

**Policy linkages between Subpolitical Actors and Regulatory Agencies: Exploring  
Regulatory Partnerships in the context of Nanotechnology in the EU**

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## Abstract

Several international actors have become active in setting up expert groups and other administrative structures to develop regulatory norms in the context of regulation of nanotechnology. Interestingly some of these actors have had international exposure and experience in developing regulations in other new and emerging technology areas. For others this is an opportune area for extending their regulatory competencies. However such actors share a common characteristic; i.e. they are essentially subpolitical in nature. This concept of subpolitics by the sociologist Ulrich Beck has been developed to characterize international actors that engage in regulatory norm setting without having the *de jure* legal mandate to do so. This paper explores three such actors within the domain of regulation of nanotechnology in detail; viz. IFCS (Intergovernmental forum on Chemical Safety), OECD (Organization for Economic Cooperation and Development) and the IRGC (International Risk Governance Council). Linkages between these three actors and EU institutions exist at numerous levels; viz. via membership, common normative foundations, functional linkages that leads to convergence of interests. Further, given the growing trend towards the acceptability of international forums/institutions as efficient and effective sites of regime creation, there exists a high probability of the norms emanating from such subpolitical actors, seeping into the EU legal regime via the pathways identified above. It analyses regulatory partnerships between EU institutions and such subpolitical actors in terms of delegation and exchange of competencies with reference to norm creation for the EU nanotechnology regulation. There have been several structural innovations which have been adopted by EU policymakers including dividing, delegating and sharing specific competences within highly technical domain areas like Nanotechnology.

Key words: actors, nanotechnology, partnerships, regulation, subpolitics.

## I Introduction

Risk regulation in the context of new technologies like biotechnology, gene therapy and nanotechnology has been one of the most contentious subject areas and has spawned not only reams of academic literature but also driven investment in fundamental research to investigate such risk perceptions (Trebilcock & Fraiberg 1998). The risk debate at the international level emerged primarily in the context of international trade regime. Prior to the debate on GM (genetic modification) technology, risks emanating from specific technologies was seen to be primarily a technocratic issue which would be dealt by domestically by national governments (Jasanoff et al 1995; Hackett et al 2008). With globalisation and the establishment of the World Trade Organization (WTO), a number of issues which were hitherto primarily domestic policy issues were linked to the international trade regime and consequently became legitimate areas of international policymaking and regulation. Intellectual property rights, food standards, environmental standards all became linked in terms of their impact on international trade (Jones 2002) and therefore their regulation would have to conform to certain agreed norms of equity and proportionality underlying the international trade obligations of member countries. Both the Sanitary and PhytoSanitary Measures and the Technical Barriers to Trade Agreement represent this agreement between member states of the WTO. Essentially these agreements recognise international standards established by organizations like the ISO, Codex Alimentarius and others as being in conformity to the legal requirements under the international trade regime, thereby creating a presumption of legal validity of domestic measures which are in conformity with these international standards. Although it provided an incentive for countries to base their domestic standards of these international standards, it did provide for domestic policy flexibility in ensuring the right of member states to adopt other standards as long as they could prove that it was not unduly trade restrictive.

. It is important to keep in mind though that these standards continued to be voluntary but now their reference within the SPS and TBT Agreements of the WTO them considerable status and almost legal validity through the international trade regime. There has been many questions asked by commentators on the non-transparent processes of standards development within these bodies and to what extent this could trigger a legitimacy crisis within the WTO (Bernstein & Hannah 2008). This is of course a digression but it does draw attention to an important aspect of the process of voluntary standards gaining legal validity via the international trade regulation regime. The WTO Agreements in this context was a watershed. Earlier these voluntary standards were in some cases adopted by member states within their legal regime and therefore gained legal validity. Thus it was entirely on its national imperative that these voluntary standards were adopted or rejected by nation states. There was therefore no international law imperative to adopt such standards. The WTO changed this entire scenario. By stating that national standards based on these international voluntary standards would gain automatic conformity with international trade obligations, it created not only a system of incentives but more lastingly established a systematic percolation of these international voluntary standards into the domestic legal regimes of member states (Meidinger 2007). These voluntary international standards have gained in importance and legality and this is reflected in both the increased participation and also competitiveness between the participants in

the meetings of these standards setting bodies like the ISO and the Codex Alimentarius. Given the high stakes, commentators have stressed the need to ensure effective participation of WTO member countries in the deliberations of these organizations (Kunzer 2001). If the above could be categorised as the first and second phases in the emergence of international soft regulatory standards, current events and develops seem to suggest the onset of a third phase. This third phase can be represented as the era of horizontal regulatory partnerships between national states and international regulatory actors like the ISO, OECD, etc (which is characterised as international subpolitical actors for various reasons explained below). This regulatory partnership is horizontal because both the parties enter into direct relationship with each other. Given that there is absence of a *via media* (in terms of an international trade agreement providing indirect incentives); both parties have to identify real, significant interests in forming these partnerships and ensure adequate reciprocity in sustaining such partnerships. Such a trend is clearly witnessed in the area of nanotechnology.

The aim of this case study is to examine these regulatory partnerships being established by the EU with the Organisation for Economic-Cooperation and Development (OECD), International Risk Governance Council (IRGC) and World Health Organization - Intergovernmental Forum on Chemical Safety (WHO-IFCS) in the context of nanotechnology. It revisits the arguments given for and against national versus international regulation of nanotechnology given by theorists (Marchant & Sylvester 2009). This is an important aspect since it provides the essential rationale for undertaking policymaking at the international level as against by nations within their domestic policy regime, hereby providing a justification for the functioning and the continued relevance of these international regulatory actors. It also traces the reasons why nanotechnology itself is opportunely situated for engendering such regulatory partnerships. The choice of these three subpolitical actors reflects both their norm setting activities which are in the forefront regulation of nanotechnology. The analysis of the activities of the three subpolitical actors and their relationship with the EU is investigated through the structurationist perspective of network governance (Jones, Hesterlay & Borgatti 1998). The analysis provides us with good first clues of whether these regulatory partnerships are singular ventures or do they represent a definitive trend towards the formation of such networks at the international level.

The paper is divided into five sections, part II provides an overview of the regulatory posturing within the field of nanotechnology. It attempts to understand the reasons for the stand taken by the majority of regulatory agencies across on the issue on both sides of the Atlantic. Part III attempts to deepen the analysis of international subpolitical actors by isolating their distinguishing features in terms of their location and their drive for legitimacy for their actions. It also explores the choice of these three actors in terms of the comparability of their actions within the nanotechnology policymaking. Part IV maps the major regulatory activities undertaken by the IFCS, WHO and the OECD. Part V elucidates on the general network theory and investigates whether sufficient conditions exist for these partnerships to grow into regulatory networks between actors.

## II Growth of Nanotechnology and International Regulatory Overtures

The explosion of academic literature within the area of regulatory governance of emerging technologies or technologies which had certain associated environmental and health risks associated with it had reached a fevered pitch during the height of the controversy surrounding genetic modification (GM). The advent of nanotechnology has also witnessed increasing volumes of academic debates and literature being produced on similar questions of the regulatory options that should be explored in the context of the uncertain health and safety risks that are associated with manufactured nanomaterials and therefore the nano applications based on them. There are subtle differences between these two seemingly similar debates on these technologies which hold the promise of drastic transformation of this twenty first century. First, the public fear vis-à-vis biotechnology was basically focused on the agriculture sectors, specifically with reference to the GM technology. Nanotechnology or manufactured nanomaterials, on the other hand, have a range of applications across disciplines and production sectors. Nanotechnology poses a far greater challenge in terms of identifying specific characteristics and also applications that could be a regulatory challenge on the basis of uncertain risks. The applications being of dispersed nature also preclude alliance formation and civil society activism with a clear focus and policy objective. Given the wide number of applications associated with nanotechnology it becomes difficult to delimit and focus efforts on a particular product sector. This partially explains the limited extent of lobbying by national Non Governmental Organizations (NGO) on issues associated with nanotechnology governance as compared with biotechnology. Most of the activism from civil society organizations has been spearheaded by international NGOs like the Action on Erosion, Technology and Concentration (ETC) Group and Friends of Earth. Second, concentrated effort have been made by the public administrations in most countries to make a differentiation between these two technologies and to a large extent push the argument that the current state of scientific knowledge is still insufficient and therefore more research investment is required.<sup>i</sup> This has been used to delay any new regulatory action in this field. Thus nanotechnology development being still at its nascent stage, regulatory agencies face an information deficit and this is seen to be an impediment in choosing regulatory options (Wilson 2006). Although widely stated, this is a half- truth. There are already several nanotechnology based applications that have been launched in the market.<sup>ii</sup> This number is expected to grow rapidly in the short and medium term (Felscher, 2008).

Most regulatory agencies in the European Union (EU) and the United States of America (USA) have taken a cautionary stance of “more research required and no regulatory decisions yet” (a wait and watch approach). Several actors within the public policy domain and many private actors have taken significant steps towards aligning themselves towards regulatory positions in the recent past. Although the regulatory agencies have not commented extensively on their choice and applicability of regulatory norms, they have taken some steps which could illustrate their regulatory leanings. On both sides of the Atlantic, regulatory agencies such as the EPA (Environment Protection Agency) and DEFRA (Department for Environment, Food and Rural Affairs) have supported voluntary information disclosure on nanotechnology based applications from the private sector. The EPA’s Nanoscale Materials Stewardship Program (NMSP) had been launched as one of the pioneering efforts in systemizing voluntary information disclosure that was to be driven by

private sector initiative. Criticism has mounted though on the lack of centralized reporting, low response from the private sector and essentially lack of vision as to the usage of this information submitted by companies.<sup>iii</sup> This should not deter from the fact that this is a new initiative that has been adopted by two important regulatory agencies and have found support (seems more vocal than actual) from the private sector. The underlying rationale behind the support for such an approach stems from the experience of the public outcry against biotechnology. Regulatory agencies have sought to differentiate between nanotechnology and biotechnology and in reiterating that it is a revolutionary technology which needs to be further studies before any kind of regulatory decision can be taken. Voluntary information disclosure by the private sector through a technology stewardship programs enables the regulators to promote the idea of a responsible private sector (Environment Protection Agency 2009). There is consensus amongst regulatory agencies both in the EU and the USA on several counts. First, nanotechnology is still at a nascent stage in its development; second and therefore, there is lack of information on which regulatory action can be based and third, private sector should adopt voluntary procedures for disclosure of information relating to toxicity and health and safety aspects of nanomaterials and fourth, the industry is in its early stages and imposing mandatory requirements at this stage would result in a regulatory burden on the private sector that could impact the development of nanotechnology.

The developments seem to suggest that most regulatory agencies have acknowledged the need to strengthen international efforts for cooperating on standards, risk regulation, etc. this may seem to make this debate irrelevant. Nonetheless revisiting the debate is important because the debate may have some impact in defining the boundaries of international regulation vis-à-vis domestic regulation. Marchant and Sylvester contend that various rationales exist that reinforce the need for international regulation of nanotechnology. These include the risk aspect of Nanomaterials and the potential for transboundary harm, the uncertainty surrounding the behaviour and health and environmental impacts of Nanomaterials and the therefore the need to share regulatory expertise and resources. The aim of preventing trade protectionism by international harmonization of risk regulation and standards is a perennial one and that has been used earlier in the case of biotechnology. Reducing the inequities of technology access and development in terms of a north-south debate has also been echoed in the context of nanotechnology and remains to be a contentious issue within international policymaking. One could make the argument that these rationales exists for other emerging technologies too and are therefore not specific to nanotechnology. To a certain extent that is correct. Similar arguments were also made in the context of biotechnology (Francioni & Scovazzi 2006). However in one aspect, there is a clear difference in degree. Nanotechnology represents a far greater challenge in terms of standardization and evaluating potential environmental and health of Nanomaterials, partly because of the nature of nanotechnology itself which is a platform technology and in which applications are therefore bound to figure in a variety of modes and sector. In this context the incentive for sharing resources in investigating these various aspects much greater given that the cost of investment is much greater. Regulatory partnerships therefore make sense not only because of efficiency arguments but also in terms of ensuring influence and securing strategic interests of the nations.

Internationally, several initiatives launched in the last few years have focused on an entire range of activities including those of pre-regulation like researching on values and standards for manufactured nanomaterials, to that of exploring regulatory

options like the application of the precautionary principle. Apart from the multiplicities of such activities along the regulatory continuum, another characteristic feature of these developments is the involvement of multi-level actors. They include national actors such as DEFRA, the EPA and civil society organizations like Environment Defense, Friends of Earth (Australia), regional actors like that of the EU (European Union), ASEAN (Association of South-East Asian Nations) and APEC (Asia-Pacific Economic Cooperation) and lastly international actors, viz. ISO (International Organization for Standardization), OECD (Organisation for Economic-Cooperation and Development), IRGC (International Risk Governance Council), IFCS (Intergovernmental Forum on Chemical Safety – an expert group promoted by the World Health Organization) and ETC Group. As is apparent from this listing (not exhaustive), the actors involved consist of both public and private organizations.

Given the multiplicity of such organizations, the focus herein will be on three such agencies, the OECD, the IFCS and the IRGC. Apart from reasons of economy several reasons that underlie the choice of these three actors. First, all these actors have displayed tremendous interest and have developed concrete plans to undertake policy development vis-à-vis nanotechnology. This has enabled them to take a lead in positioning themselves as reference points for future international policymaking on nanotechnology. Second, interestingly the basis for involvement of all these three actors with nanotechnology, have been largely an internal mandate<sup>iv</sup> Third, these subpolitical actors have made some progress in developing mandates and carving out specific areas of influence and therefore could be studied to understand whether the political dynamics of the sector influences their capability and functional spaces. Fourth, all the agencies selected also represent different organizational setup; i.e. the IRGC is a largely non-governmental grouping of experts, the IFCS is an international grouping of experts within the intergovernmental regime of the WHO. The OECD on the other hand, started out as a regional entity, which has however expanded its membership to include economically stronger nations across other regions. These differences in origin, membership and structure, provides interesting insights illustrating the influence of such structural factors on developing policy competencies in newer areas, like in this case in nanotechnology.

### **III International Sub-political Actors**

The sociologist Ulrich Beck has coined the term “subpolitics” to refer to the examples of political decision-making that could be both at the individual and organizational level but which falls outside the institutionalised and formal framework of the state. It refers to both national and the transnational realm of decisionmaking (Beck, 1996). The term has also been developed and used by Beck to characterise the “re-politicisation” of issues that have long been considered outside the realm of public policy – he has given the example of – the elimination of the negative causal impacts of the industrialization process itself (Beck, 1992). Another important aspect of “subpolitics” that is differentiated from the term “politics” is the lack of a drive to legitimise itself through democratic procedures (Beck 1986). In the context of this paper, the term “subpolitical” has been selected to characterise actors which are first, do not function within the arena of formal politics and therefore there is no urge to draw legitimacy for their actions through the democratic process. However this does not preclude from the need to legitimize their actions – however unlike their more

formal “political” institutions, the demands of legitimacy can be met through other channels, viz. reference to neutral expert opinion, representation of wide national membership, participation of civil society organizations, etc. Second, there is structural diversity amongst these actors – i.e. there is very little common between such actors in terms of their institutional framework, the extent of their membership and organizational goals. And third, these actors also function in a multi-level context. The term is used to characterise actors, who may be operating at a local, regional or even international level. Beck characterised both individual and collective level of political activities that fell outside the formal sphere as subpolitics. Herein we only develop the collective/organizational form of subpolitics that have taken institutionalized forms and that participate in politics through the production of soft law. This form of politics needs to be distinguished from reflexive forms of individual politics that although share a common characteristics of being non-formal – the issue of legitimacy has to be conceived differently for both.

Within the field of science and technology studies (STS), similar arrangements have been characterised to understand their cumulative effect on development of specific technology development. Professor Arie Rip for instance has used the term “de facto governance arrangement” (Rip 2002) to characterise the cumulative effects of a number of formal and non-formal actors operating at a multi-level to influence and shape the development of a technology in a particular societal context. Analysis of multi-level regulatory frameworks as characterised by the interplay between global, European and national normative processes is also being developed (Wessel et al 2007). This of course develops primarily from the basis of the research on multi-level governance mechanisms that have redefined policymaking in several areas (Scharpf 2001 and Jordan 2000) within the European Union.

This paper develops the concept of international subpolitical actors to characterise non-formal international institutions that are becoming the production sites of important (soft) regulatory norms. There is a high possibility of these regulatory norms seeping into formal law via countries that are establishing regulatory partnerships with these international subpolitical actors. This Beckian framework has been used primarily because it serves as a useful framework to characterise a host of developments internationally that are contributing to the development of soft norms within the field of nanotechnology. Further the concept is also useful in developing arguments of legitimacy of these subpolitical actors and their activities of norm formation in this field.

### *3.a. International Subpolitical Actors: functioning characteristics*

This paper characterise the following actors to be subpolitical in nature; IFCS, OECD and the IRGC. Before taking a detailed look at their various activities in the field of nanomedicine; we need to first establish comparability between these three organizations. In order to do so first a brief descriptive analyses is carried out, of all these actors in order to identify key aspects/functions which could justify their identification as a subpolitical actor, second, the various commonalities between these three actors are studied and third, their differences. Last, a qualitative comment is made on their comparability.

The IFCS describes itself as a “transparent and inclusive forum for discussing issues of common interest and also new and emerging issues in the area of sound management of chemicals”.<sup>v</sup> It is therefore a forum for experts and other interested

parties to discuss and debate management issues relating to chemical safety (Gartner et al 2003). Another interesting aspect is that the forum was conceived at the UN Earth Summit at Rio de Janeiro in 1992, generally as a non-institutional arrangement for enabling governmental and non-governmental organizations to meet and discuss wide ranging issues dealing with chemical safety and environmentally sound management of chemicals. The WHO serves as the administering authority and provides the secretariat for the IFCS. This umbilical linkage to the UN system provides considerable legitimacy and is the basis for authority of the decisions that it adopts in its various sessions (known as forums). The IFCS is an example of a private-public partnership operating at a global level. Essentially the drive has been to promote a consensual decision-making framework based on discussions and debates between the different members. Its decisions are non-binding in nature but carry substantial weight in terms of establishing an international normative standard and form an important part of international soft law on chemical management.

The OECD is an international organization, with membership of thirty countries primarily drawn from Europe and also includes the USA, Australia and Japan. In the recent past, it has made overtures to expand its membership to emerging economic powers like Russia, Brazil, China and South Africa.<sup>vi</sup> The focus of its activities is in economic policy areas and trade. The aim is to provide a forum for discussing comparative economic problems and policy prescriptions both internationally and across its member countries. It is an intergovernmental organization focussing on a wide range of economic policy issues. Its activities are consultative in nature, however given its membership and strong focus on economic research and analysis, policy prescriptions emanating from it have a substantial impact in identifying and pushing for policy choices.

Of the three subpolitical actors, the IRGC is the most “private” in nature. By this we mean there is no overt organization linkage between them and other international or national organizations that have a formal mandate to undertake work on global issues. By its own admission, IRGC’s work includes developing concepts of risk governance, anticipating major risk issues and providing risk governance policy recommendations for key decision-makers”.<sup>vii</sup> Despite any organizational linkages to the formal international policymaking process, the IRGC internal role definition clearly sees itself as an advisory authority for policymakers worldwide. The IRGC focuses on risk governance as an issue across sectors viz. nanotechnology, climate change, disaster management and synthetic biology (amongst others). The aim is not only to contribute to the development of risk governance as a policy tool in general but also to focus on emerging global risks that require cooperative action across countries and both state and non-state actors. The membership includes Swiss scientists, erstwhile policymakers and international, risk experts. It also aims at collaborating with a host of intergovernmental organization, civil society organisations and national policy makers on issues of common interest. The twin aim of collaborating with such external persons is to not only draw legitimacy for their work (directly through peer review but also indirectly through claiming interest representation) but also help create channels of influence through the policy recommendations could be circulated and adopted by formal state actors.

### *3.b. Comparability of Subpolitical actors in nanotechnology policymaking*

Immediately apparent from the above description of these actors' activities is that all of them define their activities with reference to governmental action and policymaking in specific areas. The IRGC's stated aim is to feed into international policymaking and in supporting governments in undertaking risk governance in dealing with emerging risks like climate change and technology disciplines like biotechnology and nanotechnology. Similarly the OECDs role has been to undertake comparative policy analysis and provide evidential based policy options to its member states in a wide range of economic policy areas. This is also true for the IFCS which although focuses more on deliberation between experts and policymakers, but its adopted declarations are also aimed toward providing policy guidance. Another important aspect is that all three are essentially non-state actors and in that sense subpolitical in nature. They do not have the formal legal authority to undertake research and policy analysis on a specific issue of international concern (unlike those given to international organization like the WMO and the WHO). Although the OECD work has focussed extensively on economic policy issues, it has undertaken work on nanotechnology related issues largely on the basis of its own interest. The question of legitimacy is another interesting aspect. All these actors have relied both on its internal mechanisms (like widely representative consultations and peer review) and as well as external mechanisms (to refer their work in the light of other policymaking work, use high impact forums to reach out to formal state actors) in order to derive legitimacy for their work. As mentioned above this derivative legitimacy needs to be distinguished from the urge of formal state actors to legitimize their activities through using democratic participation techniques.

Further there exist significant differences between these subpolitical actors, primarily in terms of their internal organisation set up. These differences though are not critical in terms of their definition of subpolitical actors. The OECD is the most recognized international organization out of these three actors and its membership composes of nation states. The intergovernmental setup does enable it to participate in a number of international policymaking activities across a wide range of economic policy issues. This is especially true in the case of participation in the deliberations of other intergovernmental organizations. The IFCS on the other hand has the overtly, the most informal structure. It calls itself a "forum", thereby referring to the rather loose grouping of interested parties (including subject experts) that come together to discuss and deliberate over certain issues within global chemicals management (Mercier 1995). In some other aspects, like operating national focal points and secretariat management by the WHO, the IFCS does also function in an intergovernmental manner. The IRGC on the other hand is a private organization (in terms of its lack of any formal linkage with any intergovernmental process, organisation, etc) but with a public agenda of influencing policymaking through research and consensus building on the issue of risk governance in specific sectors.

At this stage, it is important at this stage to reiterate that all these actors do share certain essential characteristics that enable their categorization as subpolitical actors. The obvious next question is to what extent these structural differences would preclude their comparability as subpolitical actors in the context of nanotechnology regulation? Or more appropriately, do differences in scale of operation limit or expand their functional scope to impact policymaking on nanotechnology? In order to answer this question, key elements and developments of each of these subpolitical actors engagement with the issue of nanotechnology regulation is chalked out. As will

be evident from the following discussion the difference in structure has influenced these subpolitical actors in two ways. First, it has influenced their choice of arguments for establishing legitimacy of their research results and policy prescriptions within this area. Second, it also shapes their preference of certain channels of influence over others in peddling their policy prescriptions both at the international, national and sub-national level through their interaction with formal state actors. However the hypothesis is this does not in any way impair the argument of comparability since in substantive terms all the three subpolitical actors have undertaken considerable research and developed significant policy guidance on the issue of nanotechnology regulation. Thus although their structural set-ups have to a certain extent shaped procedural issues, it has had limited effect on their substantive role definition in terms of their capacity and functional authority to undertake further deliberation of issues relating to nanotechnology regulation.

#### **IV Nanotechnology Policy Actions by International Sub-Political Actors**

##### *4.a. Intergovernmental Forum on Chemicals Safety*

In 1994, the International Conference on Chemicals Safety established the IFCS and constituted its first meeting in Stockholm. The aim was to constitute a mechanism through which governments, intergovernmental organizations and non governmental organisations could work together to promote chemicals safety and environmental sound management of chemicals globally. Since then the IFCS has had six meetings, including the last being IFCS Forum VI at Dakar, Senegal in September 2008. One of the final outcomes of this last meeting was the Dakar Statement on Manufactured Nanomaterials.<sup>viii</sup> The negotiations focussed on the role and the nature of the engagement that IFCS should have in the context of developments in nanotechnology and also on the possible policy options available in ensuring chemical safety. Another important aspect of the IFCS VI negotiations was on its future, with the development of the Strategic Approach to International Chemicals Management (SAICM) under the ICCM (International Conference on Chemicals Management). This is an important aspect since as we shall see, the decision of the ICMM2 not to accept the IFCS offer of integrating it as a subsidiary body to ICCM<sup>ix</sup>, may affect its very existence and therefore its capability to engage with safety issues in nanotechnology globally. This also illustrates the high stakes that are associated with locating and consolidating global policymaking on nanotechnology within specific international organizations and forums at the cost of others. It also reflects a deliberate choice on the part of Europe, the US and other leading countries that are exponents of nanotechnology, to support certain intergovernmental forums with clear division of policymaking between them in pushing for international harmonization and policy convergence on standardization, environmental and health safety and intellectual property rights in nanotechnology.

The primary issue was whether the IFCS mandate being limited to chemical safety, could also include social and ethical implications of nanotechnology. Several NGOs and developing country participants supported its inclusion within the IFCS agenda. However most European countries underlined the distinction between nanotechnology more generally and manufactured nanomaterials and supported the inclusion of the latter (as far as chemical safety aspects were concerned) into the IFCS

agenda. This was resolved in the Dakar statement, by including a preambular reference “to the need to address safety aspects of nanotechnology” however choosing to limit the focus of the statement only on nanomaterials. Product labelling of those containing nanomaterials and the need for a global code of conduct was also a point of heated debates. The final statement reflects these divisions in the considerable watering down to only specifying that the feasibility of global codes of conduct needs to be evaluated and that information requirements on manufactured nanomaterials could be met through product labelling, but also websites and databases. Nevertheless the statement was the first policy recommendation given by any such international forum on the issue of safety of manufactured nanomaterials.

The Dakar Statement on Manufactured Nanomaterials recommended action on several aspects of nanotechnology governance and supported specific regulatory strategies. The precautionary principle was recommended to be applied as a general principle of risk management both by the government and the industry during the entire lifecycle of the manufactured nanomaterials. Access to information, was also sought to be facilitated by cooperative actions across and between actors; viz. manufacturers, researchers, governments and other stakeholders. Information was considered crucial in evaluating potential risks, but also bringing about transparency and cooperation in managing risks. Partnerships should also be established for channelling support to developing countries and economies in transition in building scientific, legal, regulatory and technical expertise on the issue of risks associated with manufactured nanomaterials. Finally it calls upon the ICCM2 to consider these recommendations for further actions.

#### *4.b. Organisation for Economic-Cooperation and Development*

There are essentially two mechanisms through which the OECD has undertaken policymaking on nanotechnology. The OECD’s Working Party on Manufactured Nanomaterials (WPMN), was established in 2006. It is a subsidiary body under the Chemicals Committee. The WPMN focuses on the human health and environmental safety aspects of manufactured nanomaterials. The other is the Working Party on Nanotechnology (WPN) that was established by the Committee on Scientific and Technology Policy (CSTP) in 2007 and serves as a forum for discussions on emerging policy issues from nanotechnology developments globally. The 2009-2010 work program of the WPN focuses on developing statistical methodologies in order to benchmark and compare developments in nanotechnologies, addressing challenges to the business environment specific to nanotechnology, fostering international scientific cooperation in nanotechnology and in selecting key policy issues (viz. risk governance) and in enabling nanotechnology while responding to specific global challenges like climate change, energy security, water, health and the environment. Peripherally, the OECD has also cooperated with Allianz, in bringing out a report on “Opportunities and Risks of Nanotechnologies” under its International Futures Programme. It is instructive to analyse the specific aspects of the work program both in terms of substantive outputs as well as linkages between the various members of these committees and external actors in order to gauge the relevance of the work program and its uptake by national and regional actors.

The WPMN has put together a group of eight projects that focus on generating information on health and environmental safety aspects of manufactured nanomaterials and to develop internationally harmonized hazard exposure and risk

assessment standards. The projects include the following: development of a database on human health and environmental safety research, research strategies on manufactured nanomaterials, safety testing of a representative set of manufactured nanomaterials, manufactured nanomaterials and test guidelines, cooperation on voluntary schemes and regulatory programmes, cooperation on risk assessment, the role of alternative methods in nanotoxicology and exposure measurement and exposure mitigation. The fifth project mapped the national information gathering programs (whether voluntary or mandatory) and has identified similarities and differences between such programs. It also prepared recommendations on mechanisms and elements while setting up information gathering initiatives. The steering groups of the third and the fourth projects are co-chaired by the United States and the European Commission. Under the third project a sponsorship program has been launched for the testing of fourteen specific manufactured nanomaterials. Several countries of the European Union like France, Germany, United Kingdom and the European Commission itself have become lead sponsors in the case of specific nanomaterials. Outside the European Union, it is China, Japan, Korea, Canada and Australia that have been active in the sponsorship program. In terms of private participation, it is the BIAC (Business and Industry Advisory Committee) representing major business organizations in the OECD member countries. Most of the publications of the WPMN have been developed and referenced with the Inter-Organization Programme for the Sound Management of Chemicals (IOMC), thus ensuring their dissemination amongst the FAO, ILO, UNEP, UNIO, UNITAR and WHO. The deliberations of the WPMN also includes participants from non-member countries like Russia, Brazil, Singapore, Thailand and India and intergovernmental organizations like the WHO and the UNEP, ISO Technical Committee 229 on nanotechnologies as well as other environmental NGOs and Trade Union Advisory Committee to OECD. The multiplicity of actors not only underlines the importance of the topic but also illustrates the drive within the OECD to widen the representation and gain in both legitimacy and secure the support for its policy recommendations in this area.

Apart from the inclusion of several international agencies within the WPMN deliberations, the OECD is active in the deliberations of other international organizations related to nanomaterials. It has collaborated with the IEC, NIST (US National Institute of Standards and Testing) and the ISO in holding a Joint International Workshop on measurement and characterization for nanotechnologies.<sup>x</sup> One of the outcomes of the workshop was the establishment of the Nanotechnology Liaison Coordination Group to ensure coordination of activities between these international and national actors. Also the ISO has urged the members of the WPMN to ensure that at the national level they coordinate with their national representatives on ISO/TC (Technical Committee) 229. Coordination has also taken place with the IFCS secretariat and participated in the Forum VI of the IFCS that was held last year in Dakar.

#### *4.c. International Risk Governance Council*

The IRGC has been working on developing an overall framework for risk governance of nanotechnology since 2005 onwards. In 2007 they published the report (IRGC 2007), along with survey reports targeting the role of specific stakeholders viz. government, industry, research organizations and the NGOs. Currently, the second

project focuses on developing specific risk governance frameworks and techniques for nanotechnology applications in food and cosmetics. The methodology followed in both the projects included the setting up of an expert body that would author the reports, in addition to inputs from multistakeholder expert workshops. Final recommendations from the second project are expected in spring 2009.

The policy brief “Nanotechnology Risk Governance: Recommendations for a global, coordinated approach to the governance of potential risks” identified four generations of nanotechnology products and sought to differentiate between risk governance frameworks (Frame I and Frame II) based on whether these applications contained active or passive nanostructures. The first generation products were constituted by passive nanostructures (Frame One applicable), whereas the second, third and fourth generation included active nanostructures (therefore Frame II would be applicable). IRGC states that although risk assessment and risk management is a pre-requisite for frames, *current regulatory structures and processes* are adequate in responding to the risk assessment requirements under Frame I. In the case of frame two, however, applications *are likely to fall outside the remit of existing regulatory bodies and risk assessment methodologies may simply not exist*. The report seeks to underline the differences in national regulations and the lack of harmonization in risk assessment disciplines globally in this area as one of the shortcomings in the current scenario. The dearth of risk assessment data is identified as one of the major impediments in developing a suitable regulatory approach. It strongly supports collaborative measures between industry, governments and other stakeholders, viz. international voluntary agreements and sees it as the future basis for undertaking regulatory action. Another important contribution of the report has been to identify and recommend action points for stakeholder groups like Government, Industry, International Organizations, Academia and civil society. It also states that the “policy brief is targeted at policymakers engaged in planning, oversight and funding of nanotechnology regulation, research and practical applications”.

## **Part V            Regulatory Partnerships between Regulatory Agencies and Subpolitical Actors : First Steps to Network Governance?**

### *5.a. Analytical Framework*

Jones, Hesterley and Borgatti in 1997, first presented a cohesive theory of network governance by integrating transaction cost economics (TCE) and social network theories. Their seminal research laid down the foundations of a consistent framework of analysis for network governance between firms. They identified the emergence of network governance with the presence of factors viz. asset specificity, demand uncertainty, task complexity and frequency that govern exchange conditions. They defined network governance as “involving a select, persistent and structures set of autonomous firms (as well as non profit agencies) engaged in creating products or services based on implicit or open ended contracts to adapt to environmental contingencies and to safeguard contingencies. These contracts are socially-not legally-binding” (Jones, Hesterlay & Borgatti 1998).

Within this, these theorists underline three aspects or “exchange conditions” for the emergence of network governance. These include, uncertainty, asset specificity and frequency and they together also determine the efficiency of these

forms of governance. In the context of inter-firm dynamics within which this theory was developed uncertainty of environment reflected the unstable and unpredictable nature of both the market (demand, supply) as well as the policy environment (Williamson 1991). Asset-specificity refers to both the physical equipments and the knowledge developed by participants that were exchanged to produce a final product or service (Powell 1990; Powell, Koput & Smith-Doerr 1996). Frequency establishes the repeated nature of customized exchanges thereby establishing conditions for relational and structural embeddedness (Granovetter 1985; Uzzi 1997). The theory of course is developed further in order to make a series of propositions on the nature and conditions of functioning of such networks of governance. Herein, the analysis is limited to answering the following questions:

Do the interactions between the EU and the OECD, IFCS and IRGC on nanotechnology policymaking seem to suggest that there exist ideal conditions for the formation of a network?

Does each of these international subpolitical actors display the characteristics necessary for the establishment of such a network?

### *5.b. Question of uncertainty*

Uncertainty is a term, which has been used widely to characterise nanotechnology both at the physical level as well as in terms of what should be our policy and regulatory responses to these uncertainties embedded within the nature of the technology. Scientists and policymakers have reiterated that efforts should be made to enhance our limited knowledge of the risks and potential effect of Nanomaterials on the environment and human health (Maynard et al 2006). The debate on regulatory responses to these developments has also been disparate and there is yet no consensus at the international level on what is the best way to move forward. Currently there is therefore considerable uncertainty within the policy and the regulatory environment (Schriemer 2007; Macnaghten, Kearnes & Wynne 200; Bowman & Hodge 2006; Wilson 2006; Sargent Jr. 2009). Within the EU there have been several ongoing sectoral (Cosmetics and Nanomedicine are two such sectors) as well as at an overall level (for example DG SANCO – Annual Nano Safety Conference) deliberations on the nature and mode of regulatory action which is required to be taken. Regulators have been largely cautious and have underlined the need to strike a balance between regulatory obligations imposed on producers/manufactures and the need to protect innovation. The issue which is crucial to the debate is whether Nanomaterials in itself should be regulated uniformly across sectors or whether sector specific regulations should be developed according to the applications involving Nanomaterials?

### *5.c. Asset Specificity*

Asset specificity refers to the fact that knowledge on the subject is highly dispersed and is concentrated within these disparate knowledge holders. In this case it would refer to whether these international subpolitical actors have specialized in a specific sector of policymaking vis-s-vis nanotechnology? Asset specificity also assumes that the field or area is such wherein specialized inputs are required, which is referred to as task complexity (Pfeffer and Salancik; 1978). The complex nature of the tasks forces participants to coordinate their activities. Task complexity is also heightened when coupled with time pressures. The above discussion is evidence of the extremely

complex physical characteristics of nanomaterials and therefore the need to invest resources in fundamental research relating to their impact on the environment and human health. Given that there are already a number of applications involving nanomaterials and nanotechnology are in the market, it is especially urgent to develop consensus based standards (Murashov & Howard 2008) and take regulatory measures designed to cover the potential risks associated with these application. Most regulatory agencies (NIOSH Update 2008; EU 2007) have commented on the need to cooperate and coordinate efforts at the international level to develop standards and regulatory guidance on nanotechnology. This response reflects the understanding that this is a specialized area in which expertise is dispersed and has to be coordinated globally.

Amongst the three international subpolitical actors, it is IRGC which has sought to develop specialized expertise on risk governance issues. It has developed a framework for analysing the different kind of nanotechnology products to be developed over time – in terms of generations along with customised risk governance techniques to address each of these generations. Commentators have underlined the role played by IRGC in providing impetus and thus pushing forward the risk aspects of nanomaterials (Rip 2008). Swiss Re, the financial insurance giant supporting the activities of IRGC, is acting in a proactive manner in order to pre-empt asbestos like situation from arising. In this context developing risk governance models in nanotechnology has been done with the aim to influence policymaking in this field. Although institutionally the IRGC has relatively less potential to influence international policymaking on these issues (given that it is not an intergovernmental organization or an institution with state participation), it has been able to draw considerable credibility and leverage by employing several mechanisms. These include the participation and leadership of experts in developing the risk governance models and by providing for peer review through extended stakeholder participation. The nomination of stakeholders from important regulatory authorities like the FDA, DEFRA and the USEPA, and their participation within the stakeholder dialogues is expected to create opportunities for raising the policy relevance of the recommendations given by IRGC.

In the case of the OECD, its involvement on other emerging technology regulatory aspects dates back to its work on biotechnology policymaking. In 1993, it established the Working Party on Harmonization of Regulatory Oversight in Biotechnology. Its major contribution has been to develop safety assessment models for a range of cultivated crops and micro-organisms. It has produced “consensus documents” science based international dialogue on these issues. The WPMN seems to be following a similar working style in terms of a member country volunteering to be the “lead country” within the eight Steering Groups and then developing a draft standard on a specific issue, for further circulation and acceptance. OECD’s work on nanotechnology therefore could be seen as a continuation of its work in engaging with emerging technologies. It has also taken initiative to coordinate closely with the ISO, which is also in the process of developing a range of standards on nanotechnology.

Compared to the IRGC and the OECD, the IFCS can be considered to be a comparative lightweight in terms of developing specialized policy expertise on nanotechnology. Up until its Sixth Session at Dakar, the IFCS has focussed on issues that have been largely accepted to be as forming the core of the international chemical safety agenda, viz. pollutant release and transfer registers (PRTRs), Globally Harmonized System for the Classification and Labelling of Chemicals (GHS), acutely toxic chemicals, toxic pesticides, etc. The initial mandate was to map the progress of

the priorities for action in implementing Agenda 21. Thereafter it was the Bahia Declaration which provided a roadmap for the negotiations and implementation within the IFCS. In Forum V, under the discussion on topics for future forums of IFCS, “Nanoparticles, nanomaterials and nanotechnology” was accepted as part of the terms of reference for Forum VI. The legal basis for the choice of future topics was the ICMC resolution ((SAICM/ ICCM.1/7, Annex IV, Resolution I/3) which invited the IFCS to discuss topics of common interest and are new and emerging issues. This should take away from the fact that the IFCS was a frontrunner in terms of seizing the opportunity to discuss and consider issues related to nanotechnology and nanomaterials within the international chemicals agenda. In this sense, the negotiations within the SAICM on nanotechnology were an attempt to regain control over the international negotiations agenda on nanotechnology within an intergovernmental set up.

It is important to note that asset specificity is not only a factual condition. Meaning, the parties of a network have to recognize a participant as having a specific expertise and therefore the imperative to involve them. Thus although the IRGC has developed a specific expertise and to an extent its research reports have been quoted widely in formulating opinions by EU institutions<sup>xi</sup>, it has not been involved in any institutional manner by the EU institutions. The OECD on the other hand has emerged as one of the main international subpolitical actor in partnering with the EU and other countries like the USA in developing international standards and regulatory guidance on nanotechnology. In the case of the IFCS, the creation of an alternative forum and the lack of political will amongst developed countries to continue this forum could act as an impediment in further developing its mandate and expertise in this area.

#### *5.d. Frequent Exchanges Among Parties*

This is an imperative for the formation of network governance systems (Williamson 1985). However given that nanotechnology policymaking is a relatively new although an upcoming area, frequency would necessarily reflect not over a time span but more in terms of density within a short time span. Amongst the three, IRGC is a comparatively new actor and thus has limited exposure to participating in networks. However as mentioned above although institutionally it has achieved limited participation in other policy networks – it has been tacitly represented by way of individual members/experts that have participated in its deliberations in an extensive manner. The OECD as mentioned above has had a history of facilitating multilateral initiatives on a range of policy issues and therefore has had a number of frequent exchanges in the past. The IFCS as a forum is well suited for engaging in frequent and sustained interaction with regulatory agencies in EU and other countries, but given its current uncertain future, there is a high possibility that this may not be able to develop.

#### *5.e. Diagnosis*

As mentioned earlier out of the three subpolitical actors, it is the OECD which *prima facie* seems to have the strongest linkages with regulatory agencies through its member countries. It is best positioned to secure the uptake of its policymaking on nanotechnology by the regulatory agencies in its member countries. From the point of the regulatory agencies, the OECD appears to be a strategic forum in which

international harmonization efforts could be taken up. The European Commission Communication (to the European Parliament, the Council and the European Economic and Social Committee) on the Regulatory Aspects of Nanomaterials states that.<sup>xii</sup>

*The development of standards and test methods requires close international collaboration to ensure that scientific data can be compared globally and that scientific methods used for regulatory purposes are harmonised. A main forum for the coordination of activities at the international level has been provided by the OECD Working Party on Manufactured Nanomaterials. Work is also carried out in the framework of the International Organisation.*

Similarly the Nanosciences and Nanotechnologies: An action plan for Europe 2005-2009. First Implementation Report 2005-2007<sup>xiii</sup> states that:

*A principal forum for the coordination of activities at the international level has been provided by the OECD Working Party on Manufactured Nanomaterials.*

The Council conclusions on nanosciences and nanotechnologies,<sup>xiv</sup> also stated that it:

*Is convinced that Europe's chances of being and staying at the forefront in this field hinge upon its capacity for coordination; reiterates the need for a single Community focal point for coordination and the importance of the EU's speaking with one voice on the international stage, particularly in the light of the challenges presented by patent protection in China; calls therefore on the Commission and Members States to devise mechanisms to effectively coordinate actions in this field; urges the Commission to take into account in its policy making all activities within the OECD (e.g. definitions, nomenclature, risk management) and UNESCO (ethics).*

This by far has been the clearest indication that not only the EU is aware of the value of the work undertaken by the OECD, but that supports the OECD as the “main forum” for coordination of activities internationally. This kind of recognition given by the European Commission highlights the close cooperation between the regulatory agencies and the OECD and the admission that work undertaken by the OECD is of direct relevance to the development of regulatory disciplines on nanotechnology in the European Union.

The IFCS is a unique forum in terms of the equal representation that is provided to countries, intergovernmental organizations and non-governmental organizations. This however also complicates policymaking leading to disagreements between countries and NGOs, with the latter supporting more aggressive position on the social and ethical dimensions of new technologies. This division also surfaced at the IFCS Session VI in the discussions on the topic.<sup>xv</sup> The important step for the IFCS was to introduce both the environmental safety and the economic aspects of nanotechnology into the international chemicals management agenda, through the Dakar Statement on Manufactured Nanomaterials. The recommendations were to be considered by ICMM2 for further action. However the rejection of the proposal by ICMM2 to incorporate the IFCS as an advisory body puts into question the future of IFCS and therefore its capacity to take the nanotechnology agenda it has constructed any further. In the context it is important mention that although nanotechnology did feature as a part of the final omnibus resolution on emerging issues,<sup>xvi</sup> there was no

reference to the Dakar Statement. The final resolution on emerging issues in the ICCM2, while recognizing the potential human health and environmental risks that are associated with nanotechnologies and manufactured nanomaterials, only underlined the need for coordination information gathering between government and private sector and making it accessible to all stakeholders. Further the relevance of these issues, particularly to developing countries and countries with economies in transition were also underlined. It is therefore to be seen whether further work is undertaken through the Open-Ended Working Group that has going to be set up to carry out intersessional until ICCM3.

Out of the three, the IRGC represents the most “private” subpolitical actor, in the sense that it does not have any formal linkage with nations. However there exist several cleavages through which it could leverage its role as a pre-eminent actor in setting up risk disciplines in the field of nanotechnology at the global level. The first of such a cleavage appears to be in the selection of its expert body. In the first project the experts included *inter alia*; Dr. Mihail Roco of the National Science Foundation and Professor Ortwin Renn of the University of Stuttgart. Both these experts are widely recognized subject experts in the field of nanotechnology and risk regulation respectively. Second, the risk governance frames that have been developed by IRGC have also been widely circulated by the authors in high impact forums.<sup>xvii</sup> Third, the project itself was funded by the Environment Protection Agency (EPA) and the Department of State of the USA. The potential value of the policy outputs of IRGC increases tremendously given the probability of its adoption by the EPA. Similarly the multistakeholder expert workshops and stakeholder surveys have included wide representation from countries (policymakers), intergovernmental organizations, academicians and civil society organizations active on this issue.

A comparative look at all these three subpolitical actors seem to suggest the following: first, the OECD seems to be best placed to emerge as the foremost subpolitical actor to take a lead on policymaking on nanotechnology issues globally. The intergovernmental nature of OECD itself lends it to close linkages with countries and their regulatory agencies. Further the internal organization of the WPMN in terms of steering groups with substantial responsibility on representatives of national regulating agencies has also helped in the easy adoption of frameworks and strategies to put a fast track process of policy development. This has also made possible a substantial deepening of the global agenda on nanotechnology from that of making general statements to designing operational standards, terminology and regulatory options. Perhaps most importantly it is the support of European member states and the European Commission that has been instrumental in the emergence of the OECD as an acceptable and therefore legitimate forum of global policymaking on nanotechnology.

Second, in the case of the IFCS, one could imagine that there is substantial support for its work amongst NGOs and a number of developing countries – primarily because it is one of the most participatory forums at the international level. However the proceedings at the ICCM2 suggest that IFCS does not enjoy substantial support of a number of developed countries that essentially sees it as replicating the SAICM. Given that the ICCM2 rejected the proposal of the IFCS, it does seem difficult for it to continue functioning given the current resource constraints. Further the absence of any reference to the Dakar Statement on Manufactured Nanomaterials in the omnibus resolution of the ICCM2 seem to suggest that there is considerable opposition by developed countries to lend support to the IFCS policymaking on nanotechnology.

Overall it seems that there is a low probability of the IFCS as emerging as a major subpolitical actor in nanotechnology policymaking.

Third, the IRGC has potential to emerge as an important subpolitical actor on global policymaking on nanotechnology risk governance. It has been able to build and operate a network of growing stakeholders and interested parties through its periodic workshops. Also it has been able to carve a niche for itself in the field in terms of focussing on risk governance in nanotechnology. The choice of its second project – nanotechnology risk governance in food and cosmetics – is evidence of the focus on high priority policymaking area with the aim of targeting policymaker across countries.

Fourth, our analysis suggests that although the field itself is characterised by uncertainty demanding high asset specificity, there does not seem to be a network emerging at least amongst the EU and these three international subpolitical actors. At best the linkages between these three actors are at a formative stage and therefore necessarily tenuous. Despite nanotechnology as an area of policymaking necessarily involves coordination across regulatory agencies and international subpolitical actors, these linkages can be characterised as bilateral regulatory partnerships that may develop into networks with time.

## **Part VI Conclusion**

The preceding discussion is evidence of the growing importance of subpolitical actors like the IRGC, IFCS and OECD as acceptable forums of global policymaking. It reflects several trends. First is the increasing emphasis on international harmonization of standards and regulatory policies in specific fields like nanotechnology. Given that nanotechnology will have a potential global impact, it has been emphasized that there is a need to coordinate action globally and in a strategic manner. Second, countries are also aware of their own resource limitations and therefore are more willing to cooperate through international forums on standard setting and regulatory policy harmonization. Third, global policymaking is also a highly contested field, in which countries vie with each other in influencing policymaking based on their own national standards and practices. Within the EU context it is useful to highlight that internally their private and soft regulation has been increasingly adopted across policy areas in an effort to provide guidance and enable harmonization within the single market. The EU's Open Method of Coordination in the field of social policy highlights the network of EU institutions and private players that undertake policymaking (Coen & Thatcher 2008; Zeitlin et al 2005). The trend towards formation of regulatory partnerships with subpolitical actors like the OECD, could reflect the dynamics of the internal market.

It is important to stress that all these subpolitical actors have displayed agency in determining their own mandate. They have been able to secure resources and partnerships with influential stakeholders in gaining acceptability for their policy recommendations. It is in sync with empirical studies that indicate the influence of transnational institutions on national policymaking (Carney and Farashahi 2005). Nevertheless, abilities on the part of these subpolitical actors to negotiate with states and other international actors, on their policymaking tilt and priorities are imperative in determining the sustainability of these regulatory partnerships.

It is in this context that all these three actors have undertaken specific steps towards establishing policy supremacy in specific sub-fields of nanotechnology. This field is rapidly growing and given the nascent stage any actor could gain on the first

over advantage. However as is evident from the above analysis it is crucial that there is certain convergence of interest between countries and ambitions of these subpolitical actors. Since the international regulatory field continues to be dominated by countries, it is important that a number of countries identify with the goals, roles and regulatory objectives of the subpolitical actors. The EU has clearly identified the OECD to be a primary actor through which it could proceed with its harmonization efforts in the field of nanotechnology. In the case of IFCS however, despite being the first actor to identify nanotechnology as an important part of the international chemicals safety agenda – was unable to capitalize on it. The primary reason – not unexpectantly was the lack of support from developed countries, who viewed the forum to be too open and too prone to influence from NGOs for it to gain substantial control over policymaking. This seems to be the primary rationale behind their lack of support for the proposal to bring the IFCS into the fold of ICMM2 as an advisory body. First, the decision to open negotiation on nanotechnology through the OEWG and not the IFCS and second, the absence of reference to the Dakar Statement, is also evident of their intention to delegitimize the IFCS as a forum for future negotiations on nanotechnology.

Within the EU there seems to be a consensus across regulatory agencies that OECD provides an important forum for developing standards and regulatory policy on nanotechnology. In that sense one is witnessing a gradual shift towards international co-regulation between EU regulatory agencies and subpolitical actors such as the OECD and the IRGC. This partnership makes eminent political sense, not only in terms of efficiency, but also because international organizations imperatively need to legitimize their existence by extending or deepening their mandate to cover areas and issues that are of high priority in most countries. In that sense, nanotechnology represents such a priority issue, and therefore one would expect to witness a greater role for such subpolitical actors within this field. However despite such linkages the formation of network governance led by the EU is premature. This trend also underlines the urgent need to investigate policy formulation processes internationally in order to delineate the field in terms of providing more transparency and legitimacy to such processes.

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Reference:

Beck U (1996) *The Reinvention of Politics. Rethinking Modernity in the Global Social Order*. Polity Press, Cambridge, 1-55.

Beck U (1992) *Risk Society: Towards a New Modernity*. Sage, London.

Beck U (1999) Subpolitics: ecology and the disintegration of institutional power, *World Risk Society*, Polity Press, Cambridge, 91-107.

Carney, M. & M. Farashahi (2006), Transnational Institutions in Developing Countries: The Case of the Iranian Civil Aviation, *Organization Studies*, 27, 53-77.

Coen, M. & Thatcher, M. (2008). Network governance and multi-level delegation: European networks of regulatory agencies. *Journal of Public Policy* 28:49-71.

Environment Protection Agency (2009) *Nanoscale Materials Stewardship Program: Interim Report* [Last accessed 5 May 2009.] Available from URL: <http://www.epa.gov/oppt/nano/nmsp-interim-report-final.pdf>.

Felcher EM (2008) *The Consumer Product Safety Commission and Nanotechnology, Project on Emerging Nanotechnologies*, Washington.

Gartner S, Kullmer J and Schlottmann U (2003) Chemical Safety in a Vulnerable World. *Angewandte Chemie International Edition* 42, 4456-69.

IRGC (2007) *Nanotechnology Risk Governance: Recommendations for a global, coordinated approach to the governance of potential risks. Policy Brief*, Geneva.

Jordan A (2000), "The politics of multilevel environmental governance: subsidiarity and environmental policy in the European Union", *Environment & Planning* 32, 1307-24.

Rip, A (2002) *Co-Evolution of Science, Technology and Society*, Berlin-Brandenburgische Akademie der Wissenschaften, Berlin.

Mercier MJ (1995) Editorial, Chemical Safety: A Global Challenge. *Environmental Health Perspectives* 103, 10.

New economic diplomacy - [http://books.google.co.in/books?id=ELDv-26byMwC&pg=PA112&lpg=PA112&dq=Intergovernmental+Forum+on+Chemical+Safety+policy+making&source=bl&ots=reK\\_RrAiRZ&sig=kHVBafoXOka0R-IY-](http://books.google.co.in/books?id=ELDv-26byMwC&pg=PA112&lpg=PA112&dq=Intergovernmental+Forum+on+Chemical+Safety+policy+making&source=bl&ots=reK_RrAiRZ&sig=kHVBafoXOka0R-IY-)

[swQcNUF3Ws&hl=nl&ei=Gz0dSsvoHcvN-Qbxx8jDCw&sa=X&oi=book\\_result&ct=result&resnum=8#PPA118,M1](http://www.scribd.com/doc/118118118/Sabel-Zeitlin-2006-Learning-from-difference)

Sabel, C. & Zeitlin, J. (2006). Learning from difference: The new architecture of experimentalist governance in the European Union. Paper prepared for the presentation at the Arena seminar. Centre for European Studies, University of Oslo, Norway, June 13.

Scharpf FW (2001), "Notes toward a theory of multilevel governing in Europe", *Scandinavian Political Studies* 24, 1-26.

Fraiberg JD and Trebilcock MJ, (1998) Risk Regulation: Technocratic and Democratic Tools for Regulatory Reform, *Mc Gill Law Journal* 43, 846.

S. Jasanoff, (1995) "Product, Process, or Programme: Three Cultures and the Regulation of Biotechnology," in M. Bauer, ed., *Resistance to New Technology* Cambridge: Cambridge University Press, 311-331.

Hackett, E. J., Amsterdamska, O., Lynch, M. and Wajcman, J. (Eds.) (2008) *The Handbook of Science and Technology Studies*: Third Edition, MIT Press, Cambridge MA. 63-7.

K. Jones (2002), 'The WTO Core Agreement, Non-trade Issues and Institutional Integrity' *WorldTrade Review*, 1, 257.

Wessel RA, Follesdal A and Wouters J (2007) *Multilevel Regulation and the EU: The Interplay between Global, European and National Normative Processes*. Martinus Nijhoff, Leiden.

Wilson RF (2006) Nanotechnology: The Challenge of Regulating Known Unknowns. *The Journal of Law, Medicine & Ethics* 34, 704-713.

Zeitlin, J., Pochet, C. & Magnussen, L. (eds.). (2005) *The Open Method of Coordination in Action: The European Employment and Social Inclusion strategies*. Peter Lang: Brussels

Berstein S, Hannah E (2008), Non-State Global Standard Setting and the WTO: Legitimacy and the Need for Regulatory Space, *Journal of International Economic Law*, 1–34, 3.

Meidinger E(2007) "Beyond Westphalia: Competitive Legalization in Emerging Transnational Regulatory Systems," in C.Bruetsch & D. Lehmkuhl, eds., *Law and Legalization in Transnational Relations*. London and New York: Routledge. 124-26.

KUNZER KE (2001). The Effects of International Trade Treaties on Public Participation in Health, Safety, and Environmental Decisions. *Risk, Decision and Policy*, 6, 135-138.

Marchant GE. & Sylvester D (2006) Transnational Models for Regulation of Nanotechnology. *Journal of Law, Medicine and Ethics*, pp. 714-725.

Jones C, Hesterly WS & Borgatti SP (1997) A General Theory of Network Governance: Exchange Conditions and Social Mechanisms, *The Academy of Management Review*, 22.4, 911-945.

Wilson RF (2006), Nanotechnology: The Challenges of Regulating Known Unknowns, POSTERS / *Nanomedicine: Nanotechnology, Biology, and Medicine* 2 313– 318.

Felcher EM (2008), *The Consumer Product Safety Commission and Nanotechnology*, PEN 14, Woodrow Wilson Centre, 5-7, 25.

US EPA (2009), *Nanoscale Materials Stewardship Program-Interim Report*, United States Environment Protection Agency, 5-13.

Francioni F(2006), Genetic Resources, Biotechnology and Human Rights: The International Legal Framework, *European University Institute Law Working Paper* No. 2006/17, 3-8.

Rip A (2002), Co-Evolution of Science, Technology and Society, An Expert Review for the Bundesministerium Bildung und Forschung's Förderinitiative Politik, Wissenschaft und Gesellschaft (*Science Policy Studies*), 41-50.

## Notes

<sup>i</sup> See for instance the DEFRA (Department for Environment, food and Rural Affairs) study, "A regulatory gaps study for the products and applications of nanotechnologies - CB01075", April 2006. Also see European Commission, "Nanosciences and Nanotechnologies: An action plan for Europe 2005-2009: First Implementation Report 2005-2007", 8, 2007.

<sup>ii</sup> See, Project on Emerging Nanotechnologies, Nanotechnology Consumer Products Inventory <http://www.nanotechproject.org/inventories/consumer/> accessed on 5 May 2009.

<sup>iii</sup> See Chemistry World, 'Nano Review to assess policy progress' 12 July 2006.

<sup>iv</sup> By this we differentiate between a mandate which is from an external source – e.g. UNFCC calling upon the ICAO to consider GHG emissions from climate change as a topic for further policymaking – and that which is internally driven – e.g. members of IFCS voting for inclusion of nanotechnology and manufactured nanomaterials as an agenda item.

<sup>v</sup> <http://www.who.int/ifcs/en/> Accessed on 12 March 2009.

<sup>vi</sup> See <http://business.timesonline.co.uk/tol/business/economics/article1800929.ece> Accessed on 7 March 2009.

<sup>vii</sup> [http://www.irgc.org/IMG/pdf/IRGC\\_SumInfo\\_24\\_Sept\\_08.pdf](http://www.irgc.org/IMG/pdf/IRGC_SumInfo_24_Sept_08.pdf) Accessed on 10 March 2009.

<sup>viii</sup> IFCS/FORUM-VI/07W

<sup>ix</sup> SAICM/ICMM.2/CRP.33

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<sup>x</sup> <http://www.standardsinfo.net/info/livelink/fetch/2000/148478/7746082/index.html> accessed on 15 April 2009.

<sup>xi</sup> See for instance, Opinion 21 on the Ethical Aspects of Nanomedicines, formulated by the European Group on Ethics in Science and New Technologies to the European Commission

<sup>xii</sup> COM(2008)366, SEC(2008) 2036.

<sup>xiii</sup> COM(2007) 505 final.

<sup>xiv</sup> 2832nd COMPETITIVENESS (Internal market, Industry and Research) Council meeting Brussels, 22 and 23 November 2007.

<sup>xv</sup> See Summary of the Sixth Session of the Intergovernmental forum on Chemical Safety: 15-19 September 2008, Earth Negotiations Bulletin, IISD, September 2008.

<sup>xvi</sup> SAICM/ICMM.2/CRP.25/Add.4

<sup>xvii</sup> See for instance, Ortwin Renn, presentation on “Nanotechnology: Risk Governance”, Second Annual Nanotechnology Dialogue, October 2 2008, Brussels.