambiguous EPA regulation of nano-silver products in the US prior to the filing of the ICTA lawsuit in May 2008. In November 2006, following complaints made to the EPA by environmental groups concerning the *Samsung Silvercare Washing Machine*, the EPA reportedly announced that they had taken a decision to regulate consumer nanosilver products as pesticides and to require registration for nano-silver products that made pesticidal claims in line with FIFRA requirements. In their *Nanotechnology White Paper* (2007) the EPA further acknowledged that pesticide products containing nanomaterials would be subject to FIFRA's review and registration requirements. However, in their Federal Notice Register of 21 September 2007 entitled 'Pesticide Registration: Clarification for Ion-Generating Equipment', released in response to the Silvercare washing machine controversy, the EPA limited their regulatory action to 'ion-generating machines' (such as the Samsung Washing Machine) rather than nanotechnology products, per se and in public statements made at the time they made it clear that the notice 'does not represent an action to regulate nanotechnology' [EPA, *Pesticides: Topical and Chemical Fact Sheets, Pesticide Registration: Clarification for Ion Generating Equipment*]. For a detailed discussion of the EPA's ad hoc approach to this issue see ICTA petition (pp 17 - 27), *Supra* note 3.

[23] See, in particular, Chaundry, et al. (2005), & Frater, et al. (2006).

[24] Directive 98/8/EC of the European Parliament and of the Council of February 1998 concerning the placing of biocidal products on the market.

[25] Directive 2009/107/EC of the European Parliament and of the Council of 16 September 2009 amending Directive 98/8/EC concerning the placing of biocidal products on the market as regards the extension of certain time periods

[26] *Supra* note 12

[27] Ibid. The European Commission later confirmed that 'a substance controlling harmful organisms is regarded as an active substance acting by chemical means when the control is linked to the interference of that substance in biological/physiological processes through direct chemical interaction (inside or outside the target organisms) or indirect modifications because of the physical/chemical properties of the substance'. See European Commission, *Manual of Decisions for Implementation of Directive 98/8/EC concerning the Placing on the Market of Biocidal Products.* ~available at: http://ec.europa.eu/environment/biocides/pdf/action_mode.pdf

[28] Ibid

[29] Ibid (at p. 67, para. 3.2)

[30] Art. 3, EC Regulation 1896/2000

[31] Art. 4, EC Regulation 1896/2000

[32] Art. 5, Para. 1, EC Regulation 2032/2003

[33] Art. 4, Para. 2, EC Regulation 2032/2003; Regulation 28(a), *Biocidal Products (Amendment) Regulations* 2007

[34] SI 2001/880

[35] Annex II, EC Regulation 2032/2003

[36] Article 4(1), EC Regulation 2032/2003

[37] Article 4(2) EC Regulation 2032/2003

[38] Pursuant to Article 4(2), EC Regulation 2032/2003.

[39] Whilst some of those products could undoubtedly be considered as either medical or cosmetic in nature, and thus expressly excluded by the Directive, we considered that many others would readily fall within its scope.

[40] For a High Court challenge in the UK, client costs would ordinarily include the costs of a solicitor (who takes instructions from the client, corresponds with the other side and builds the foundation of the case) and a barrister (who provides specialist advice on court procedure, expert advice on the prospects of the case, and ultimately argues the case before the judge in the Court).

[41] The ordinary rule in English civil litigation is that 'costs follow the event' - that is, that the unsuccessful party will be ordered to pay the costs of the successful party. See, for example, Rule 44(3), Civil Procedure Rules. In a judicial review claim that proceeds to hearing before the Administrative Court, it is not unusual for the costs of the other side to exceed 50,000 pounds. Should subsequent appeals be brought to the Court of Appeal or the Supreme Court then such estimates, depending on the complexity of the claim, can easily double.

[42] In particular, Protective Costs Orders (PCOs) are increasingly being used by non-government organisations and others to provide costs protection in judicial review challenges. For more information on PCOs see Liberty (2006) Litigating the Public Interest: Report of the Working Group on Facilitating the Public Interest (at pp. 27 - 33) and Jaffey, B. (2005). 'Protective Costs Orders in Judicial Review'. Focus on Public Law and Human Rights lecture, 18 November 2005.

[43] The absence of organisations like Greenpeace or Friends of the Earth on these stakeholder panels indicates a lack of faith in their effectiveness.

[44] Argos, a catalogue outlet chain and household name throughout Britain was a distributor of this product. A recall might have generated publicity.

[45] Public understanding of science expert, Brian Wynne has pointed to the muted response of publics whose identity is mediated to them by scientific expertise (Wynne, 1996). Thus in the absence of clear danger, publics will cautiously monitor the institutional body language of those they expect to protect them. Only when it is very clear that they have been betrayed will angry reaction finally emerge.

[46] For example, workers exposed directly to the health impacts of an industrial material. For alternative expertise discussion see Wynne (1996).

[47] Other civil society organisations which had ultimately refused to engage as stakeholders in this process (such as Corporate Watch UK) were, however, much more helpful - offering research support and assistance to the development of the case. For more information on Corporate Watch's position on this issue, see Corporate Watch (2007) *Nanomaterials: undersized, unregulated and already here*. Corporate Watch Report: Oxford

[48] Nanotechnologies converge previously separate (and separately regulated) functions so further litigation possibilities are to be expected. Put more simply, no one ever expected washing machines, socks, or toothbrushes to be covered under pesticide law. More surprises can be expected.

[49] Direct action can be defined in distinction to mediated action, action which petitions or addresses authority figures to rectify the situation rather than rectifies the situation directly itself. A legal challenge is a form of mediated action, whereas a consumer boycott, a workers refusal to work in a potentially toxic situation, or sabotage of a nanomaterials fabrication plant would be forms of direct action.

BIBLIOGRAPHY

Aitken RJ, Hankin SM, Ross B, Tran CL, Stone V, Fernandes TF, Donaldson K, Duffin R, Chaudhry Q, Wilkins TA , Wilkins SA, Levy LS, Rocks SA, and Maynard A (2009a) 'EMERGNANO: A review of completed and near completed environment, health and safety research on nanomaterials and nanotechnology', Report TM/09/01 on DEFRA project CB0409.

Aitken RJ, Aschberger K, Baun A, Christensen F, Fernandes T, Foss Hansen S, Hankin SM, Hartmann NB, Hutchison G, Johnston H, Micheletti C, Peters SAK, Ross BL, Solkull-Kluettgen B, Stark D, Stone V &Tran L (2009b)*Engineered Nanoparticles: Review of Health and Environmental Safety (ENRHES)*, Report on EC FP7 CSA #218433.

Arthur, Brian (1994) *Increasing Returns and Path Dependency in the Economy*, (Ann Arbor, MI: University of Michigan).

Bobo, Kimberley A., Kendall, Jackie, and Max, Steve (1991), *Organizing for social change : a manual for activists in the 1990's*, 1st edition (Washington: Seven Locks Press).

Bowman, D and Fitzharris, M. (2007) 'Too small for concern? Public health and nanotechnology' *Australian and New Zealand Journal of Public Health* Volume 31, Issue 4, pp382-384.

Brekelmans, C. (2009) 'Regulatory developments', Brussels, Swedish Presidency Nanotechnology Event, European Commission, November 2009. Summary available at http://ec.europa.eu/nanotechnology/pdf/swedish-presidency-event-summary_en.pdf pp.5-6.

Chaundry Q, Blackburn J, Floyd P, George C, Nwaogu T, Boxall A, Aitken R. (2006) *A Scoping Study to Identify Gaps in Environmental Regulation for the Products and Applications of Nanotechnologies* (Department for Environment, Food and Rural Affairs: London).

Cheng JP, Flahaut E, and Cheng, SH (2007), Effect of carbon nanotubes on developing zebrafish (Danio rerio) embryos, *Environ. Toxico. Chem.* 26: 708-716.

Collinridge, David (1980) *The Social Control of Technology* (Michigan: Francis Pinter).

Corporate Watch (2007) *Nanomaterials: undersized, unregulated and already here.* (Oxford: Corporate Watch).

Crocetti, Gregory and Illuminato, Ian (2011), *Nanosilver: policy failures puts public health at risk,* (USA: Friends of the Earth).

David, Paul (1997), *Path Dependency and the Quest Historical Economics*, University of Oxford, Discussion Papers in Economic and Social History, No. 20.

Deleuze, Gilles (1962), *Nietzsche and Philosophy* (London, New York: Continuum Press (1986)).

Drexler, K. Eric (1986), *Engines of Creation: The coming era of nanotechnology*, (New York: Anchor Books).

ETC Group (2010), *The Big Downturn? Nanogeopolitics*, (Ottawa: ETC Group).

ETC Group (2005a), *Nanotech's 'Second Nature' Patents: Implications for the Global South*, (Ottawa: ETC Group).

ETC Group (2005a), *The potential impact of nano-scale technologies on commodity markets: The implications for commodity dependent developing countries*. South Centre research paper 4 , (Ottawa: ETC Group).

ETC Group (2003), *The Big Down*, (Ottawa: ETC Group).

ETUI (2010), Del Castillo, Aída María Ponce (ed.) *The EU approach to regulating nanotechnology: Working Paper 2010.05* (Brussels: European Trade Union Institute aisbl).

European Commission (2011) 'Nanoparticles: Exposure and health impacts' in *European Research on Environment and Health Funded by the Seventh Framework Programme Volume 1* pp.215-288 ~available at http://www.eurosfaire.prd.fr/7pc/doc/1301058341_fp7_catalogue_eh_2011.pdf

European Commission (2008), Follow-up to the 6th meeting of the REACH Competent Authorities for the implementation of Regulation (EC) 1907/2006 (REACH). Nanomaterials in REACH, CA/59/2008 rev., December 2008. ~available at http://ec.europa.eu/environment/chemicals/reach/pdf/nanomaterials.pdf

European Environmental Agency (2001), *Late lessons from early warnings: the precautionary principle 1896-2000*, (Copenhagen: EEA).

European Parliament. Committee on the Environment, Public Health and Food Safety (2009), *Report on regulatory aspects of nanomaterials*, A6-0255/2009, 7 April 2009.

Frater, L.; Stokes, E.; Lee, R.; Oriola, T. (2006) *An Overview of the Framework of Current Regulation affecting the Development and Marketing of Nanomaterials: A Report for the DTI*, (UK: Department of Trade & Industry).

Gee, David and Greenberg, Morris (2001), 'Asbestos: from 'magic' to malevolent mineral' in European Environmental Agency, editor, *Late lessons from early warnings: the precautionary principle 1896-2000*, (Copenhagen: EEA).

Griffitt RJ, Luo J, Gao J, Bonzongo JC, and Barber DS (2008), Effects of particle composition and species on toxicity of metallic nanomaterials in aquatic organisms, *Environ. Toxicol. Chem.* 27: 1972-1978.

Grove-White, Robin, Matthew Kearnes, Paul Miller, Phil Macnaghten, James Wilsdon, and Brian Wynne (2004), 'Bio-to-Nano? Learning the Lessons, Interrogating the Comparison', Working Paper by the Institute for Environment, Philosophy and Public Policy, Lancaster University and Demos.

Guchet, Xavier and Bensaude-Vincent, Bernadette (2008), 'Nanomachine: Technology Concept of Metaphor?' in Fabrice Jotterand, ed. (2008) *Emerging Conceptual, Ethical, and Policy Issues in Bionanotechnology* (Springer Press).

Hodge, Graeme, Bowman, Diana, Maynard, Andrew (2010), *International Handbook on Regulating Nanotechnologies* (USA, UK: Edward Elgar).

Jones, James (2009), 'Trends Impacting the Legal Profession', Building a Better Legal Profession National Conference of Student Leaders April 3, 2009 ~available at http://www.law.stanford.edu/display/images/dynamic/events_media/031709%20Trends%20Impacting%20Legal%20Profession.pdf

Jessop, Bob (1991) 'Recent Theories of Law, the State and Juridico-political Ideology' in Jessop, Bob, editor, *State Theory: Putting the Capitalist State in its Place* (Oxford: Blackwell Publishers).

Jones, Richard (2010), 'What has nanotechnology taught us about contemporary technoscience', Darmstadt Conference Society for the Study of Nanoscience and Emerging Technologies, October 2010.

Jones, Richard (2004), *Soft Machines: Nanotechnology and Life* (Oxford: Oxford University Press).

Ludlow, K, DM Bowman and D Kirk (2009), 'Hitting the mark or falling short with nanotechnology regulation?' *Trends in Biotechnology*, 27(11) pp.615-20.

Marx, Karl (1867) *Capital, vol.1* (London: Lawrence and Wishart (1976).

Maynard, Andrew (2011) 'Don't define nanomaterials,' *Nature* 475 pp.30-31.

Maynard et al. (2011) 'The problem of regulating sophisticated materials' *Nature Materials* 10 pp.554-557.

Miller, Georgia and Scrinis, Gyorgy (2010), 'Nanotechnology and the extension and transformation of inequity' in S.E. Cozzens, J.M. Wetmore (eds.), *Nanotechnology and the Challenges of Equity, Equality and Development, Yearbook of Nanotechnology in Society 2*, (Springer Press).

National Science Foundation (2001), *Societal Implications of Nanoscience and Nanotechnology*, March 2001 (USA:NSF)

Owen, Richard (2011) 'Rising to the Challenge of Responsible Innovation'at Royal Geographic Society, London Conference, A New Mandate? Research Policy in the 21st Century, March 2011.

Obseratory Nano (2011), Mantovani, Elvio and Porcari, Andrea (eds), *Developments in Nanotechnologies Regulation and Standards- 2011*, (ObservatoryNano).

ObservatoryNano (2010) Environmental, Health and Safety (EHS) *Impacts, Technology Sector Evaluation: Environment*, editor: Bernd Nowack, E., V 1.0 June 2010

Pashukanis, Eugen (1978), *A General Theory of Law and Marxism*, (London: Ink Links).

PCAST (2010), *Report to the President and the Congress on the Third Assessment of the National Nanotechnology Initiative*, (Washington: PCAST).

Plows, Alexandra and Reinsborough, Michael (2011) 'Encountering 'the Politics of Technology': Public Engagement from the Bottom-up' in Zülsdorf, T.B. et al. (Eds.) *Quantum Engagements* (Heidelberg: AKA Verlag).

Reinsborough, Michael (2008) *Social and technical forces constituting the Silent Valley Reservoir Project: Mourne Mountains to Belfast 1893 -1932*, Ph.D thesis, Queen's University Belfast.

Roco, M.C., (2004) 'Nanoscale Science and Engineering: Unifying and Transforming Tools', AIChE Journal, Vol. 50, No. 5, 890-897.

Rosenberg, Nathan (1994), *Exploring the Blackbox: Technology, Economics and History*, (Cambridge: Cambridge University Press).

Royal Commission on Environmental Pollution (2008) *Novel Materials in the Environment: The case of Nanotechnology* (UK:RCEP)

The Royal Society and The Royal Academy of Engineering (2004) *Nanoscience and Nanotechnlogies: Opportunities and Uncertainties*, London: The Royal Society and The Royal Academy of Engineering. ~available at http://www.royalsoc.ac.uk/policy

Seaton A, Tran L, Aitken R, and Donaldson K (2009), 'Nanoparticles, human health hazard and regulation', *J R Soc Interface* 7:S119-S129.

Stamm, H. (2011) 'Nanomaterials should be defined' *Nature* 476 p.399.

Sutcliffe, H. (2009) *The DEFRA Nano Stakeholder Forum: Stakeholder reflections - its history and its future impact*, Responsible Nano Forum.

Toumey, Chris (2010) 'Tracing and Disputing the Story of Nanotechnology' in *International Handbook on Regulating Nanotechnologies*, edited by G. Hodge, D. Bowman & A. Maynard (Northampton MA: Edward Elgar Publishing) pp. 46-59.

Wullweber, J. (2007) 'Enclosure of Knowledge and the Emergence of a Global Nano-Divide', Paper presented at International Studies Association 48th Annual Convention.

Wullweber, Joscha (2009) *Der Nanotechnologie-Diskurs. Eine hegemonie- und diskurstheoretische politisch-ökonomische Analyse*. Doctoral Dissertation, University Kassel.

Wynne, B. (1996) May the Sheep Safely Graze? A Reflexive View of the Expert-Lay Knowledge Divide, pp. 27-83 in Lash, S., Szerszynski, B., and Wynne, B. (eds.) (1996) *Risk, Environment & Modernity: Towards a New Ecology* (London: Sage).

Youtie, Jan et al. (2010) 'Silos or systems in emerging science domains? The use of environmental, health and safety knowledge by nanotechnology researchers' Darmstadt Conference Society for the Study of Nanoscience and Emerging Technologies, October 2010.

van Zijverden & Sips (eds.) (2009) *Nanotechnology in Perspective - risks for man and the environment*, RIVM Report 601785003, ~available at www.rivm.nl/bibliotheek/rapporten/601785003.pdf