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The Proposed Ban on Certain Nanomaterials for electrical and Electronic Equipment in Europe and Its Global Security Implications: A Search for an Alternative Regulatory Approach

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1. Introduction

On 15 June 2010, a Member of the European Parliament, Jill Evans, introduced the Report on the Proposal for a Directive of the European Parliament and of the Council on the Restriction of the Use of Certain Hazardous Substances in electrical and Electronic Equipment (Recast), to the Committee on the Environment, Public Health and Food Safety of the European Parliament. This Report was seen by many as a remarkable step of the European Union (hereinafter EU) towards making Europe the first region to ban certain types of nanomaterials. The Report (Evans, 2010c, p.9) provides:

> There is scientific uncertainty about the safety of nanomaterials for human health and the environment, no internationally agreed definition of a nanomaterial and no internationally agreed test guidelines... There is increasing scientific evidence that some carbon nanotubes may behave like asbestos fibres and thus have severe impact on human health. The same applies to nanosilver particles which may end up in the environment and may have severe impacts on soil, aquatic and terrestrial organisms.

On this basis, the Report recommended that two specific types of nanomaterial - silver nanomaterials (hereinafter nanosilver) and long multi-walled carbon nanotubes - be banned from use, by listing them as Annex IV prohibited substances under the Directive on the Restriction of the Use of Certain Hazardous Substances in electrical and Electronic Equipment (hereinafter RoHS Directive) (Evans, 2010c, p.61). The proposal to ban the use of nanosilver and multi-walled carbon nanotubes in electrical and electronic equipment was eventually removed from the revised RoHS Directive, which was adopted on 8 June 2011. However, the preceding debate, as to whether and to what extent regulation of nanomaterials is required, illustrates the tension between health and environmental concerns (as the basis for regulation of nanomaterials), and the potential benefits to a broader range of security concerns in Europe and beyond. On one hand, the move towards a ban finds justification in the precautionary principle - a fundamental principle which underpins the EU's health and environmental policy. On the other hand, nanotechnology enables the development of novel products relevant to global efforts to address a range of security issues such as energy security, resource security, counter-terrorism and counter-insurgency (Kosal, 2009). In fact, the Nanotechnology Advancement and New Opportunities (NANO) Bill, [2] which was introduced by Representative Michael Honda to the United States (hereinafter US) House of Representatives on 1 August 2011 with the aim of promoting the development and responsible stewardship of nanotechnology in the US, specifically authorises the funding for nanotechnology research to address the need for renewable energy, remediation of pollution and other environmental protection technologies, as well as sensors and other equipment related to homeland security.

Security is an elastic and diverse concept that is no longer limited to the protection of national interest by military means in a traditional sense. Particularly since the end of the Cold War, security agendas have multiplied to include various non-traditional security issues such as environmental security (Dalby, 2009; Dalby, 2002), food security (Allam, 2006), energy security (Raphael and Stokes, 2010), health security (Fidler, 2005; Chen and Narasimhan, 2003), and bio-security (Fidler and Gostin, 2008). Yet, the legal implications of the expansion of security have not fully been explored (Nasu, 2011), even though the question is of particular relevance when the legal regulation adversely affects efforts to alleviate security concerns.

This article aims to examine the challenges posed to the regulation of nanomaterials, and in particular to the implementation of the precautionary principle in that context, when nanotechnology has the great potential to enable the development of novel products relevant to global efforts to counter various security threats in contemporary Europe and beyond. To that end, it will examine, as a case study, the recent debate over the ban on the use of nanosilver and multi-walled carbon nanotubes in electrical and electronic equipment in Europe. Section 1 reviews the development of nanotechnology regulation in Europe, highlighting the general absence of security considerations in contrast to the centrality of health and environmental safety concerns. Section 2 explains in detail how the move to ban the use of nanosilver and multi-walled carbon nanotubes in electrical and electronic equipment emerged, developed and failed in a relatively brief period of time, from January 2010 to June 2011. Drawing on this debate, Section 3 will critically examine the challenges confronting the application of the precautionary principle in the context of nanotechnology regulation where the regulatory decision-making may have broader security implications. Finally, Section 4 sets out an alternative regulatory approach by which a more balanced and targeted decision-making process concerning the use of nanomaterials can be achieved to accommodate broader security concerns.

2. Security Consideration in the European Nanotechnology Regulation

electrical and electronic equipment is now central to security operations throughout the world. It is relevant not only to surveillance, but also to collection and analysis of criminal record and customs data. As a large component of the infrastructure in modern society involves computing, ensuring protection against cyber crime including hacking of defence and governmental infrastructure is increasingly seen as a national security priority in many countries. Nanotechnology in electrical and electronic equipment offers a capacity to significantly improve such operations, enabling more sensitive and rapidly responsive sensors, high-density data storage, and long-lasting energy generation (Ibrügger, 2005; Wang and Dortmans, 2004). The application of nanotechnology in electrical and electronic equipment is also relevant to other consumer products such as hybrid vehicles, solar panels, smart phones, plasma and LCD screens, and rechargeable batteries, which do have implications for non-traditional security threats such as environmental security, energy security, and resource security. For example, nanotechnology has potential applications to increase energy storage capacity, improve the efficiency of solar cells (Chen, et al, 2011; Jehng and Chen, 2010), and as an alternative to rare earth metals (Bourzac, 2011). [3] Further, the application of nanotechnology in the context of 'artificial photosynthesis' - technology making use of molecular nanoparticles to improve the natural photosynthesis process by maximising light capture, water splitting and carbon reduction activities - is expected to produce cheaper, lighter, and more environmentally sound solar fuels, while at the same time reversing global warming, as the process consumes carbon dioxide and releases oxygen (Faunce, 2011). Thus the existing and potential use of engineered nanomaterials in consumer electrical and electronic products has global security implications beyond the European boundaries.

Notwithstanding such global significance, the security implications of the use of nanomaterials in electrical and electronic equipment have not been a predominant focus of nanotechnology regulation in any jurisdiction, including Europe. The Europe-wide attempts to develop an integrated nanotechnology regulation commenced in 2004, when the European Commission adopted its Communication 'Towards a European Strategy for Nanotechnology' (European Commission, 2004). While acknowledging great potential and a wide variety of benefits from applications of nanotechnology, the 2004 Communication confirms that the obligations under Articles 152, 153 and 174 of the Treaty Establishing the European Community, [4] to ensure a high level of human health protection and to preserve, protect and improve the quality of the environment, are applicable to nanotechnology research and development (European Commission, 2004, p.5). It also notes the significance of identifying and resolving safety concerns, real or perceived, at the earliest possible stage, requiring a sound scientific basis for both consumer and commercial confidence (European Commission, 2004, p.5). Similarly, the Commission's 2005 Communication, 'Nanosciences and Nanotechnologies: An Action Plan for Europe 2005 - 2009', committed itself to identifying and addressing safety concerns associated with applications of nanotechnology, as well as examining and, where appropriate, proposing adaptations of EU regulations. This is especially pertinent in the areas of '(i) toxicity thresholds, (ii) measurement and emission threshold, (iii) labelling requirements, (iv) risk assessment and exposure thresholds and (v) production and import thresholds' (European Commission, 2005, p.10).

The primary and overarching legislation relevant to general regulation of nanomaterials in Europe has been the Registration, Evaluation, Authorization and Restriction of Chemicals (REACH) regulation since its entry into force in 2007.[5] The REACH regime is underpinned by the precautionary principle and the 'no data, no market' principle, as enunciated in Article 5 of the regulation. In short, this regime puts the onus on private actors who manufacture or import chemicals to demonstrate the safety of those chemicals by collecting and providing all necessary information on their chemical use and toxicity (Fleurke and Somsen, 2011, pp.362-363, 373-375; Breggin, et al, 2011, pp.217-234; van Leeuwen and Vermeire, 2007, pp.516-543). The regulation requires manufacturers and importers to submit a registration dossier for all substances that they manufacture or import at or above 1 tonne per year, and an additional safety assessment report if the amount is more than 10 tonnes per year (Fleurke and Somsen, 2011, pp.366-367). The European Chemicals Agency (ECHA) has the power to evaluate the registration dossier and even the substance itself, set additional authorisation requirements, and impose restrictions on use if it is shown to be hazardous (Fleurke and Somsen, 2011, pp.367-370; Eisenberger, I, et al, 2010, p.3). Substances are regulated irrespective of their form or size and therefore, in principle, include nanomaterials (European Commission, 2008b, p.6). However, significant gaps have been identified in this framework. This has significant security implications particularly in the counter-terrorism context, for example, in relation to the tonnage threshold and the scope of various exceptions, and require regulatory re-adjustments specifically tailored to nanomaterials (Faunce and Watal, 2010, p.624; Eisenberger, et al, 2010, p.3).

In addition, there are a number of Directives in the areas of worker protection, product safety, and environmental protection, which the European Commission deemed to apply to nanomaterials (European Commission, 2008a). Because of such a wide coverage of EU regulations, the European Commission, in its 2008 Communication on 'Regulatory Aspects of Nanomaterials', took the position that the existing legislative frameworks are adequate in addressing the risks posed by nanotechnology (European Commission, 2008a, p.3). Yet it also acknowledged that the lack of health and environmental data was a problem (European Commission, 2007, pp.8-9). In this context, the Observatory NANO was set up to conduct scientific and economic analysis of the development of nanotechnology with funding provided by the EU. Further, the European Commission took the initiative in developing the Code of Conduct for Responsible Nanosciences and Nanotechnologies Research, confirming its commitment to ensure human health and environmental protection based on the precautionary principle (European Commission, 2008c).

However, Members of the European Parliament (MEPs) criticised the Commission's approach as lacking 'a proper evaluation of the de facto application of the general provisions of the Community law in the light of the actual nature of nanomaterials' (European Parliament, 2009a, para.2). Advocating for the principle of 'no data, no market' for nanomaterials, the European Parliament called upon the Commission to review all relevant legislation 'to ensure safety for all applications of nanomaterials in products with potential health, environmental or safety impacts over their life cycle' (European Parliament, 2009a, para.5). Importantly, the MEPs recognised that a single regulatory framework of Community level would not adequately address different risks and concerns arising from the diverse applications of nanotechnology, and instead favoured a multi-faceted, differentiated and adaptive body of law (European Parliament, 2009a, preamb paras.P-R). Thus, the cosmetics directive was recast in 2009, [6] to include comprehensive provisions in relation to nanotechnologies and nanomaterials (Bowman, et al, 2010). In addition, the new regulation on novel foods is expected to include similar requirements specific to nanotechnologies and nanomaterials, although this has been delayed by the European Council on an unrelated matter (Mantovani, et al, 2011, p.7; European Parliament, 2011). It is in this context that the legislative move to ban the use of nanosilver and multi-walled carbon nanotubes in electrical and electronic equipment has taken place.

3. The Move to Ban Certain Nanomaterials in electrical and Electronic Equipment in Europe

A proposal to amend the RoHS Directive was first made in 2008, prior to the European Parliament's decision to initiate the recast of specific Directives with a focus on the regulation of nanomaterials. This proposal, therefore, initially did not concern the use of nanomaterials in electrical and electronic equipment. However, the health and environmental concerns with respect to the manufacture and use of nanomaterials have prompted NGOs and members of the Committee on the Environment, Public Health and Food Safety to expand the scope of the amendment to include nanomaterials and, in particular, nanosilver. Thus, proposals for specific provisions on nanomaterials were added to the Committee's agenda in January 2010.

Uncertainty surrounding the potential risks to health and the environment from the manufacture and use of nanomaterials has been one of the major focuses of scientific study in Europe. Yet, regulatory efforts have not specifically paid attention to the security implications of nanomaterials or their use in electrical or electronic equipment. In 2004, the UK Royal Society and the Royal Academy of Engineering, at the request of the UK government, reviewed the opportunities and uncertainties of nanotechnologies, which identified the potential risks involved in exposure to nanoparticles to health and the environment (UK Royal Society and the Royal Academy of Engineering, 2004). The European Commission's Scientific Committee on Emerging and Newly Identified Health Risks (SCENIHR) adopted on 28-29 September 2005 an opinion echoing the concern that there were major gaps in scientific knowledge necessary for risk assessment of nanomaterials (SCENIHR, 2005, p.56). In 2009, having reviewed more than 260 relevant scientific studies conducted worldwide, the EMERGNANO project identified carbon nanotubes, silver nanoparticles, and titanium dioxide nanoparticles as potentially adversely affecting human health and the environment (Aitken, et al, 2009, p.vi).

Relying specifically on the 2009 report of the EMERGNANO project, three European NGOs - the European Environmental Bureau, the Health and Environmental Alliance, and the Women in Europe for a Common Future - demanded the RoHS recast to restrict the use of nanosilver in electrical and electronic equipment. Their letter raised particular concerns regarding environmental damage, toxicity to aquatic organisms even at very low concentrations, and the effect on bacteria necessary for water treatment in the plants when nanosilver is released in its ionic form particularly from the inside coatings in refrigerators or washing machines (EEB, HEAL and WECF, 2010, p.4). They also allege that the widespread use of nanosilver would promote anti-bacterial resistance (EEB, HEAL and WECF, 2010, p.3). In the European Parliament, the Committee on the Environment, Public Health and Food Safety took the lead on the recast of the RoHS Directive, and MEP Jill Evans was appointed Rapporteur to prepare a report on the proposal for the recast of the RoHS Directive. Among a number of proposed amendments, six were specifically addressed to the regulation of nanosilver and carbon nanomaterials capable of use in electrical and electonic equipment, which demonstrate two competing positions.

The first position, mainly advanced by Rapporteur Evans, is that there is sufficient information available to prohibit the use of nanosilver and certain carbon nanotubes, as opposed to other nanomaterials, in electrical and electronic equipment. Based on this understanding was Draft Amendment 97, proposed by Rapporteur Evans, which suggested the requirement for economic operators to notify the Commission and consumers (through labelling) of the use of nanomaterials in electrical and electronic equipment and to provide the Commission with all relevant data with regard to their safety for human health and the environment as the basis for necessary legislative action (Evans, 2010a, pp.18-19). Rapporteur Evans also authored Draft Amendment 316, which added nanosilver and long multi-walled carbon nanotubes to the list of prohibited substances in Annex IV of the Directive (Evans, 2010b, p.98). Another member, Sabine Wils, in her Draft Amendment 313, called for the banning of detectable nanosilver as one of the substances that 'present a major hazard to people and the environment in the phases of production and/or use and recovery' (Evans, 2010b, pp.95-96).

The competing position, on the other hand, emphasises scientific uncertainty about the effect of nanomaterials in electrical and electronic equipment on human health and the environment as the premise for amendment proposals. This position is clearly stated in Draft Amendment 80 proposed by Shadow Rapporteur Kathleen Van Brempt, Judith A Merkies and Åsa Westlund. They also acknowledge that: 'There is a common agreement amongst nanotoxicologists that risks of severe impacts on health and the environment are real' (Evans, 2010a, p.5). However, they took a different position, and even disagreed amongst themselves, as to how nanomaterials should be regulated as part of the RoHS recast. Thus, Draft Amendment 317, supported by all three, proposes labelling as a first step to support careful handling of nanomaterials in electrical and electronic equipment, on the premise that further research remains necessary (Evans, 2010b, p.99). In contrast, Draft Amendment 310, which was proposed only by Van Brempt and Merkies, states that: 'These substances [including nano-materials] need further examination before a decision on the need for a ban or labelling requirements can be taken' (Evans, 2010b, p. 92).

Rapporteur Evans finalised the report to the Committee, which contains the final form of the proposed amendments in relation to nanomaterials in electrical and electronic equipment. Amendment 6 in the final report almost mirrors Draft Amendment 80 originally proposed by Van Brempt, Merkies and Westlund (Evans, 2010c, pp.9-10), whereas Amendment 15 has only partially adopted the original Draft Amendment 97, removing the statement that: 'There is sufficient information available to prohibit the use of nanosilver and certain carbon nanotubes in electrical and electronic equipment' (compare Evans, 2010c, pp.15-16; with Evans, 2010a, pp.18-19). Nevertheless, the final report still maintains the Rapporteur's original position that two specific types of nanomaterial - nanosilver and long multi-walled carbon nanotubes - be banned from use by listing them as prohibited substances in Annex IV of the RoHS Directive (Evans, 2010c, p.61). In relation to the use of other nanomaterials in electrical and electronic equipment, by contrast, the final report only recommends notification and labelling obligations for economic operators, and the provision of all relevant data with regard to their safety for human health and the environment over their life cycle (Evans, 2010c, pp.37-38). The final report was tabled for the first reading in the European Parliament on 15 June 2010.

Those proposed amendments to regulate nanomaterials in the recast of the RoHS Directive have met strong opposition by various industry stakeholders (TechAmerica Europe, et al, 2010; Association Connecting Electronics Industries, 2010). The proposals were criticised on a number of grounds, some of which are purely of a procedural nature, such as for the lack of industry consultation, or of a technical nature, for example, concerning the definition of nanomaterials. However, three substantive points deserve particular attention for further analysis from a security perspective. First, the Joint Industry Position, issued on 6 July 2010, claims that there is insufficient scientific evidence or justification for introducing a ban on the use of nanosilver and multi-walled carbon nanotubes (TechAmerica Europe, et al, 2010, p.1). Likewise, the Association Connecting Electronics Industries observes that the proposal to restrict the use of nanomaterials 'is premature and has a limited scientific basis' (Association Connecting Electronics Industries, 2010). Their position that appears to run counter to the EU's precautionary principle is clearly expressed as follows: 'Decisions about restricting substances should only be made after a full scientific analysis, allowing all facts to be evaluated and uncertainty to be removed from the process' (Association Connecting Electronics Industries, 2010).

Second, the point was made that '[p]lacing broad restrictions on the use of nanomaterials would hinder the R&D / innovation that has driven unparalleled, beneficial improvements in the performance and functionality of EEE [electrical and electronic equipment]' (TechAmerica Europe, 2010, p.7). In fact, there is increasingly strong scientific evidence that suggests that there are feasible and commercially-viable applications of nanotechnology in consumer electrical and electronic products, such as in lithium ion batteries (Lee, et al, 2010; Reddy, et al, 2009) and solar cells (Chen, et al, 2011; Jehng and Chen, 2010). Although the industry position is presumably biased by its direct business interest, beneficial improvements in the performance and functionality of electrical and electronic equipment are also envisaged for potential positive impacts on global security issues.

Third, industry stakeholders consider that the REACH regulation is an appropriate and fully harmonised framework for the regulation of nanomaterials as it provides legal certainty across a wide range of different nanotechnological applications (TechAmerica Europe, et al, 2010, p.2), introduces a scientific process into the RoHS Directive and supports the unity of the EU regulatory scheme (Association Connecting Electronics Industries, 2010). It remains unclear whether and how the differentiated approach would undermine legal certainty (and not just pose practical difficulties) in the regulation of nanomaterials used for different purposes. Yet, this industry view clearly challenges the position taken by the MEPs who recognise that a single regulatory framework at Community level would not adequately address different risks and concerns arising from diverse applications of nanotechnology.

When member state permanent representatives to the European Council gathered in November 2010, the decision was made to remove the proposed ban on the use of nanosilver and multi-walled carbon nanotubes in electrical and electronic equipment. The revised RoHS Directive, adopted on 8 June 2011, goes only so far as to state that:

> As soon as scientific evidence is available, and taking into account the precautionary principle, the restriction of other hazardous substances, including any substance of very small size or with a very small internal or surface structure (nanomaterials) which may be hazardous due to properties relating to their size or structure, and their substitution by more environmentally friendly alternatives which ensure at least the same level of protection of consumers should be examined. [7]

Thus, while still acknowledging the application of the precautionary principle, the adopted text represents a significant setback backwards from the original premise that there is sufficient scientific evidence to prohibit the use of nanosilver and multi-walled carbon nanotubes - the point that found general agreement amongst different members of the Committee on the Environment, Public Health and Food Safety.

The policy outcome of this debate so far may be subject to different evaluations. Environmentalists may express disappointment with the failure of the European Parliament to take a tough regulatory stance against the use of certain nanomaterials that would cause serious health and environmental harm. On the other hand, sceptics of the precautionary principle and industrialists may see this as a victory of science over perception, enabling them to pursue further the industrial application of nanomaterials. The focus of this article, however, is not to evaluate the policy decision made on the regulation of certain nanomaterials in electrical and electronic equipment. Rather, this article aims to examine the particular challenges posed to the regulation of nanomaterials, specifically to the implementation of the precautionary principle in that context, when there are implications for global efforts to address wider security concerns. To that end, the next section will critically examine: (1) the ambiguity of the precautionary principle as a legal concept to direct regulatory decision-making; and (2) the limit of the precautionary principle for accommodating various security concerns.

4. The Scope for Global Security Consideration in the European Nanotechnology Regulation

4.1 The Ambiguity of the Precautionary Principle for Nanotechnology Regulation

The precautionary principle is an enabling principle that allows and justifies a regulatory action even in the absence of conclusive scientific evidence of harm with regard to a specific risk (Cameron, 1999, pp.29-30). The notion of the precautionary principle has been well entrenched in the European Communities ever since the adoption of the 1992 Treaty Establishing the European Community, as amended by the Treaty on European Union (Maastricht Treaty). [8]Article 191(2) of the Treaty on the Function of the European Union, which has incorporated Article 174(2) of the Maastricht Treaty, provides:

> Union policy on the environment shall aim at a high level of protection taking into account the diversity of situations in the various regions of the Union. It shall be based on the precautionary principle and on the principles that preventive action should be taken, that environmental damage should as a priority be rectified at source and that the polluter should pay.

The precautionary approach has the status of a general and autonomous principle of EU law, given that the protection of public health, safety and the environment applies to all spheres of its activity (Joined Cases T-74/00, T/76/00, T-83/00 to T-85/00, T-132/00, T-137/00 and T-141/00, *Artegodan and Others v Commission* (Court of First Instance) [2002] ECR II-4945, paras.183-184; de Sadeleer, 2007). At the core of the precautionary principle lies the scientific uncertainty of risk that potentially poses a threat of irreversible damage to human health or the environment, which provides the basis for regulatory decision-making. In the European context, it has been inextricably linked to risk management that would enable decision-makers to overrule scientific risk assessments (Graham and Hsia, 2002). This position was clearly expressed in the 2000 Communication from the Commission on the Precautionary Principle, in which risk assessment was to be relied upon only 'where feasible' (European Commission, 2000, p.14).

The European Court of Justice (ECJ) has developed its jurisprudence on the precautionary principle taking the view that risk assessment is a compulsory prerequisite for the application of the precautionary approach (Case C-236/01,*Monsanto Agricoltura Italia SpA v Presidenza del Consiglio dei Ministri* [2003] ECR I-8105, para.107; Case T-70/99, *Alpharma Inc v Council of the European Union* ,(Court of First Instance) [2002] ECR II-3495, paras.204-213; Case T-13/99, *Pfizer Animal Health SA v Council* [2002] ECR II-3305, paras.155, 157). Risk assessment is not required to provide conclusive scientific evidence of risk (*Pfizer v Council*, para.142), but must provide an ascertainable risk, as opposed to a 'purely hypothetical' risk (Monsanto, para.107). It remains far from clear, however, how much scientific evidence is required to prove an ascertainable risk. Those who are suspicious about the scientific basis may even look into the adequacy of the methodology adopted for risk assessment. Further scientific advancement in the future is unlikely to remove scientific uncertainty, due to the impossibility of adequately accounting for combined toxic effects of and interactions between different substances (Ashford, 2005).

Thus, disagreement often arises over the method for assessment of risk and the degree of scientific evidence that should be available as the basis for a precautionary measure. The debate in the RoHS recast process in fact involved disagreement as to whether sufficient information was available to prohibit the use of nanosilver and certain carbon nanotubes in electrical and electronic equipment. The decision not to impose a ban inadvertently prevented regulatory decision-making from becoming an obstacle to harnessing the potential of nanotechnology, in its application to electrical and electronic equipment as a means of addressing various global security concerns in the face of scientific uncertainty. However, had the decision been made to ban the use of certain nanomaterials based on the precautionary principle, the lack of consensus over the adequacy of the risk assessment would have made it extremely difficult to challenge its legality (cf Alemanno, 2011). Thus, the ambiguity of the precautionary principle, and in particular the ambiguity of the risk to be evaluated in a risk assessment, does not ensure that regulatory decision-making will take into account the global implications of European nanotechnology regulation in the context of various security concerns shared by states internationally.

4.2 The Limit of the Precautionary Principle for Accommodating Security Concerns

Criticism is often levelled at the precautionary principle's narrow and selective application to a particular environmental or health risk, to the exclusion of other political, legal, economic, and social factors from regulatory decision-making processes (Marchant and Mossman, 2004, pp.14-18; Morris, 2000; Goklany, 2000). The application of the precautionary principle, for instance, may well result simply in shifting the source of pollution, causing another hazard to the environment or human health, or preventing development of new technologies that may serve to alleviate the environmental harm (Sunstein, 2005, pp.23-24; Cross, 1996). Relevant in this context is the concern raised by industry stakeholders that broad restrictions on the use of nanomaterials would hinder the beneficial development of nanotechnology in its application to consumer products (TechAmerica Europe, 2010, p.7). As mentioned above, some of the beneficial applications of nanotechnology are expected to play a crucial role in global response to energy, resource and climate security.

The growth in population and industrialised economy means an ever increasing demand for resources, which poses a greater strain on scarce resources notably including fossil fuel and rare earth metals (Barnett, 2001, pp.34-35). Some commentators even predict that large-scale conflicts will arise over deposits of those precious resources (Homer-Dixon, 1999, pp.133-168; Gleick, 1991, pp.19-20; Ullman, 1983, pp.139-146). The actual and potential applications of nanotechnology to increase energy storage capacity, improve the efficiency of solar cells, and as an alternative to rare earth metals, therefore, not only directly address global energy, resource, and climate security concerns, but also help stem the potential causes of armed conflicts. A premature and comprehensive ban on the use of certain nanomaterials may therefore result in an unnecessary barrier or delay in technological advancement that helps prevent the spiral of suffering.

Regulatory decision-making based solely on technical and scientific considerations may well be seen as a way of responding to health and environmental security concerns in Europe. However, it does not leave much room for the consideration of competing global security concerns and the broader implications of European nanotechnology regulation for global efforts to address those concerns. The legal ground still remains weak for asserting developed countries' obligation to facilitate access to new technologies by under-developed countries as a way of meeting security threats that confront those countries such as environmental security, climate security, energy security, and water security. The commitments for innovation and technology transfer in the Cotonou Agreement between the EU and African, Caribbean and Pacific (ACP) countries, [9] for example, do not impose a legal obligation on the EU to adopt policies that improve prospects of technology transfer (Okediji, 2010). It is notable that the second amendment to the Cotonou Agreement, signed on 22 June 2010, [10] explicitly acknowledges non-traditional security threats such as food security and climate changes as global challenges and major subjects for their partnership. This imbalance in legal considerations has, in effect, resulted in the creation of a legal hierarchy in the EU's nanotechnology regulation with an almost exclusive focus on the application of the precautionary principle and a limited scope to consider its international commitment to technology transfer and cooperation for responding to global non-traditional security concerns.

5. An Alternative Approach to Nanotechnology Regulation from the Security Perspective

The precautionary principle has been central to the EU's health and environmental policy. Although in essence it allows decision-makers to adopt a regulatory measure under the condition of scientific uncertainty, it is not clear how much scientific uncertainty is acceptable, nor ultimately does it determine what measure should be adopted to address a perceived risk. In fact, the application of the principle has been expressed variably in different fields, and the introduction of a definition of the precautionary principle specific to the General Food Regulation has further complicated the conceptual issue (Szajkowska, 2010). As discussed above, the ambiguity of the principle does not help ensure that the implications of a regulatory measure for global efforts to address various security concerns will be taken into account in the course of regulatory decision-making processes.

The controversy over the appropriate regulatory framework for nanomaterials in Europe must be considered in this wider context. The regulation of nanomaterials under REACH may well be seen as comprehensive and providing coherent legal certainty, as the regime shifts the regulatory focus away from the often controversial hazard assessment to exposure assessment and risk management (Fleurke and Somsen, 2011, p.375). However, the European Parliament has to date favoured a more tailored, issue-specific approach to nanotechnology regulation. Towards the end of 2011, it is expected that the European Commission will issue a comprehensive review of nanotechnology regulation, with a view to proposing regulatory changes where necessary and developing more nano-specific instruments. Also, the Competent Authorities Sub Group on Nanomaterials (CASG Nano), established by the European Chemicals Agency, is expected to publish its findings about the application of REACH to nanomaterials, which will be taken into consideration in the future review of REACH. It remains to be seen which approach - a comprehensive or a more tailored, issue-specific approach - will be pursued and may better accommodate global security concerns into the regulatory decision-making processes.

Morris et al (2011, p.76) emphasise the need for more robust exposure measurements and information on the effectiveness of exposure mitigation approaches, not only in the occupational health settings but more broadly for consumers, the environment and general populations. Favouring a life-cycle perspective, Morris et al (2011, p.77) support the development of 'safer-by-design' methods in the use of nanomaterials for consumer products. The idea is not alien to European debates on nanotechnology regulation. The European Commission, in its 2004 Communication, recognised the importance of taking into account the impacts of nanotechnologies throughout the whole of their life cycle during nanotechnology research and development, and recommended that 'risk assessment be integrated into every step of the life cycle of nanotechnology-based products' (European Commission, 2004, p.20).

Such a conception of risk assessment may lead to a more targeted application of the precautionary principle, by requiring the assessment of not only the hazardous effects of a regulated material in laboratories, but also causality as to how the material in question can be released into human bodies and the environment in the real world (Ladeur, 2003, pp.1461-1462). A more targeted regulatory measure based on a risk assessment throughout the life cycle of the material at issue would mitigate the adverse impacts of the regulatory measure for global efforts to address various security concerns. Notably, in EC - Measures Concerning Meat and Meat Products (Hormones) (WTO Doc WT/DS26/AB/R, WT/DS48/AB/R, 16 January 1998), the Appellate Body of the World Trade Organization (WTO) discussed the concept of risk assessment in the context of the 1994 Agreement on the Application of Sanitary and Phytosanitary Measures and defined the risk to be evaluated in a risk assessment as:

> not only risk ascertainable in a science laboratory operating under strictly controlled conditions, but also risk in human societies as they actually exist, in other words, the actual potential for adverse effects on human health in the real world where people live and work and die (para.187).

Life cycle assessment of the potential exposure or transformation of a material is of pertinent significance for nanotechnology, because nanomaterials may change in size and/or composition as they are incorporated into products, used and ultimately disposed of or recycled (Morris, et al, 2011, pp.74-75). Yet, much of the scientific literature has so far focused on health and environmental hazards in case of contact, and not on how engineered nanomaterials will in fact be released and exposed to human bodies and the environment (Gottschalk and Nowack, 2011, pp.1145-1146).

In this respect, the recast of the 2003 Directive on Waste electrical and Electronic Equipment (WEEE recast) is an interesting development. During the Parliamentary debate on the draft legislative resolution on the WEEE recast, concern was raised about the danger posed by nanomaterials that are firmly embedded in large structures at the recycling stage. Based on that concern, two amendments were proposed to the draft legislative resolution, [11] which were both adopted in the final text. As a result, the European Parliament's legislative resolution, tabled for the first reading on 3 February 2011, has called upon the European Commission to assess whether selective treatment should be applied to nanomaterials, like asbestos waste and components that contain asbestos. [12] This approach makes better sense from the perspective of accommodating wider security concerns in the regulatory decision-making, given that nanomaterials are bound up in electrical and electronic equipment, making the potential exposure to nanomaterials of human beings and the environment more unlikely than, for example, personal care products which are more likely to end up in the environment. Based on this observation, Steffi Friedrichs, Director General of the Nanotechnology Industries

Association, reportedly cautioned that '[t]he properties of each material must be evaluated according to application, and on a case-by-case basis' (Houlton, 2010).

The legislative resolution is currently awaiting the delivery of a report by the Environment, Public Health and Food Safety Committee, prior to its tabling for the second reading in the European Parliament. It remains to be seen, therefore, whether the European Parliament adopts the resolution in its current form, and even if it does, how the European Commission might assess the feasibility of selective treatment of nanomaterials within the existing framework of the WEEE Directive. Challenges may well be posed in identifying and defining the components containing nanomaterials, and monitoring and enforcing the regulation especially in relation to export products.

6. Conclusion

International collaboration on nanotechnology governance has so far paid little attention to security implications of regulating the use of nanotechnology. For example, the Coalition of Non-Governmental Organizations (initiated by the International Centre for Technological Assessment) developed 'Principles for the Oversight of Nanotechnologies and Nanomaterials' to provide a set of ethical standards for nanotechnology research and development (Kimbrell, 2009). Similar initiatives are observed at the national level, as has been seen in the Swiss Retailers Association Code of Conduct and the UK's Responsible NanoCode (Bowman and Hodge, 2009, pp.149-152). The Organization for Economic Co-operation and Development (OECD) has also been active in developing policies and guidelines for regulation of nanotechnology research, which still remains an exceptional initiative taken by an inter-governmental body. However, such international and transnational regulatory initiatives, which focus on the technical and ethical aspects of nanotechnology, are incapable of holistically dealing with the competing safety and security issues within and beyond Europe.

The recent development of debates in Europe over the regulation of nanomaterials in electrical and electronic equipment illustrates the need for all-encompassing discussion about not only the potential health and environmental risks involved in the manufacture and use of nanomaterials, but also the exposure and transformation assessment of nanomaterials and the broader impacts of nanotechnology regulation on global efforts to address various security issues such as energy security and resource security.

The precautionary principle guiding Europe-wide regulatory decision-making across sectors tends to be understood as favouring the narrowly-focused protection of a specific environmental or health concern. However, ambiguity of the principle, as well as the ambiguous role of risk assessment, has inadvertently prevented regulatory decision-making from inhibiting the potential of nanotechnology in its application to electrical and electronic equipment to address various global security concerns. Although the recent attempt to regulate the use of nanomaterials in electrical and electronic equipment was simply discontinued, more tailored and specific regulation pertinent to the way in which relevant nanomaterials are to be used should be developed. Such a targeted regulatory approach would allow decision-makers to address the competing safety and security concerns when, as a result of risk assessment, scientific evidence of health and environmental harm remains inconclusive.

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[2] 112th Congress 1st Session, H.R.2749 of 1 August 2011.

[3] Rare earth metals are a group of special metals with unique physical, chemical and light-emitting properties, which are increasingly used to produce high-tech products such as hybrid vehicles, smart phones, plasma and LCD screens, and laptop computers.

[4] OJ C 325 of 24 December 2002. Currently, Articles 168, 169, 191 of the Treaty on the Functioning of the European Union: OJ C 83/47 of 30 March 2010.

[5] Regulation EC 1907/2006; OJ L 396 of 30 December 2006.

[6] Directive EC 1223/2009 (entered into force 1 January 2010).

[7] OJ I 174/88 of 1 July 2011, preamb para.16.

[8] 1755 UNTS 3, as amended by [1997] OJ C-340/03.

[9] OJ L 317/3 of 15 December 2000.

[10] OJ L 287/3 of 4 November 2010.

[11] CRE 03/02/2011-5.

[12] P7_TA(2011)0037.

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