Transnational Arrangements in the Governance of Emerging Technologies: The Case of Nanotechnologies

Evisa Kica and Ramses A. Wessel

To be published in: in E. Stokes, D. Bowman and A. Rip (Eds.), *Embedding and Governing New Technologies: A Regulatory, Ethical & Societal Perspective*, Singapore: Pan Stanford Publishing, 2014

1. Introduction

Nanotechnologies, the science of controlling the structure of matter at the nanoscale, are expected to provide the platform and tools for innovative products and applications for consumers while adding value to solutions designed to address a myriad of human and environmental challenges. This has triggered agents within government and industry to invest heavily in nanotechnology research and development programs (EC, 2006; Hullman, 2006). The results of this investment are steadily coming to fruition, as evidenced by the increasing number of self-reported products incorporating nanomaterials making their way into commerce (Woodrow Wilson International Center for Scholar's Project on Emerging Technologies (PEN), 2013).

In 2006 PEN inventory[1] contained 212 products for purchase. This number increased to 580 in 2007. In 2011 it was 1317 products, and in 2013 the number was 1628 (PEN, 2013; Hansen et al., 2013; Bergeson, 2013). The majority of these products are health and fitness related products including sporting equipments, cosmetics and sunscreens (PEN, 2011; Hansen et al., 2013).

In February 2014 the US National Science Foundation (NSF) identified that the global revenue from nano-enabled products in 2013 was more than US$1 trillion. In a similar vein, Lux Research indicated that the revenue from nano-enabled products has continued to grow during the period of 2010-2012; their estimates suggest an increase from US$339 billion to US$371 billion. By 2018 the value of nano-enabled products is predicted to be US$4.4 trillion, driven by the expected commercialization success in the healthcare

[1] An online inventory of nanotechnology consumer based products. The inventory is *available at*: http://www.nanotechproject.org/cpi/about/ (accessed 2 -10- 2014).

and electronics sectors (NSF, 2014; Lux Research, 2014; Ruggie, 2014). Whether this will be the case it remains to be seen. However, earlier studies make important points indicating that estimations about the value of products incorporating nanotechnologies can also be "over-hyped" by news media or ambiguous due to uncertainties related to the size of the "nanotechnology value chain" and the "(sub)areas of nanotechnology that the market evaluation includes" (e.g. Seear et al., 2009: 54; Ebeling, 2008).

Concomitant to these debates have been concerns over the unintended consequences of some manufactured nanomaterials (MNs). These debates have focused on the environmental, health & safety (EHS) risks that some MNs may pose to workers handling nanomaterials, to consumers of nanobased products, and to the public and the environment at large (Maynard et al., 2011a; Medina et al., 2011; Nel et al., 2006; RCEP, 2008). Maynard and his colleagues (Maynard et al., 2011) have already indicated that some engineered nanoparticles (ENPs) such as carbon nanotubes and other bio persistent-insoluble nanoparticles such as titanium dioxide may under certain conditions present toxicological hazard to humans and the environment. One of the main issues is that the unique characteristics of nanomaterials followed by rapid advancement and commercialization of nanoscience, have challenged the application of risk and toxicological assessment methodologies, and regulatory oversight strategies outlined in current environmental, health and safety regulations (Brown, 2007; Davies, 2006).

Scientific reviews, such as those carried out by the *United Kingdom's Royal Society and Royal Academy of Engineering* in 2004 (RS-RAE, 2004), the *United Kingdom's Royal Commission on Environmental Protection* in 2008 (RCEP, 2009) and the *Center for International Environmental Law* in 2012 (Azoulay, 2012), emphasize that there are scientific and knowledge gaps on the hazardous components, the specific properties of the components, the behavior of nanomaterials in the environment and/or living organisms, as well as the duration of the anticipated levels of exposure (Hodge et al., 2010: 14). Groups such as the Scientific Committee on Emerging and Newly Identified Health Risks (SCENIHR) in the EU, have also reported that "the adverse effects of nanoparticles cannot be predicted (or derived) from the known toxicity of material of macroscopic size, which obey the laws of classical physics" (SCENIHR, 2006: 6). The main uncertainties in this regard relate to determining which physico-chemical properties impact the toxicokinetics and the environmental distribution of nanomaterials (SCHENIHR, 2006). As such, formulating even small components of hard regulatory frameworks for nanotechnology remains difficult.

In relation to new industrial nanomaterials, several tentative responses have been observed in jurisdictions such as France (FMD, 2012), Australia (Australian Government, 2010) and California (William et al., 2011), which have moved to set specific requirements for some materials. The European Parliament and Council have adopted more wholesale approaches with the introduction of nano-specific provisions for cosmetics as part of the recast of the Cosmetic Regulation (Bowman et al., 2010; Bowman, 2014). The vast majority of countries, on the other hand, have opted to retain the regulatory status quo (Stokes and Bowman, 2012). For example, countries such as China, the US, the EU, but also the Organization for Economic Co-operation and Development (OECD), have proposed to treat nanomaterials within the existing regulatory frameworks covering their conventional chemical counterparts (OECD, 2013; Hansen et al., 2013). This is not surprising given the evolving state of the scientific art and the uncertainties that surround so many facets of the technology.

Scientific reports authored by Davies and Azoulay have added to the broader policy and regulatory debate (Azoulay, 2012; Davies, 2006). These authors argue that the application of risk and toxicological assessment methodologies and regulatory oversight strategies outlined in current environmental, health, and safety regulations are inappropriate and too inflexible to cope with the rapid advancements and the potential risks of nanoscience. At the other hand of the spectrum, other reports such as those issued by the OECD (OECD, 2013), emphasize that existing approaches for the testing and assessment of traditional chemicals are in general adequate to deal with nanotechnology and only in some cases they may have to be adapted to the specificities of nanomaterials. Accordingly, the debate on how to embrace nanotechnology developments continues among policy makers, while the public and private sectors have voiced fears of the potential for under - and over - regulation.[2]

Whereas consensus amongst regulators and policy makers on the most appropriate regulatory response remains elusive, a number of stakeholders coming from the industry, non-governmental bodies and other public/private sectors, have joint forces to address and respond to the regulatory challenges of nanotechnology. These actors have focused on the development and implementation of voluntary governance arrangements and innovative measurement techniques.

[2] Both US and European Union key bodies including, for example, the US Executive Office of the President and the European Commission claim that the existing regulations covering chemicals and materials, as well as environmental and health issues are adequate to deal with nanotechnologies.

These arrangements are voluntary, non-binding and utilize the expertise of a wide range of governmental, industrial and civil society actors. The involvement of multiple actors, knowledgeable experts and epistemic communities in one regulatory setting are considered the key elements that shape the governing authority of these arrangements (Abbott et al., 2009; Börzel and Risse, 2005; Black, 2008; Quack, 2010). Furthermore, many scholars argue that these arrangements provide for voluntary rules or guidelines that are continuously revised to provide the most up-to-date information on technology developments and cope with situations of regulatory uncertainty (Abbott and Snidal, 2009; Abbott et al., 2012; Dorbeck-Jung and Amerom, 2008; EC, 2008; Forsberg, 2010). As such they are expected to be able to respond quickly to the speed, complexity and uncertainty of nanotechnology's development.

The landscape of these arrangements is very broad. For instance, at national level we can observe governmental and non-governmental (e.g. NGOs) actors such as the Department for Environment, Food and Rural Affairs (DEFRA) in UK, the US Environmental Protection Agency (EPA), as well as Friends of the Earth (FoE) in Australia. Amongst the main objectives of these arrangements have been to develop "voluntary reporting schemes" or "stewardship programs" to gather scientific data (from the manufacturers and importers of manufactured nanoscale materials) on the characteristics, toxicity and eco(toxity) of MNs, and assist regulators with developing appropriate risk management frameworks for nanoscale materials (Bowman and Hodge, 2009).

Voluntary initiatives have also been initiated by private actors, such as for example the *Responsible NanoCode* in UK (developed by four partners - the Royal Society, Insight Investment, the Nanotechnology Industries Association and the Nanotechnology Knowledge Transfer Network); BASF in Germany (which developed the *Code of Conduct for Nanotechnology*); DuPont - Environmental Defense in the US (which developed the *NanoRisk Framework*). The main objectives of these developments have been (amongst others) to develop "in-house" innovative regulatory mechanisms that govern the manufacture of nanoproducts, manage occupational, health and safety risks associated with the development of nanotechnology across all lifecycle phases, and ensure the responsible development, production, use and disposal of nanoscale materials (e.g. BASF *NanoCode*; DuPont *NanoRisk Framework*).

There have been several initiatives taken at the European level as well. For instance, the European Commission (EC) voluntary *Code of Conduct for Responsible Nanoscience and Nanotechnologies Research* - invites Member States to foster their collaboration with industry, research organizations and civil society, and provide a "tangible

contribution to the good governance of nanotechnology" (EC, 2007: 2). In 2005 the European Committee for Standardization (CEN) set up a Technical Committee on Nanotechnologies (i.e. TC 352) to develop consensus standards related to broader issues of nanotechnologies, such as terminology and nomenclature, metrology and instrumentation, specifications for reference materials, test methodologies, as well as science-based health, safety and environmental practices (British Standards Institution (BSI), 2007).

However, some commentators have been highly critical with the operation of some of these arrangements (e.g. the DEFRA and EPA voluntary reporting schemes), noting that even though they are voluntary in nature they have failed to make a positive impact in practice, resulting in a low number of submission (or the lack of buy-in) from relevant organizations and stakeholders (Bowman and Hodge, 2007; Dorbeck-Jung and Amerom, 2008; EPA, 2007; Hansen et at. 2013). Other arrangements (e.g. the EC Code of Conduct) have also been criticized by some scholars for failing to promote trust-building amongst key stakeholders, disseminate their activities effectively and raise awareness about the potential benefits of implementing these arrangements (Dorbeck-Jung and Shelley-Egan, 2013; Mantovani et al., 2009). Furthermore, the global significance of issues accompanying nanotechnologies (e.g. scientific, regulatory and socio-environmental), the evolvement of the new generations of nanomaterials, the rapid pace of the commercialization of nano-enabled products, as well as the potential of MNs to cross national boundaries are amongst the key factors which pose further challenges for these arrangements to deal with nanotechnologies (Abbott et al., 2010; Falkner and Jaspers, 2012).

Since the mid-2000 a wide range of transnational governance arrangements (TGAs) have emerged in the field of nanotechnology. By the term "transnational" we refer to "non-territorial policy making or interactions that cross national-borders at levels other than sovereign to sovereign"(Hallström and Boström, 2010: 2; Hale and Held, 2011: 4). We use the term transnational governance arrangement to refer to a set of rules/mechanisms within an institutional setting that influence the interaction between various actors (state and non-state actors not bounded by territorial borders), to provide for voluntary rules or guidelines grounded in practical experience and expertise.

For instance, the two most important TGAs in the field of nanotechnologies are the OECD and the International Standardisation Organization (ISO) (Breggin et al., 2009). In addition, there are other public-private and private governance arrangements in which nanotechnologies are discussed. These arrangements are mostly focused on a specific sector (e.g. nanomaterial safety) and

have led to a range specific projects, workshops or dialogues. For instance, the International Council on Nanotechnology (ICON); the International Risk Governance Council (IRGC); and the International Cooperation on Cosmetic Regulations (ICCR). Intergovernmental initiatives that seek to contribute to nanotechnology related safety issues and foster the cooperation of scientists, policy-makers and industrial actors, are based on the United Nations (UN) and the World Health Organization (WTO) processes. For instance, the United Nations Industrial Development Organization's International Centre for Science and High Technology (UNIDO) and the WHO's intergovernmental forum on Chemical Safety (IFCS) (Breggin et al., 2009; Falkner and Jaspers, 2012).

In many of these arrangements states have become only one type of participating actor amongst others in the decision-making process (Djelic and Andersson, 2006). As such, they depart from traditional forms of regulation that are based on the exclusive authority of the nation state to make collectively binding decisions. They are based on different governance actors, networking strategies, processes and structures (Handl, 2012). While these arrangements have received significant attention in political science, international relation (IR) theory and (international) law (Koppell, 2010; Pauwelyn, 2012; Slaughter, 2004), the analytical questions provided by these studies are not fully complete. Current discussions focus mostly on explaining the differences between transnational arrangements and traditional state-based forms of regulation. However, they focus less on explaining the key factors that drive the emergence of these arrangements.[3] In these studies it is still unclear why certain arrangements have gained a leading role at transnational level or which arrangements are likely to have the highest potential to contribute to the governance of nanotechnology.[4] What are their key attributes and power sources? This chapter purports to further answer these questions.

---

[3] Exceptions are the studies of: Abbott, W. K., Marchant, E.G. and Sylvester, J.D. (2006). A Framework Convention For Nanotechnology?" *Environmental Law Review.* 36, pp. 10931-42 ; Abbott, W. K. and Snidal, D. (2009). Strengthening International Regulation Through Transnational New Governance: Overcoming The Orchestration Defici*t, Vanderbilt Journal Of Transnational Law*, 42, pp. 501, 506–07; Abbott, W.K., Sylvester, J.D. and Marchant, E.G. (2010). *Transnational Regulation Of Nanotechnology: Reality or Romanticism?*, eds Hodge, A.G., Bowman, M.D. and Maynard, D. A., "International Handbook On Regulating Nanotechnologies", (Edward Elgar, UK, USA), pp. 525-545.

[4] Yet, in legal science a debate was started on the reasons explaining a shift from formal legal agreements to informal arrangements, including transnational actors. It has been argued that this can partly be explained by: (a) saturation with the existing treaties and changed policy preferences of States; (b) deep societal changes that are not unique to international law but affect both international *and* national legal systems, in particular: the transition towards an increasingly diverse network society; and (c) an increasingly complex knowledge society. See: Pauwelyn, J., Wessel, R.A. and Wouters, J. (2014). When Structures Become Shackles: Stagnation and Dynamics in International Lawmaking, *European Journal of International Law*, pp.11-34.

Building upon the regulatory challenges of nanotechnologies, this chapter analyzes the attributes and the potential of the key transnational nanotechnology governance arrangements, which provide forums of debate at transnational level and contribute to establishing informal coordination mechanisms. In particular, our focus is on: ISO Technical Committee on Nanotechnology (ISO/TC 229); OECD Working Party on Manufactured Nanomaterials (OECD/WPMN); IFCS; IRGC and ICON

There are several reasons that justify our decision to focus on these arrangements. To begin with, these arrangements have displayed well-defined strategies and plans to develop voluntary mechanisms that are relevant to the governance of nanotechnology. In addition, there has been no formal delegation or legal mandate for these arrangements to contribute to the field of nanotechnology or set norms which can serve as reference points. However, all of them have managed to establish internal mandates by securing resources and collaboration with influential stakeholders and experts in the field. As a result, the potential of these arrangements to the regulatory governance of nanotechnologies has been acknowledged in various reports (e.g. Breggin et al., 2009; Davies, 2006; Mantovani et al., 2009 & 2010; Hansen et al., 2013; Renn and Rocco, 2006), policy documents (e.g. EC, 2007a; EC, 2008a; EC, 2008b; EC, 2011) and scholarly debates (e.g. Abbott and Snidal, 2009; Abbott et al., 2010; Bowman and Hodge, 2009; Bowman, 2014; Blind and Gauch, 2009; Falkner and Jaspers, 2012; Miles, 2007).

This chapter is organized as follows. In the first section, we discuss the factors that have contributed to the emergence of TGAs and emphasize why these modes of governance are considered appropriate to respond to the nanotechnology regulatory challenges. In the second section, we introduce a typology that distinguishes governance arrangements on the basis of actors involved, as well as the functions and the regulatory stages in which the arrangements contribute. We emphasize that TGAs can be characterized not only by these attributes, but also by their degree of institutionalization[5] as well as the normative and substantive depth of transnational outcomes. In the third section, we assess the characteristics and the potential of the five aforementioned nanotechnology TGAs. With these cases we demonstrate that the typology developed in this chapter is useful to study the evolution of transnational governance in the field of nanotechnologies. Specifically, it allows us to understand and investigate the actions taken by various

[5] For more information on the institutionalization of regulatory networks see also: Berman, A. and Wessel, R.A. (2012). *The International Legal Status of Informal International Law-making Bodies: Consequences for Accountability*, eds. Pauwelyn, J., Wessel, R.A. and Wouters, J., *"Informal International Lawmaking"*, (Oxford University Press, Oxford), pp. 35-62.

arrangements to enhance their capacity to contribute effectively to the governance of nanotechnologies. The last section provides analysis and concluding remarks.

Section 2. The Transnationalisation of Nanotechnology Governance

The proliferation of TGAs in the field of nanotechnologies can be related to several political, regulatory and technological factors. First, over the last few decades nanotechnologies have emerged as a new transformative force in industrial society, covering a broad range of applications in chemicals, pharmaceuticals, electronics, energy, goods and cosmetics (Breggin et al., 2009). Therefore, these emerging technologies have attracted the attention of a wide range of actors coming from regulatory, civil society and business organizations whose activities span beyond national borders (Abbott et al., 2010; Mantovani et al., 2010). Nanotechnologies have also attracted a diverse range of skilled scientists,[6] who contribute to the creation of new products/services and advice for any innovation in this field. As a result, nanotechnology governance has become highly exposed to the direct influence of non-state actors (Abbot et al., 2012; Breggin et al., 2009).

Second, the research, manufacturing, use and commerce of nanotechnologies are all global in nature (Abbot et al., 2010; Abbot et al., 2010; Marchant et al., 2012). The experience with other technology developments on genetically modified organisms (GMOs) and regulatory issues associated with asbestos, have led to many debates on how to develop appropriate and congruent governance frameworks for nanotechnologies (Bonny, 2003; Forsberg, 2012; Vogel, 2006). Furthermore, the case of GMOs emphasize clearly the challenges and issues that may arise when products that may be traded internationally face a patchwork set of national rules and regulations (Marchant et al., 2012).[7] Abbott and other colleagues (2010) argue that a transnational approach to nanotechnology regulation can contribute to providing better opportunities for dialogue and learning by which harmonized regulatory requirements could be established for product testing, risk assessment, reporting

[6] Most of these scientists have expertise in physics, chemistry, biology, information technology, toxicology, engineering and materials science.

[7] The various regulatory frameworks and standards used at the EU and US has created a wide range of problems, including restrictions on trade in products that were approved in some countries and not in others, as well as many conflicts with regards to the technical issues on the labelling of products containing GMO components (see: Marchant, E.G., Abbot, W.K., Sylvester, J.D and Gulley, M.L., 2012. Transnational New Governance and International Coordination of Nanotechnology Oversight, in Dana, A.D. (Eds), *The Nanotechnology Challenge: Creating Legal Institutions for Uncertain Risks*, Cambridge University Press : NY (pp.179-203)).

and labeling. Harmonized requirements would in turn assist producers, manufacturers and distributors to benefit throughout the product life-cycle, and regulators to avoid regulation that is "ill-informed or too stringent" (Abbott et al., 2010: 541). In addition, it will assist multinational companies at the supply, manufacturing, consumer and disposal stage to deal with environmental, occupational health and safety issues. A transnational approach to these issues can lead to uniform compliance requirements, product stewardship, worker training, occupational safety and reporting programs (Abbott et al., 2010; Bonny, 2003; Breggin et al., 2009; Falkner and Jaspers, 2012). Furthermore, the global reach of nanotechnology research and trade provide additional incentives for developing regulatory frameworks at transnational level, which are expected to facilitate commerce, underpin good industrial practice and avoid regional divide (Abbott and Snidal, 2009; Abbott et al., 2010; Falkner and Jaspers, 2012).

Third, whereas nanotechnologies are surrounded by great expectations, scientific evidence indicates that the ongoing expansion of nanotechnologies may lead to the production of novel nanostructures that cause unknown forms of hazard (Breggin et al. 2009). As emphasized in the previous section regulators are facing many challenges and uncertainties about the adequacy of the existing risk assessment and management frameworks to define, characterize and assess the (potential) risks associated with nanotechnologies. The rapid pace of commercialization followed by the evolvement of new generations of nanomaterials pose additional challenges to the current regulatory frameworks to deal with emerging technologies (EPA, 2007). Regulatory systems are expected to face several challenges, which relate mainly to their ability to:

- deal with novel materials and uncertain risks;
- anticipate and respond rapidly to the new and changing technological systems;
- develop frameworks that offer sufficient flexibility and adaptability;
- expand the scientific capacity to include a diversity of mixed experts from public and private sectors; and
- develop globally oriented information-gathering systems to cope with the globalization of nanotechnology (Davies, 2006).

Given the fundamental nature of these challenges and the inability of the individual states to tackle these issues effectively, many scholars urge for transnational coordination and cooperation (Abbott et al., 2010; Breggin et al., 2009; Cadman, 2011; Falkner and Jaspers, 2012; Forsberg, 2010).

Finally, over the last two decades, nanotechnologies have exploded from a purely technical field, into an arena that has to cope with constitutionally recognized interests also. The development of nanotechnologies involves issues related to health, environment, occupational safety, employment, scientific research, technological development, national security and so on (Dorbeck-Jung and Amerom, 2008). The potential of nanotechnologies to manipulate properties at the nano scale (i.e. making materials stronger, thinner, more elastic and so forth) has made these technologies to impact almost every industrial sector (Forsberg, 2012). However, the growing production and use of nanomaterials (in particular MNs) may increase the potential of exposure for workers, consumers and environment (NRC, 2012). This has triggered representatives of various civil society and labor coalitions to become highly interested on the benefits and risks of nanomaterials, as well as on the regulatory responses addressing these issues (ETC, 2007; Mantovani et al., 2010). As a result, nanotechnologies have experienced an evolving political landscape, with many countries, national regulators, socio-environmental actors and international organizations, participating in voluntary (and often privately led) initiatives to promote the regulatory coordination of nanotechnologies (Abbott and Snidal, 2009; Abbot and Snidal, 2009a; Abbott et al., 2010; Kica and Bowman, 2012). These developments, we would argue, provide additional incentives for the emergence of TGAs. In the following section we provide a typology for understanding the characteristics and the potential of various governance arrangements at the transnational level.

Section 3. Transnational Governance Arrangements Generally and Their Attributes

TGAs come in different forms at transnational level. Whereas there is no single characteristic that would distinguish TGAs from the traditional modes of governance, Pauwelyn (2012) indicates that new governance arrangements are characterized by:

1) *process informality* - (these arrangements build on the cross-border cooperation between public and private actors in a forum other than a traditional international organization);
2) *actor informality* - (these arrangements build upon the cooperation of actors other than traditional diplomatic actors (e.g. regulators or agencies))[8]; and

[8] In is interesting to note that in these arrangements the governance contributions are not explicitly restricted to those actors whose organizational objective lies in the provision of certain

3) *output informality* - (these arrangements do not result in a formal treaty or legally enforceable commitment).

These characteristics come close to the characteristics of the transnational new forms of governance that Abbott and Snidal have discussed (2009). In their framing new forms of governance are fundamentally distinguished from old governance models by:

1) *differing roles of the state in regulation* - (in new governance the state is a significant player, it acts as a facilitator for supporting voluntary and cooperative programs, rather than as a top-down commander);
2) *decentralization of the regulatory authority* - (in new governance regulatory responsibilities are shared among different actors coming from the state agencies and private sectors);
3) *dispersed expertise* - (new governance seeks to harness the expertise of a wide range of actors, it looks beyond professional regulators and also seeks to incorporate those who may have 'local' expertise on relevant issues); and
4) *non-mandatory rules* - (new governance relies on flexible norms and voluntary rules).

In a similar vein, Börzel and Risse (2005) argue that the more we enter the realm of new modes of governance, the more we decentralize the regulatory authority, include non-hierarchical forms of steering and share the regulatory responsibilities between public and private actors.[9] As a result, various forms of governance arrangements have emerged at transnational level encompassing different actors, modes of steering, processes and outcomes (Handl, 2012). Therefore, a typology of TGAs is important to understand their key features and their role to respond to regulatory issues (Andonova et al., 2009; Börzel and Risse, 2005).

Scholars have proposed various typologies painting the key features of TGAs. To begin with, Andonova and colleagues (2009) propose a typology according to which governance arrangements can be characterized on the basis of actors involved (*types of actors*) and

---

public goals (e.g. regulators, humanitarian or environmental organizations). Rather, the authority of transnational governance arrangements might also emerge from various private actors, such as business associations, industry or multinational companies. See: Knill, Ch. and Lehmkuhl, D., 2002. Private Actors and the State: Internationalization and changing patterns of governance, *Governance* 5, p. 42.

[9] Building upon the constellations of state and non-state actors to induce regulation at transnational level, Börzel and Risse (2005) distinguish four types of arrangements: *cooptation* (regular consultation and cooptation of private actors in international negotiation systems); *delegation* (delegation of state functions to private actors); *co-regulation* (co-regulation of public and private actors); *self-regulation* (private self-regulation in the shadow of hierarchy).

functions. With regards to the *types of actors*, they argue that TGAs involve a variety of state and non-state actors that contribute different capacities and sources of authority. They distinguish between:

1) *private arrangements* - (established and managed by non-state actors);
2) *public arrangements* - (established by public actors acting independently from the state); and
3) *hybrid arrangements* - (established by public and private actors jointly).

However, the *types of actors* are considered as a necessary, but not a sufficient condition for distinguishing amongst transnational arrangements. The authors argue that these arrangements should be clustered also in terms of the *functions* that they can or do perform. In their framing, *functions* determine the resources and the power used within a particular arrangement to steer members to achieve certain goals (Andonova et al., 2009). In principle, the *functions* of the TGAs are divided into five categories:

1) *information sharing* - (arrangements that influence political and civil discourse through learning forums or collaborative events);
2) *capacity building* - (arrangements that provide resources or institutional support through fundraising campaigns or sponsorship);
3) *coordination* - (arrangements that coordinate state and non-state activities in a particular sector);
4) *rule-setting* - (arrangements that contribute to adopting international norms, regulations or standards that respond to respective regulatory problems); and
5) *implementation* - (arrangements that provide monitoring and service provision to enable action or implementation of national or international policy goals).

A different approach is taken by Abbott and Snidal (2009a), who propose the concept of a governance triangle to depict the involvement of various actors (i.e. states, firms and NGOs) in respective governance arrangements. Similar to the framework employed by Andonova et al. (2009), the typology of Abbott and Snidal focuses on rule-setting. These authors take a wider perspective and divide rule-setting (in the authors' words - the regulatory process of standard setting) into five distinct phases:

1) *agenda-setting* - (ability of the arrangement to place an issue on the regulatory agenda);
2) *negotiations* - (ability of the arrangement to draft and promulgate standards);
3) *implementation* - (ability of the arrangement to contribute to the implementation of the standards);
4) *monitoring* - (ability of the arrangement to monitor compliance); and
5) *enforcement* - (ability of the arrangement to ensure effective compliance).

Their basic premise is that in order for the TGAs to succeed in the regulatory process they need a suite of competences, such as: independence from the targets of regulation, representativeness, expertise of several kinds and concrete operational capacity (including resources) (Abbot and Snidal, 2009a). However, since in the most cases single-actor schemes do not have all the necessary competences, the authors argue that collaboration with different types of actors is essential for these governance schemes to assemble the needed competences and act effectively in the regulatory process. According to their line of argumentation, the potential of TGAs can be understood by looking at the design choice of these arrangements - in particular at the relative input that states, NGOs and firms exercise in a respective arrangement and the actions taken by the TGAs to fulfill any competency deficit. Focusing on the regulatory standard setting schemes of pre – and – post –1985, the authors observe a shift from old to newly emerging multi-actor schemes, characterized by high level of decentralization and dispersed expertise (Abbott and Snidal, 2009a). Whereas these characteristics make these arrangements better suited to address regulatory gaps at transnational level, the authors suggest that some form of "facilitative state orchestration" is important to reduce the bargaining problems between firms and NGOs to achieve socially desirable outcomes (Abbott and Snidal, 2009a: 88).

In addition to the *types of actors* and *functions*, Abbott and his colleagues (2012), Liese and Beishem (2011), Homkes (2011) and Martens (2007) suggest a typology for mapping TGAs based on the *level of institutionalization* and the *design choice*. In the view of Martens (2007) and Homkes (2011) these are the key factors driving the decision-making power of the governance arrangements. Martens (2007) notes that governance arrangements can be classified in *low*, *medium* and *high levels of institutionalization*. Whereas *high levels of institutionalization* refer to permanent multistakeholder institutions that have formal membership, firmly established governing bodies, institutionalized rules of decision-making, a secretariat and budget

authority; *medium levels of institutionalization* refer to institutions that have a clearly defined membership, but not a separate legal status or formalized decision-making structures; and *low levels of institutionalization* refer to ad-hoc initiatives with narrowly defined objectives, no formalized membership or governing body. Scholars of transnational governance have also given increasing credence to the *regulatory design* - referring in particular to the stages of the regulatory process that the arrangement addresses, the relative precision of the rules (they frame this as *normative scope*), as well as the obligatory status of the transantional outcomes (they frame this as *substantive depth*) (Abbott et al., 2012; Liese and Beishem, 2011).

In this way, the typology of TGAs has become a complex and multidimensional phenomenon, which cannot be analyzed through one prism only (Djelic and Andersson, 2006). To assess the potential of these arrangements in a regulatory governance one should understand how various attributes characterizing TGAs interact with each other and contribute to the efficiency of the arrangement (Abbott et al., 2012). Table 1.1 emphasizes the key attributes of the TGAs, which can be used to categorize them into various groups and assess their role in a structured way. In the next Section we apply these attributes to understand the landscape and the potential of current transnational governance arrangements in the regulatory governance of nanotechnologies.

Table 1.1. The Key Attributes of Transnational Governance Arrangements

Actors Involved	**Functions**	**Regulatory Process**	**Normative Scope**	**Substantive Depth**	**Degree of institutionalization**
Public Actors Only (Single Actor Scheme)	Information sharing	Agenda-Setting	Narrow	Significant constraints	Low Level
Private Actors Only (Single Actor Scheme)	Capacity building	Negotiations	Broad	Excessive Flexibility	Medium Level
Public and Private Actors (Multi-Actor Scheme)	Coordination	Implementation			High Level
	Rule Setting	Monitoring			
	Implementation	Enforcement			

Section 4. The Governance Of Nanotechnologies: A Typology Of Transnational Governance Arrangements

Since the mid-2000, various TGAs have emerged to discuss nanotechnology. In the following we focus on five key arrangements and discuss their activities in the field of nanotechnologies:

4.1. ISO Technical Committee on Nanotechnology

In January 2005, the ISO Technical Management Board (TMB) established a new technical committee focused specifically in developing nanotechnology standards (TC 229). A technical committee that "would provide industry, research and regulators with a coherent set of robust and well-founded standards in the area of nanotechnologies […] whilst at the same time providing regulators, and society in general, with suitable and appropriate instruments for the evaluation of risk and the protection of health and the environment" (ISO, 2005).

In the first plenary meeting of the TC 229 the scope of the Committee was articulated as well as the internal structure and the business plan. Kica and Bowman (2012 and 2013), provide a detailed discussion on the internal structure of TC 229. The main work in the TC 229 is done by its Working Groups (WGs) (ISO/IEC, 2011). The Committee allocates specific tasks to the WGs, which tasks are carried out by experts, who are individually appointed by a participating ISO member body, a liaison organisation, or both, to a particular WG when new projects are approved. TC 229 consists of four WGs working on:

a) *Terminology and Nomenclature* (WG1- develops uniform terminology and nomenclature for nanotechnologies to facilitate communication and promote common understanding);
b) *Measurement and Characterization* (WG2 - develops measurement and characterization standards for use by industry in nanotechnology-based products);
c) *Health, Safety and Environment* (WG3 - develops science-based standards that aim to promote occupational safety, consumer protection and environmental protection); and
d) *Measurement and Characterization* (WG4 - develops standards that specify relevant characteristics of engineered nanoscale materials for use in specific applications) (ISO, 2012).

Besides the central Secretariat leading the work of the TC 229, each of the WGs has its secretaries and convenors who arrange the meetings and communicate important information to the participants. The

inclusion of various WG with different aims and objectives, emphasizes that TC 229 has shifted the focus from working only on technical issues related to defining the size and concept of nanomaterials, to addressing broader aspects of the technology such as risk management, health, environment and safety issues (Kica and Bowman, 2013).[10] Following this evolution in the development of standards, in 2009 the former chair of the TC 229 stated that ISO standards now serve three key objectives:

a) supporting commercialization and market development;
b) providing a basis for procurement through technical, quality and environmental management; and
c) supporting appropriate legislation/regulation and voluntary governance structures (Hatto, 2008).

Therefore, TC 229 and its standards seem to have multiple functions. TC 229 provides a forum for debate for various actors. Its "plenary week" meetings organized every tenth month of the year, as well as WG meetings provide the best opportunities for experts to meet with other delegates exchange knowledge and information on standardisation issues, and set appropriate and uniform standards.

Regarding the representation of actors in TC 229, it is important to note that nanotechnology standards are developed by groups of experts under the overarching TC umbrella. ISO applies the principle of national delegation and its administrative work takes place through a Secretariat located in one of the National Standardization Bodies (NSBs). Delegates participate in the ISO/TC meetings in negotiations and consultations that are intended to lead to the development of an international consensus. As indicated in the ISO/IEC Directives, all national bodies have the same rights to participate in the work of the committees and subcommittees (ISO/IEC, 2011). TC 229 has 34 participatory and 13 observatory members.

ISO has established procedures for including industrial actors as well as other actors in the standardization process (Forsberg, 2010). Within ISO the participating actors are divided into: industry and trade associations; consumer associations; governments and regulators; as well as societal and other interests. In that sense, ISO standardization process is considered as a multistakeholder process

[10] In 2011 ISO/TC229 took a leading role to developing a guidance document related to labeling of nanomaterials, which complements the current regulatory initiatives on the labelling of food and cosmetic products containing manufactured nano-objects. An increasing focus on health, safety, and environmental issues appear to have provided TC229 with the impetus to publish ISO/TR12885 on *Nanotechnologies - Health and Safety Practices in Occupational Settings Relevant to Nanotechnologies.*

open to a variety of actors and experts. TC 229 has a number of collaborations and relationships with other organisations and standardization bodies as well (David, 2007). TC 229 is opened to a broader range of stakeholders who are not connected with ISO through national bodies. These stakeholders are known as *liaison* members, and include manufacturer associations, commercial and professional associations, industrial consortia, user groups, as well as groups concerned with the rights of consumers workers and environment, (e.g. the European Consumer Voice in Standardisation (ANEC), the European Environmental Citizens Organisation for Standardisation (ECOS) and the European Trade Union Institute (ETUI)). Furthermore, as part of its outreach strategy TC 229 has established two Task Groups working on Sustainability (TGS)[11], as well as on Consumer and Societal Dimensions of Nanotechnologies (TGCSDN) (ISO, 2012).

Regarding the outcomes, as of start 2013, TC 229 has published three standards, while the majority of deliverables have been normative and informative documents developed in the form of technical specifications (TSs) and technical reports (TRs).[12] As articulated in the TC 229 business plan, the Committee has given priority to developing horizontal standards that "provide foundational support across all sectors that use nanotechnologies or nanomaterials" (ISO, 2012).[13] These deliverables have no strict legal value nor provide for excessive constraints. However, they constitute important statements, provide concrete and practical information and address a broader range of products and activities.

4.2. OECD Working Party on Manufactured Nanomaterials (OECD/WPMN)

OECD/WPMN was established in 2006 to promote "international co-operation in human health and environmental safety related aspects of manufactured nanomaterials (MNs), in order to assist in the development of rigorous safety evaluation of nanomaterials" (OECD, 2012). The WPMN work programme was adopted by the Chemicals Committee in November 2006 and focuses on three key working areas:

a) *Work Area 1* - which aims to develop working definitions for MNs

[11] TGS have the mandate to advise the TC229 on how to include sustainability within its strategic priorities.
[12] Such documents are usually approved while the subject matter is still under development or when there is no immediate agreement to publish an International Standard .
[13] See also Hatto, P . and *MacLachlan, S. (2010).* Standardising nanotechnologies, Available from: http://www.iom3.org/news/standardising-nanotechnologies;

for regulatory purposes within the context of environmental, health and safety (EHS) issues;

b) *Work Area 2* - which aims to encourage cooperation and coordination on risk assessment frameworks; and

c) *Work Area 3* - which aims to foster co-operation and share information on current and planned initiatives in risk assessment, risk management and regulatory frameworks (Visser, 2007).

To fulfill these overarching aims, WPMN has developed eight projects. These projects focus on:

a) the development of an OECD Database on EHS research for approval (*Project 1*);
b) the EHS research strategies on MNs (*Project 2*);
c) the safety testing of a representative set of MNs and test guidelines (*Project 3*);
d) MNs and test guidelines (*Project 4*);
e) co-operation on voluntary schemes and regulatory programmes (*Project 5)*;
f) co-operation on risk assessments (*Project 6*);
g) the role of alternative methods in nanotoxicology (*Project 7*);
h) exposure measurement with an initial focus on occupational settings (*Project 8*) ; and
i) cooperation on the environmentally sustainable use of MNs (*Project 9*).

Each project is carried out by specific steering groups (SGs) (OECD, 2011). These groups are composed of experts nominated by the delegation heads participating in the work of the OECD/WPMN.

WPMN is a subsidiary body established under the Chemicals Committee. This Committee functions under the OECD Environment, Health, and Safety Division and consists of governmental officials from the OECD countries responsible for chemicals management. As such, WPMN encourages the participation of observers and invited experts that participate in the work of the Chemicals Committee. There are 34 OECD member countries that participate in the work of the WPMN. Member countries drive the agenda and the output of the WPMN, while financing a major part of its work and voting on proposals and policy recommendations. These countries are represented at the WPMN

meetings by the delegation heads[14], each of whom is drawn from their national agencies responsible for chemicals regulation and the safety of human health and the environment. Nominated delegates are selected by consensus on the basis of merit, and their roles and duties are set up by the Committee and the WPMN.

Since its establishment in 2006, there have been ten meetings of the OECD/WPMN, which have been supplemented with several workshops, expert meetings and conferences (Kica and Bowman, 2012). In addition to these actors, the OECD has taken several steps to establish close relationships with nonmember countries like Russia, China, Thailand, South Africa, India, the E.U. Commission (EC), U.N. bodies, ISO, WHO and other stakeholder groups such as those represented through the Trade Union Advisory Committee (TUAC) and the Business and Industry Advisory Committee (BIAC). The wide range of actors emphasizes clearly the drive within the OECD to opt for a multistakeholder representation and secure support for its policy recommendations through a broader range of experts. This also allows us to assess the WPMN as a transnational arrangement.

With regards to the outcomes, it is important to note that WPMN does not have regulatory power, but it serves as a center for international collaboration and policy dialogue, building "communities of practice that promote information sharing and harmonization" (Abbott et al., 2012: 291; Falkner and Jaspers, 2012). The key achievements to date are the *Sponsorship Programme*[15], the *OECD Database on Manufactured Nanomaterials to Inform and Analyse EHS Research Activities*, and the *Preliminary Guidance on Sample Preparation and Dosimetry for the Safety of Nanomaterials* (OECD, 2011; OECD, 2011a; OECD, 2012).

[14] These delegates serve as the main contacting point to the Working Party, and provide information on the experts that are nominated by member countries to participate in the work of the SGs (see Kica and Bowman, 2012).

[15] The *Sponsorship Programme,* as one of the key outcomes of the WPMN, gathered a number of countries and the BIAC, who volunteered to sponsor and cosponsor the testing of one or more MNs and provide test data, reference or testing materials to the lead sponsors. In 2011-2012 the results of the *Sponsorship* testing programme were analyzed by the OECD to determine whether its member countries needed to modify the existing test methods or guidelines used for testing traditional chemicals (OECD, 2012). In September 2013, the Council of the OECD issued a recommendation on the *Safety Testing and Assessment of MNs*. The recommendation indicates that member countries apply the "existing international and national chemical regulatory frameworks to manage the risks associated with manufactured nanomaterials" and that only in few cases these "systems may need to be adapted to take into account the specific properties of manufactured nanomaterials" (OECD, 2013).

4.3. International Risk Governance Council (IRGC)

IRGC is an independent foundation that was initially founded by the Swiss government, to help the understanding and management of emerging global risks (Renn and Rocco, 2006). Since the beginning of 2005 the Council has also been working actively on nanotechnology issues. The key objectives of IRGC in relation to nanotechnology are: "to develop and make available specific advice for improving risk governance; to provide a neutral and constructive platform on the most appropriate approaches to handling the risks and opportunities of nanotechnology and to enable all actors to reach a global consensus" (Renn and Rocco, 2006: 6).

The key bodies within the IRGC are the Board Members, Advisory Committee and the Scientific & Technical Council (S&TC). Members of the Board are drawn from governments, industry, science and non-governmental organisations.[16] The Advisory Committee is the key body, which comprises of individual members (17 members) appointed by the Board to act as advisors and make proposals to the S&TC on the possible issues that need to be addressed by the IRGC. These members come from USA, Germany, France, Belgium, Korea, Switzerland, China and Canada. The S&TC is the leading scientific authority of the foundation. It comprises experts form a range of scientific and organisational background, who review the scientific quality of the IRGC work and its deliverables. The participation of these actors at the IRGC is voluntary, but there is less available information on how they are selected and how the decision making process is structured in this arrangement.

The IRGC's nanotechnology programme is a key forum for dialogue and is supported mainly by the Swiss Reinsurance Company, EPA and the US Department of State (IRGC, 2007). To tackle issues of nanotechnology the IRGC, and the S&TC in particular, proposed the establishment of the working group on nanotechnology to provide an independent and cross-disciplinary approach to nanotechnology risks and hazards. The group has focused on two projects: *on the risk governance of nanotechnology* (in 2005) and *on nanotechnology applications in food and cosmetics* (2007). These projects were led by expert bodies consisting of recognized subject experts in the field of nanotechnology and risk governance, who prepared and reviewed the project reports (IRGC, 2007). For instance, the first project was led by Dr. Mihail Roco of the National Science Foundation (NSF) and a team of scientific experts coming from universities, research centers, governmental bodies,

[16] The members of the board come from USA, Portugal, Switzerland and China.

laboratories.

Over a period of two-years, the IRGC undertook two expert workshops (May 2005 and January 2006) (IRGC, 2006; IRGC, 2007). During the second workshop, the IRGC working group also organized four surveys on the implications of nanotechnology with stakeholders coming from research organisations, standardisation organisations, nanotechnology start-ups, NGOs. The aim of the surveys was to identify the organisation interest in nanotechnology research, the governance gaps as well as measures needed to address potential risks. These activities resulted in the publication of the "*White Paper on Nanotechnology Risk Governance*" in 2006 and the "*Policy Brief: Recommendations for a global, coordinated approach to the governance of potential risks*" in 2007 (Breggin et al., 2009; IRGC, 2007).

The *White Paper* and the *Policy Brief* suggest a regulatory framework, which anticipates two frames for four generations of nanotechnology. Frame one includes the first generation of nanostructures (the steady function nanostructures), which have stable behaviour and do not constitute excessive risks. Frame two involves the second generation (active function nanostructures), the third generation (systems of nanosystems) and the fourth generation of nanostructures (heterogeneous molecular nanosystems). In the second frame are involved nanostructures which change their design and it is more difficult to predict their behaviour (IRGC, 2007). It is important to note that these deliberations have been amongst the first publications to provide detailed recommendations for the risk governance of nanotechnology (IRGC, 2007). They recommend national and international decision makers who are involved in the nanotechnology risk issues "to improve knowledge base, strengthen risk management structures and processes, promote stakeholder communication and collaboration, and ensure social benefits and acceptance" (IRGC, 2007: 15). As such, the *White Paper* and the *Policy Brief* have become widely cited reference points in various reports and documents (Breggin et al., 2009; Mantovani et al., 2012; Pelley and Saner).

4.4. International Council on Nanotechnology (ICON):

ICON was created in late 2004 within the program of the federally funded Center for Biological and Environmental Nanotechnology (CBEN) at Rice University. Shortly after its creation, ICON extended its activities beyond CBEN to include other national and international centers. ICON has been actively involved on tackling issues related to nanotechnologies (Pelley and Saner, 2009). Its mission is to "assess, reduce and communicate information regarding the potential environmental and health risks of nanotechnology, while maximizing

its societal values" (ICON, 2009: 3).

The key bodies of ICON are the Director and the Executive Director, who are responsible for managing the internal coordination of the Council and ensuring an effective external presence. The Council is largely funded by industry[17] and it has established an Advisory Board which is composed of prominent nanomaterial safety experts coming from industry, government agencies, academic institutions and nongovernmental groups. Participation in ICON is voluntary and non-compensated, and there are around 27 members participating in the Advisory Board coming from France, Japan, the Netherlands, Switzerland, Taiwan, the United Kingdom and the United States. The Executive Committee, consisting of the Director and Executive Director, has the ultimate authority over ICON's finances, the membership of the Advisory Board and of the setting of new committees (ICON, 2009).

ICON has been working on several projects related to nanotechnology such as the *International Assessment of Research Needs for Nanotechnology Environment, Health and Safety*; *Current Practices for Occupational Handling of Nanomaterials and the Good NanoGuide*. The main objectives of the first two projects have been to: a) facilitate the documentation of current best practices for identifying and managing risks that come during the production, handling, use and disposal of nanomaterials, and b) prioritize research needs related to the classification nanomaterials (ICON, 2009). As such they have resulted in several workshops and conferences. ICON's third project - *the GoodNanoGuide* – is an internet based collaboration platform designed to help experts in the field of nanotechnology to exchange ideas on how best to handle nanomaterials safely (Kulinowski and Matthew, 2009). The key objective of the *GoodNanoGuide* is to establish an open forum that complements other nanotechnology information projects by providing up-to-date information on good practices for handling of nanomaterials in an occupational setting. The *GoodNanoGuide* is freely accessible for everyone, but only experts who are members of the *GoodNanoGuide* are able to post information (Kulinowski and Matthew, 2009). The forum has attracted a wide range of stakeholders to collaborate and contribute at both intellectual and financial levels. However, according to its Director, the main weakness of the *GoodNanoGuide* is its reliance on industry funds only, which "reduces the credibility [of this platform to] stakeholders and challenges [its] sustainability in a down economy" (Abbott et al.,

[17] The key sponsors of ICON's work are: DuPont; Intel; Lockheed Martin; L'Oreal; Mitsubishi Corporation; Procter & Gamble; Swiss Reinsurance Company.

2012: 296). The platform was set in 2008 and in the website it is indicated that the *GoodNanoGuide* is still in a beta version.[18]

4.5. Intergovernmental Forum on Chemical Safety (IFCS)

IFCS was established in 1994 in the International Conference of Chemicals Safety. The main objective in establishing IFCS was to create an "over-arching framework through which national governments, intergovernmental organisations and NGOs could work together and build consensus to promote chemical safety and address the environmentally sound management of chemicals" (IFCS, 1997: 2).

The idea to establish IFCS was created in 1991, during the preparations for the United Nations Conference on Environment and Development (UNED). The Forum is under the administration of WHO, which also provides the secretariat for IFCS. Participation in the IFCS is open to *governmental participants* (which include all member state of the UN and its specialized agencies); *intergovernmental participants* (including participants representing subregional, regional, political and economic groups of countries involved in chemical safety); and *non-governmental participants* (including NGOs concerned with science, health and workers interest). Participation is voluntary and supported by the members. The work of IFCS is organized in sessions at intervals of 2-3 years. To achieve its objectives, IFCS has established the Forum Standing Committee (FCS) to provide advice and assistance during the preparations of Forum meetings, monitor progress on the work of the IFCS and assist with regional efforts. FCS is composed of 25 participants, who serve as representatives of the views of participant countries in respective IFCS regions, NGOs or intergovernmental organisations.

Since its creation IFCS has held six meetings/sessions. In its sixth session in 2008, IFCS considered for the first time the opportunities and challenges of nanotechnology and MNs. The final outcome of this meeting was the *Dakar Statement on Manufactured Nanomaterials* calling for more international cooperation in information sharing and risk assessment (Breggin et al., 2009). The meeting had around 200 delegates, representing 70 governments, 12 intergovernmental organisations and 39 NGOs. Amongst other issues, two main items were discussed in this session. The primary

[18] This means that this web-based application is running, but it is still not fully ready and is being continuously revised.

issue was whether to distinguish between nanotechnologies and MNs and to integrate them into the IFCS VI agenda.

Whereas most NGOs and developing countries argued for including both the MNs and nanotechnology, European countries supported the inclusion of only MNs in the IFCS agenda. As a result, delegates agreed to include a preambular paragraph in the Dakar statement acknowledging the need to address the safety aspect of nanotechnologies "while limiting the focus of the statement on safety aspects of nanomaterials only" (IFCS, 2008: 5). Amongst other recommendations the Dakar Statement called the governments and the industry to apply the "precautionary principle throughout the lifecycle of manufactured nanomaterials" (IFCS, 2008: 12). The Statement recommended the evaluation of "the feasibility of developing global codes of conduct in a timely manner" and the provision of information "through product labeling, websites, databases […] and cooperative actions between governments and stakeholders" (IFCS, 2008: 6). These recommendations provided an important contribution for advancing the sound management of chemicals globally and were sent to the International Conference on Chemicals Management (ICCM) for consideration and further actions (ENB, 2012; IFCS, 2008). Another key agenda item during the sixth meeting of the IFCS was the future of this Forum. In light of the agreement on the Strategic Approach to International Chemical Management (SAICM) in 2006, the delegates of IFCS agreed to invite the ICCM (during its second session - ICCM2) to integrate the Forum as an advisory body into the ICCM (ENB, 2012). This invitation was crucial for IFCS, since the decision of the ICCM2 to reject the request of the IFCS put into question the existence and the potential of this Forum to contribute to the field of nanotechnologies. This is further elaborated in the next Section.

Section 5.Concluding Remarks

This chapter aimed to assess the potential of different TGAs in the field of nanotechnologies and to explain the key factors that drive the emergence of these arrangements. It highlights the growing importance and relevance of five TGAs, such as: ISO/TC 229, OECD/WPMN, IRGC, ICON and IFCS. Building upon current debates on the modes of governance and transnationalisation, the chapter developed a framework to determine the main attributes of TGAs. This framework proved to be very useful for understanding the potential of different types of governance arrangements to contribute to the field of nanotechnologies. A comparative look at these arrangements suggests the following:

First, in the field of nanotechnologies TGAs have all taken

various initiatives to assemble the needed competencies while combining the expertise and experiences of multiple actors. Yet, the relative input that states, NGOs and firms have in these arrangements differs considerably. We elaborate this further in below. Furthermore, the arrangements differ considerably in terms of their institutional structure, organisational goals and substantive scope, all of which impact their potential to contribute effectively to the governance of nanotechnologies.

Second, all of the arrangements reviewed in this chapter have engaged in agenda setting and related preliminary steps. For instance, ICON and IRGC have focused mainly to internationalize the nanotechnology safety and regulatory debate. They have served as leading fora for gathering information on the risks of nanoscale materials to inform future regulation, and supporting coordination amongst decision makers on handling these issues (Breggin et al., 2009). IFCS was a pioneer in identifying nanotechnology as an important part of the international chemical safety agenda. It aimed at sharing information and promoting coordination on nanotechnology and MNs to increase awareness on the potential benefits, challenges and risks posed by nanotechnologies. In addition to health and safety issues, the leaders of the TC 229 have addressed other issues that are essential to nanotechnology regulation, such as nomenclature, specifications and measurement. The OECD/WPMN has also served as the main forum for gathering and exchanging information on the risk assessment of MNs. Therefore, these arrangements differ in their functions, but also on the normative scope of the issues that they address.

This leads us to our third point. A comparative look at these arrangements suggests that some arrangements seem to be narrower, focusing almost entirely on certain products (i.e. IFCS on safety aspect of MNs), settings (ICON - and *GoodNanoGuide* in particular - on workplace) or activities (IRGC on risk governance) (Abbott et al., 2012). OECD/WPMN concentrates on human health and environmental safety implications (including risk assessment and safety testing) of MNs (OECD, 2011a). TC 229 addresses a broader range of products, setting and activities. With its standards, TC 229 provides terminology and nomenclature, measurement techniques, calibration procedures, reference materials, test methods to detect and identify nanoparticles, occupational health protocols relevant to nanotechnologies as well as risk assessment tools - which aim to support regulation, research, commercialization, and trade of the materials and products at the nanoscale.

A number of these arrangements (such as TC 229, OECD/WPMN) have also adopted norms that call relevant actors to act in accordance to certain standards. In this way, these

arrangements have started to move towards the negotiation stage. TC 229 for instance has been able to negotiate several standards, as well as technical specifications and recommendations (e.g. ISO/TS 27687; ISO/TR 12885). From a governance point of view, these deliberations may provide the "best available options to industries requested to demonstrate product compliance with regulation" (EC, 2008: 17). The *Sponsorship Programme* has also served as an incentive for countries to collaborate, share best practices, and follow a consistent approach with regards to the testing of specific endpoints of representative MNs. The substantive scope of these deliberations differs, with the TC 229 standards and technical specifications providing practical information, and being more concrete and complete (Abbot et al., 2012).

Fourth, a comparative look on these arrangements emphasizes that ISO and OECD seem to have the highest potential to contribute to the governance of nanotechnologies. In our view, there are two key factors that contribute to this. On the one hand, it is the high level of institutional structure that characterizes these governance arrangements. On the other hand, it is the collaboration and the (political) support that these arrangements have ensured with key actors in Europe (EP, 2006; EC, 2008). Regarding the first point, our case studies emphasize that nanotechnology transantional governance arrangements differ considerably in terms of their structure, membership and organisational goals. TC 229 and WPMN are the most organized working groups with secretariats, clear rules of membership, governance structure and decision making procedures (Forsberg, 2010; Kica and Bowman, 2013). Furthermore, they have organized regular meetings for their members to share knowledge and information and developed concrete roadmaps that guide future actions and strategies. Such a well-defined structure has helped these arrangements to contribute substantially to shaping nanotechnology regulatory agenda at transantional level, promote collaboration and harmonization, and establish concrete regulatory governance mechanisms (e.g. standards, guidelines or other regulatory options) for nanotechnologies (Abbott et al., 2012; EC, 2008; Forsberg, 2010; Kica and Bowman, 2013).

ISO is amongst the most recognized international organisations, which has strongest linkages with key experts and dominant industrial actors coming from more than 40 countries around the world. However, to ensure representation of other stakeholders TC 229 has established *liaisons* with other actors representing government, trade unions, consumer associations, NGOs and the EU. In addition to this, the establishment of the Task Groups (i.e. TGS and TGCSDN) appears to have been one approach to opening up the membership of TC 229, and thus making its actions

accountable to a broader range of actors. Since 2005, TC 229 has been able to broaden its activities, membership and the diversity of actors involved in the process (Forsberg 2010 and 2012; Kica and Bowman, 2012). TC 229 plenary meetings involve a wide range of practitioners, industrial hygienists, pharmacologists, toxicologists and ecotoxicologists, chemists and physicists who exchange knowledge and contribute substantially to establishing international standards (Kica and Bowman, 2012).

In a similar vein, OECD/WPMN and its SGs are highly structured. WPMN has strong linkages with national regulatory agencies, which is not surprising given the intergovernmental nature of the OECD. However, the inclusion of high level experts nominated by member countries has helped SGs to proceed faster in developing well-defined strategies for tracking nanotechnology policy developments. OECD has also developed *liaisons* with other industrial actors, trade unions, NGOs as well as European Commission. While serving as a center for policy dialogue between high level governmental officials and nongovernmental experts, there is the potential for the outputs of the OECD/WPMN to lay the groundwork for collective agreements and contribute to overcoming the uncertainties and regulatory puzzles related to nanomaterials and risk assessment practices (Bowman and Gillian, 2007; Kica and Bowman, 2013). This is not without precedent; for example it is widely acknowledged that the OECD Chemicals Committee played a leading role in promoting harmonized chemical control policies through the system of the Mutual Acceptance Data (MAD) (Kica and Bowman, 2013; Visser, 2007).

Regarding the support that these arrangements have ensured with key actors in Europe, perhaps of greatest importance is the support of the EU members and the EU Commission. In 2007, the European Commission Communication on the *Nanosciences and Nanotechnologies: An action plan for Europe 2005-2009*, stated that OECD/WPMN and TC229 are "principal forums for the coordination of activities at the international level" and that "the Commission, the European Bodies and Member States are expected to continue contributing to these international efforts" (EC, 2007: 10). The Council's conclusions on *Nanoscience and Nanotechnologies* also stated that, " the Commission needs to take into account in its policy making all activities within the OECD (e.g. definitions, nomenclature, risk management)" (EP, 2006: 428). Regarding, the role of international standards in the field of nanotechnologies, in 2010 the EU Commission addressed a mandate to the European Standardisation Bodies (ESOs) (i.e. CEN, CENELEC and ETSI) to develop European standards related to the characterization and toxicity testing of the nanomaterials, as well as to the occupational

handling and exposure (EC, 2008b).[19] An important element of the Mandate is that the EC requests the ESOs to develop and adopt European standards in support of the European policies and legislations, while taking into account and giving priority to the existing ISO standards (EC, 2008). Furthermore, the Mandate asks the ESOs to work in close collaboration with ISO and OECD. These statements indicate clearly that the EU not only is aware of the work undertaken by ISO and OECD, but it also suggests that these arrangements and their deliverables are relevant and can contribute to the nanotechnology regulatory debate in the EU.[20]

Other governance arrangements analyzed in this chapter, have also been able to ensure collaboration with influential stakeholders. IFCS for instance managed to provide equal representation to state actors, NGOs and intergovernmental actors. Regarding its structure, IFCS has the most informal structure. IFCS operates under the intergovernmental regime of the WHO, but it considers itself as a "non-institutional arrangement", a forum that builds on the loose grouping of interested parties and experts, who come together to integrate national and international efforts to promote chemical safety (Mercier, 1996: 886). However, even though being one of the key actors to consider issues related to nanotechnologies within the international chemicals agenda, the rejection of the ICMM2 to include IFCS as an advisory body put into question the ability of this forum to contribute effectively to nanotechnology governance (ENB, 2012). Furthermore, in the final resolution on the emerging issues the ICMM2 recognized the potential health and environmental issues related to nanotechnologies and MNs, but no reference was made to the Dakar Statement. In light of these events, in the last session of the Forum (Forum IV) the FCS agreed to suspend its work for the foreseeable future (ENB, 2012).

ICON and IRGC have a moderate level of institutionalization with both having established several workshops and a network of growing stakeholders. Both of these arrangements focus on nanotechnology risk governance, but none of these arrangements aspires to go beyond mere information exchange and international coordination. The IRGC in the initial phases of its work on nanotechnologies developed an ad-hoc working group on

[19] In the mandate the EC stated that nanotechnology standardisation is crucial and is viewed as "a means to accompany the introduction on the market of nanotechnologies and nanomaterials, and a means to facilitate the implementation of regulation".

[20] That this will also have a positive impact on the effectiveness of the norms is concluded in Wessel, R.A. and Wouters, J. (2008), *The Phenomenon of Multilevel Regulation: Interactions between Global, EU and National Regulatory Spheres*, eds Føllesdal, A. Wessel, R.A. and Wouters, J. "Multilevel Regulation and the EU: The Interplay between Global, European and National Normative Processes", Leiden, Boston: Martinus Nijhoff Publishers, pp. 9-47.

nanotechnology to provide an independent and cross-disciplinary approach to nanotechnology risks and hazards. However, this group does not have the same structure with clear rules for membership, formalized decision making structures as well as strategies for future work like TC 229 for instance. Its Advisory Committee is representative of a less number of European countries, but it has the support of EPA. In 2006, IRGC organized a Conference to promote stakeholder dialogue and feedback on the IRGC *White Paper* (ISO, 2007; IRGC, 2008).What we can observe here is the participation of actors from regulatory agencies (e.g. DEFRA) as well as industrial actors (e.g. DuPont). The inclusion of these actors combined with the support that EPA has for IRGC can contribute to increasing the relevance of the Council's recommendations in the field of nanotechnologies. ICON, on the other hand has also a moderate level of institutionalization. Compared to ISO and OECD, its working groups are less structured with few members and less formalized decision making strategies. The Council started initially as an affiliate programme of the CBEN center at Risse University, but it has been able to build a network of growing stakeholders. Council has also been working with EPA to review the best practices for nanomaterial safety (IRGC, 2006). *GoodNanoGuide* is one of the main outcomes of ICON which still continues to be in a beta version (IRGC, 2006). Whereas the relevance of IRGC and ICON has been mentioned in some documents (EC, 2007; EC, 2007a; Mantovani et al., 2010), none of them has been involved formally by the EU institutions. Furthermore, compared to TC 229 and OECD/WPMN, these arrangements have not established any formal collaboration with the EU institutions or Commission.

In conclusion, our analysis on nanotechnology TGAs suggest that IRGC and ICON have the potential to become important actors on the transnational governance of nanotechnology risk regulation. However, the institutional structure, the actors, the normative scope, the political support and the strategies incorporated by TC 229 and OECD/WPMN places these arrangements in a better position to take a lead on the transnational debates of nanotechnology governance. The huge potential of these arrangements, which operate beyond the state level, brings forward many concerns. In these arrangements the rule making authority rests on the hands of those who operate beyond the state level and are "neither elected nor managed by elected officials" (Thatcher, 2011). They build on non-hierarchical steering principles and are characterized by interaction amongst various public and private actors. As such, they have become the "hard case" for legitimacy (Black, 2008), raising therefore many questions over the clear lines of accountability, stakeholder representation, roots of decision-making and reasons for social

acceptability. Such questions are beyond the scope of this chapter, but pose an urgent need for further research.[21]

References

1. Abbott, W. Kenneth and Snidal, Duncan., 2009. Strengthening International Regulation Through Transnational New Governance: Overcoming the Orchestration Deficit, *Vanderbilt Journal of Transnational Law* **42**, pp. 501-578.
2. Abbott, W.K. and Snidal, D. (2009). *The governance triangle: Regulatory standards institutions and the shadow of the state*, eds. Mattli, W and Woods, N, "The Politics of Global Regulation", (Princeton University Press, USA), pp.44-88.
3. Abbott, W.K., Sylvester, J.D. and Marchant, E.G. (2010). *Transnational Regulation of Nanotechnology: Reality or Romanticism?*, in International Handbook on Regulating Nanotechnologies, eds Hodge, A.G., Bowman, M.D. and Maynard, D. A., "International Handbook on Regulating Nanotechnologies", (Edward Elgar, UK &USA), pp. 525-545.
4. Abbott, K., Marchant, G and Corley, E. (2012). Soft Law Oversight Mechanisms for Nanotechnology, *Jurimetrics* **52**, pp. 279-312.
5. Australian Office of Nanotechnology. (2008). *National Nanotechnology Strategy Annual Report 2007–08*, http://www.innovation.gov.au/industry/nanotechnology/NationalEnablingTechnologiesStrategy/Documents/NNSAnnualReport_2007-08.pdf (accessed 10-04-2014).
6. Australian Government. (2010). *Adjustments to NICNAS New Chemicals Processes for Industrial Nanomaterials*, Chemical Gazette No.C.10. (October 5).
7. Andonova, L., Betsill , M. and Bulkeley, H. (2009) .Transnational Climate Governance. *Global Environmental Politics* **9 (2),** pp. 52-73.
8. Azoulay, D. (2012). *Just Out of REACH: How REACH is Failing to Regulate Nanomaterials and How it Can be Fixed*, http://www.ciel.org/Publications/Nano_Reach_Study_Feb2012.pdf (accessed 10-05-2014).

[21] A first start was made by pointing to the 'thick stakeholder consensus' in these types of arrangements, rather than the 'thin state consent' in more traditional intergovernmental forms of cooperation. In fact, it was argued that both new and traditional arrangements can offer legitimate forms of cooperation and that the conventional dividing line between formal and informal legal/regulatory arrangements – with only the former being effective, needing control or deserving legitimacy – no longer holds. See Pauwelyn, J., Wessel, R.A. and J. Wouters. (2014). When Structures Become Shackles: Stagnation and Dynamics in International Lawmaking, *European Journal of International Law*, pp.11-34.

9. Black, J. (2008). Constructing and Contesting Legitimacy and Accountability in Polycentric Regulatory Regimes. *Regulation and Governance* **2**, pp. 137–164.
10. Börzel, T. and Risse, Th. (2005). *Public-Private Partnerships: Effective and Legitimate Tools of International Governance?*, eds Grande, E and Pauly, W.L., "Complex Sovereignty: On the Reconstitution of Political Authority in the 21st Century", (University of Toronto Press, Canada), pp. 195-217.
11. Bonny, S. (2003). Why Are Most Europeans Opposed to GMOs? Factors Explaining Rejection in France and Europe. *Electronic Journal of Biotechnology* **6(1)**, pp. 50 -58.
12. Bowman, M.D. and Gillian, G. (2007). *How Will the Regulation of Nanotechnology Develop? Clues from Other Sectors*, eds Hodge, G et al., "New Global Frontiers In Regulation: The Age Of Nanotechnology", (Edward Elgar Publishing, UK, USA), pp. 353- 385.
13. Bowman, D. M. and Hodge, G.A. (2008). Governing 'Nanotechnology without Government?, *Science and Public Policy* **35 (7)**, pp. 475-487.
14. Bowman, D.M. and Hodge, G. A. (2009). Counting on Codes: An Examination of Transnational Codes as a Regulatory Governance Mechanism for Nanotechnologies. *Regulation & Governance* **3**, pp. 145-164.
15. Bowman, D.M. et al., (2009). Correspondence, Nanomaterials and the Regulation of Cosmetics, 5 *Nature Nanotechnology* **5**, pp. 92.
16. Bowman, D. M. (2014). Two Steps Forward One Step Back: Shaping the Nanotechnologies Landscape Through Regulatory Choice, *in* Hull, M., and Bowman, D. M. (Eds.), *Nanotechnology Environmental Health and Safety: Risk, Regulation, and Management, 2nd Edt.*, Elsevier Inc: UK (pp.315-329).
17. Brown, S. (2007). Nanotechnology Environmental Health and Safety Standards. *The Magazine of the International Organization for Standardization* 4.
18. Breggin, L. et al. (2009). Securing the Promise of Nanotechnologies: Towards Transatlantic Regulatory Cooperation Report. Chatham House, London.
19. Cadman, T. (2012). *Quality and Legitimacy of Global Governance*. (Palgrave Macmillan, USA).
20. Clarence, J. D. (2009).*Oversight of Next Generation Nanotechnology*. PEN 18. Washington, DC: Project on Emerging Nanotechnologies.
21. Davies, C. J. (2006). *Managing the Effects of Nanotechnology*, http://www.nanotechproject.org/file_download/files/PEN2_MngEffects.pdf (accessed 0-02-2014).
22. David, E. S.(2007). Update on ISO nanotechnology Standards Activities. *Clean Rooms* **12**, pp. 12–13.

23. Dörbeck-Jung, B.R. and van Amerom, M. (2008) The hardness of soft law in the United Kingdom: State and non-state regulatory conceptions related to nanotechnological development, eds Schooten, V.H and J. Verschuren, J., "International Governance and Law. State Regulation and Non-state Law," (Cheltenham: Edgar Elgar), pp. 129-147.
24. Dörbeck-Jung, B.R. and Shelley, C. (2013). Meta-regulation and Nanotechnologies: The Challenge of Responsibiltisation within the European Commission's Code of Conduct for Responsible Nanosciences and Nanotechnologies Research, Science and Engineering Ethics. *NanoEthics* **7 (1)**, pp. 55-68.
25. Earth Negotiations Bulletin (ENB). (2012). International Institute for Sustainable Development (IISD), **15 (191),** http://www.iisd.ca/chemical/iccm3/compilatione.pdf (accessed 10-09-2014).
26. Ebeling, M. (2008). Mediating Uncertainty: Communicating the Financial Risks of Nanotechnologies. *Science Communication* **29(3)**, pp. 335-361.
27. European Parliament. (2006). Nanoscience and Nanotechnology. European Parliament Resolution on Nanosciences and Nanotechnologies: An Action Plan for Europe 2005-2009. *Official Journal of the European Union*.
28. European Commission. (2006) . Press Release - Council approves EU research programmes for 2007-2013, 18 December. EC: Brussels.
29. European Commission. (2007). Opinion 21 on the Ethical Aspects of Nanomedicines, formulated by the European Group on Ethics in Science and New Technologies to the European Commission.
30. European Commission. (2007a). Communication From the Commission to the Council, the European Parliament and the European Economic And Social Committee . Nanosciences and Nanotechnologies: An action plan for Europe 2005-2009. First Implementation Report 2005-2007.
31. European Commission. (2008). Communication from the Commission to the Council, the European Parliament and the European Economic and Social Committee. Towards an increased contribution from standardisation to innovation in Europe. Brussels.
32. European Commission. (2008b). Commission Mandate M/409 addressed to CEN, CENELEC and ETSI, Report From CEN/TC 352 Nanotechnologies 17, http://www.bozpinfo.cz/priloha/euroshnet080701_02.pdf (accessed 15-04-2014)
33. ETC Group. (2007). An Open Letter to the International Nanotechnology Community at Large http://www.etcgroup.org/sites/www.etcgroup.org/files/publication/610/01/coalition_letter_april07.pdf (accessed 7-04-2013).

34. Falkner, R. and Jaspers , N. (2012).Regulating Nanotechnologies: Risk, Uncertainty and the Global Governance Gap. *Global Environmental Politics* **12(1)**, pp. 30-55.
35. Forsberg, E.M. (2010). *The Role of ISO in the Governance of Nanotechnology*. Work Research Institute of Norway, pp.1-76.
36. Forsberg, E. M (2012). Standardization in the Field of Nanotechnology: Some Issues of Legitimacy. *Science and Engineering Ethics* **18**, pp. 1-21.
37. French Ministry. (2012). Décret n° 2012-232 du 17 février 2012 Relatif à la Déclaration Annuelle des Substances à L'état Nanoparticulaire Pris en Application de L'article L. 523-4 du code de L'environnement http://www.legifrance.gouv.fr/affichTexte.do?cidTexte=JORFTEXT000025377246&dateTexte=&categorieLien=id (accessed 24-10-2013).
38. Hansen, S.F., Maynard, A., Baun, A., et al. (2013). *Late Lessons from Early Warnings: Science, Precaution and Innovation*, EEA Report, pp.562-591.
39. Hatto, P. (2008). Chairman, ISO TC 229 & BSI NTI/1 Nanotechnologies Standardization Comms., Presentation at The George Washington University Law School Nanogovernance 2008 - *Innovative Approaches to Nanotechnology Environmental Governance: Standardization-In Support of "Nanogovernance* .
40. Hallström. K. T. and Boström, M . (2010). *Transnational Multistakeholder Standardization*. (Edward Elgar, Cheltenham,UK).
41. Hale, Th. and Held, D. (2011). Handbook of Transnational Governance: New Institutions and Innovations. (Polity Press, USA).
42. Handl, G. (2012). *Introduction,* eds Handl, G., Zekoll, J . and Zumbansen. P." Beyond Territoriality: Transnational Legal Authority in an Age of Globalization", Martinus Nijhoff Publishers, pp. 3-13.
43. Homkes, R. (2011). Analysing the role of Public-private partnerships in global governance: Institutional dynamics, variation and effects., PhD Thesis. at p.33.
44. Hullman, A. (2006). *The economic development of nanotechnology – An indicators based analysis.* European Commission Unit: Nano S&T – Convergent Science and Technologies ftp://ftp.cordis.europa.eu/pub/nanotechnology/docs/nanoarticle_hullmann_nov2006.pdf (accessed 12-11-2014)
45. ISO Central Secretariat. (2005). Proposal For A New Field Of Technical Activity. http://www.lawbc.com/other_pdfs/ANSI-NSP%20SC%20049-2005%20BSI%20Proposal.pdf (accessed on 14-10-2013).
46. ISO/IEC, Directives. (2011), Part 1: Procedures For The Technical Work https://www.jisc.go.jp/international/pdf/isoiec_directives_part1_2012.pdf (accessed 12-07-2014).

47. ISO, *ISO TC/229 Business Plan* 8. (2012), http://isotc.iso.org/livelink/livelink/fetch/2000/2122/687806/customview.html?func=ll&objId=687806&objAction=browse&sort=name (accessed 09-07-2014).
48. IRGC. (2006). The Risk Governance of Nanotechnology: Recommendations for Managing a Global Issue 6–7 July 2006. Conference Report. http://irgc.org/wp-content/uploads/2012/04/report85.pdf (accessed 06-11-2013).
49. IRGC. (2006). Survey on Nanotechnology Governance: The Role of NGOs.
50. IRGC. (2007). Policy Brief: Nanotechnology Risk Governance, Recommendations for a Global, Coordinated Approach to the Governance of Potential Risks.
51. International Council on Nanotechnology. (2009). *Governance Structure and Operational Plan*. http://cohesion.rice.edu/centersandinst/icon/emplibrary/ICONmanagementv2009_1_Full_Text.pdf (accessed 10-10-2014).
52. Intergovernmental Forum on Chemical Safety. (1997). President's Progress Report 1994–1997, Forum II Second Session of the Intergovernmental Forum on Chemical Safety., pp. 1-14. http://www.who.int/ifcs/documents/forums/forum2/pres_e.pdf (accessed 07-08-2014).
53. Intergovernmental Forum on Chemical Safety. (2008). Sixth Session of the Intergovernmental Forum on Chemical Safety: Final Report. http://www.who.int/ifcs/documents/forums/forum6/f6_finalreport_en.pdf (accessed 10-06-2014).
54. Kica, E and Bowman, D. M. (2012). Regulation by means of standardization: Key legitimacy issues of health and safety nanotechnology standards, *Jurimetrics: The Journal of Law, Science and Technology* **53**, pp.11-56.
55. Kica, E and D.M Bowman. (2013). Transnational Governance Arrangements: Legitimate Alternatives to Regulating Nanotechnologies?, *NanoEthics*, **7(1).**
56. Koppell, S.G.J. (2010). World Rule, Accountability, legitimacy, and the Design of Global Governance. (University of Chicago Press, Chicago/London).
57. Kulinowski, M. K. and Matthew, J.P. (2009). The GoodNanoGuide: A Novel Approach for Developing Good Practices for Handling Engineered Nanomaterials in an Occupational Setting, *Nanotechnology Law & Business* **6 (37),** pp.37-44.
58. Lux Research. (2014). Nanotechnology Update: Corporations Up Their Spending as Revenues for Nano-enabled Products Increase. State of the Market Report

https://portal.luxresearchinc.com/research/report_excerpt/16215 (accessed 10-07-2014).
59. Liese, A and Beisheim M. (2011). *Transnational Public-Private Partnerships and the Provision of Collective Goods in Developing Countries.*, eds. Risse, Th., "Governance Without a State – Policies and Politics in Areas of Limited Statehood", (Columbia University Press, USA), pp. 115-144.
60. Mantovani, E., et al. (2010). Developments in Nanotechnologies Regulation and Standards. http://www.steptoe.com/assets/htmldocuments/ObservatoryNano_Nanotechnologies_Regulation%20and%20Standards_June%202010.pdf (accessed 13-07-2014).
61. Djelic. M.L and Andersson.K. S. (2006). *Introduction: A World of Governance: The Rise of Transnational Regulation, eds.* Djelic, L.M. and Andersson, S.K. "Transnational Governance: Institutional Dynamics of Regulation", (Cambridge University Press: UK), pp. 1-31.
62. Martens, J. (2007). Multistakeholder Partnerships - Future Models of Multilateralism?., Dialogue on Globalization. Occasional Papers-Berlin, **No.29**, pp. 1-75.
63. Maynard, A., Warheit, B. David B. and Philbert, M. (2011). The new toxicology of sophisticated materials: Nanotoxicology and beyond, *Toxicological Sciences* **120**, pp 1-64.
64. Mercier, J. M. (1995). Chemical Safety: A Global Challenge. *Environmental Health Perspectives* **103(10)**, pp. 886-887.
65. National Research Council. (2012). A research strategy for environmental, health and safety aspects of engineered nanomaterials. Washington, DC: The National Academies Press.
66. OECD. (2011). *Safety of Manufactured Nanomaterials*, Environmental Health and Safety News, http://www.oecd.org/env/chemicalsafetyandbiosafety/47794529.pdf (accessed 12-09-2014).
67. OECD. (2011a). Nanosafety at the OECD: The First Five Years 2006-2010. http://www.oecd.org/env/ehs/nanosafety/47104296.pdf
68. OECD. (2012). *Six years of OECD Work on the Safety of Manufactured Nanomaterials: Achievements and Future Opportunities*. http://www.oecd.org/chemicalsafety/nanosafety/Nano%20Brochure%20Sept%202012%20for%20Website%20%20(2).pdf (accessed 10-05-2013).
69. OECD. (2013). *Recommendation of the Council on the Safety Testing and Assessment of Manufactured Nanomaterials* . http://acts.oecd.org/Instruments/ShowInstrumentView.aspx?InstrumentID=298&InstrumentPID=314&Lang=en&Book=False (accessed 12-09-2014)

70. Pauwelyn, J. (2012). *Informal international lawmaking: Framing the concept and research questions*, eds. Pauwelyn, J., Wessel, R.A. and Wouters, J., "Informal International Lawmaking", (Oxford University Press, Oxford), pp. 13-34.
71. Project on Emerging Nanotechnologies (PEN)., 2013. Consumer Products Inventory, http://www.nanotechproject.org/cpi (accessed 10-07-2014).
72. Pelley, J. and Saner, M. (2009). *International Approaches to the Regulatory Governance of Nanotechnology*. Carleton University: School of Public Policy and Administration. http://www.nanowerk.com/nanotechnology/reports/reportpdf/report127.pdf (accessed 10-05-2014).
73. Quack, S., 2010. Law, Expertise and Legitimacy in Transnational Economic Governance: An Introduction. *Socio Economic Review* **8(3)**, pp. 5–7.
74. Renn, O. and Roco, M. (2006). *White Paper on Nanotechnology Risk Governance*. International Risk Governance Council, Geneva.
75. Risse, Th. (2006). *Global Governance and Communicative Action*, eds. Held, D and Koenig- Archibugi, M., "Global Governance and Public Accountability", (Wiley Publishing, USA), pp. 167.
76. Roco, C.M., Mirkin, C.A. and Hersam, C.M. (2010). *Nanotechnology research directions for societal needs in 2020: Retrospective and Outlook*. National Science Foundation/World Technology Evaluation Center Report.
77. Royal Commission On Environmental Pollution. (2008). *Twenty-Seventh Report: Novel Materials in the Environment: The Case of Nanotechnology*. http://www.official-documents.gov.uk/document/cm74/7468/7468.pdf (accessed 10-07-2014).
78. Ruggie. H. G. (2014). Global Governance and New Governance Theory: Lessons from Business and Human Rights. *Global Governance: A Review of Multilateralism and International Organizations* **20(1)**, pp. 5-17.
79. Ryan, B. et al. (2011). Towards Safe and Sustainable Nanomaterials: Chemical Information Call-In to Manufacturers of Nanomaterials by California as a Case Study, *European Journal of Law and Technology* **2(3)**, pp. 1-11.
80. Seear, K., Petersen, A. and Bowman, D. (2009). *The social and economic impacts of nanotechnologies: A literature review*. Monash University Victoria, Australia.
81. Smith, P. (2008). Can't afford to waste a nano in this industry. *Australian Financial Review* **26**, pp. 32
82. Slaughter, M.A. (2004). *A New World Order*. (Princeton University Press, Princeton).
83. Thatcher, M.S. (2011). Delegation to non-majoritarian institutions. *West European Politics*, pp. 1–22.

84. United States Environmental Agency. (2007). *Nanotechnology White Paper. EPA* 100/B-07/001.
85. US National Science Foundation (NSF). (2014). Market Report on Emerging Nanotechnology Now http://www.nsf.gov/news/news_summ.jsp?cntn_id=130586&org=NSF&from=news (accessed 10-07-2013).
86. Visser, R. (2007). *A Sustainable Development for Nanotechnologies: An OECD Perspective, eds. Hodge, G et al.,"*New Global Frontiers In Regulation: The Age Of Nanotechnology",(Edward Elgar Publishing, UK, USA), pp. 320-333.
87. Vogel, D. (2004). *The Politics of Risk Regulation in Europe and the United States*, eds. Somsen, H., "Yearbook of European Environmental Law", pp.34.