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Discovering specific conditions for compliance with soft regulation related to work with nanomaterials

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Introduction

Worldwide, millions of employees are potentially exposed to nanoparticles when producing nanomaterials (e.g. in the chemical industry) or handling them in the process of manufacturing certain products (e.g. tires, coatings, paints, sunscreens). According to the European Directives 89/391/EEG, 98/24/EG, 2004/37/EG and the labour law of the member states, employers are legally obliged to care for occupational health and safety (OHS). Similar obligations are effective in other non-European countries. The employer's duty to care includes risk assessment and risk management according to the latest state of science. At workplaces where nanomaterials are produced or used, risk assessment and risk management are extremely difficult tasks since there is still no evidence about the risks of nanomaterials. Measurement methods for nanoparticles are contested and safety standards have not yet been developed. This does not mean, however, that regulators can wait and see. For instance, the 2000 Communication of the European Commission on the Precautionary Principle clarifies that scientific uncertainty about technological risks is no reason for regulatory inaction if there might be immense adverse effects (EC, 2000). Additionally, the ALARA Principle commits employers to minimize the exposure to nanomaterials at the workplace and to minimize the release of nanoparticles into the environment as low as reasonable achievable.[2]

To support compliance with the duty to care for safe workplaces a large number of tools have been developed (amongst which guidelines for safe handling of nanomaterials, benchmarks for exposure limits, standards, reporting schemes and codes of conduct). Regulators have introduced these tools

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[2] See, European Court of Justice 14-06-2007 (European Commission/United Kingdom), C-127/05 and the Opinion of the European Economic and Social Committee on the Proposal for a Directive on the minimum health and safety requirements regarding the exposure to workers to the risks arising from electromagnetic fields OJ EU C 43/47 (2012).

in the context of soft regulation.[3] They expect that employers will comply with soft regulation because of reputational advantages and liability issues. However, empirical studies on soft regulation indicate that compliance rates can be very low (Koutalakis et al., 2010; Braithwaite & Fisse, 1987). In the field of nanotechnologies regulation, studies of regulatory practice show that nanospecific soft regulation is facing compliance and implementation problems. The voluntary reporting, notification and assessment schemes (Defra, 2008; NICNAS, 2008) and stewardship programs (EPA, 2008) have seen 'underwhelming' industry participation and the European Commission's 2008 Nano Code of Conduct has not yet been implemented in the member states (NanoCode, 2010). These effectiveness problems raise the question under which conditions soft regulation can contribute to responsible nanotechnological development. Answers to this question are highly important since soft regulation has always played a crucial role in the governance of technologies.

This paper explores specific prerequisites to compliance with soft regulation that serves to support the legal duty to care for occupational health and safety in the work with nanomaterials. Recent research on benchmarks that serve to limit the exposure to nanoparticles at the workplace points out that technology related conditions and particular motivational postures exert influence on compliance behavior (Van Broekhuizen & Dorbeck-Jung, 2012). The importance of technological factors has been mentioned earlier in regulation theory (Black, 2002, pp. 14; 16). Yet, further elaboration of those conditions is lacking. This paper seeks answers to the question how compliance with soft regulation can be enhanced when technical devices and other technology-related factors are involved. Regarding the large range of soft instruments that have been introduced to support occupational health and safety we focus on this policy field. Setting the scene, problems of risk assessment and risk management related to nanomaterials will be briefly discussed. We explore why soft regulation is used to support these tasks in the context of the legal obligation to care for safe workplaces. Thereafter we discuss some examples of soft regulation that have been launched to achieve occupational health and safety in the work with nanomaterials. The exploration of these examples shows that the capacity of the regulated parties to comply depends on the availability of appropriate technological factors related to technical devices, technical expertise and other resources. When technological prerequisites are met, compliance is likely to increase.

Risk assessment and risk management – regulatory problems

As the asbestos case shows, being exposed to nanomaterials at the workplace may be harmful for employees. In the context of the legal duty to care employers are required to conduct risk assessment and risk management according to the state of science.[4] Employers are required to take stock of risks and to evaluate them. This implies efforts to become more knowledgeable, which includes a proactive search for information about the state of science and alternative operating procedures. In the case of (potential) hazardous substances, like nanomaterials, risk assessment and risk management refer also to unknown risks. In many countries measures of occupational health and safety (OHS) focus on prevention. One of the main tasks of risk management is to reduce risks which include the prevention or minimization of exposure to hazardous substances, substitution of

[3] By soft regulation we mean rules of conduct which do not have legally binding force, but which nevertheless may have binding force in regulatory practice (see also, Senden, 2004, p. 112).
[4] See, for instance, Articles 3 and 5 Dutch Labour Conditions Act; Articles 3-6 German Occupational Health and Safety Act and the Laws on hazardous substances.

carcinogens, labeling of hazardous substances and health control including medical check-up of employees. When risks of hazardous substances cannot be prevented additional measures must be taken.

According to OHS methods, risk assessment follows the process of hazard identification, hazard characterization, exposure assessment and risk characterization (OECD, 2012, p. 14; Safe Work Australia, 2009, p. 10, NRC, 1983, p. 191). Traditionally, risk is understood in terms of a quantitative relationship between a person's exposure to a particular substance or specific circumstances and the harm which is caused as a result; the potential of a substance to cause harm is presented as hazard, varying from substance to substance and circumstance to circumstance (Hodge, et al., 2010, p. 13). This risk assessment approach is problematic in the case of nanomaterials because of uncertainties both in regard to scientifically coherent data that relates to hazard and human exposure (comprising potential exposure pathways) and the duration of anticipated levels of exposure (NIOSH, 2009; Poland et al 2008; Oberdörster et al., 2007; SCENIHR, 2006; Nel et al., 2006). Especially the toxicology of most engineered nanomaterials is by no means fully understood. Hence, related risks cannot be articulated precisely (Safe Work Australia, 2009, p. 17). According to influential commentators, it will take 5 to 10 years until scientific evidence on the risks of nanomaterials can be provided.[5] Regarding these uncertainties it is extremely difficult to undertake appropriate risk assessment and risk management in order to comply with the legal duty to care. Regulators have introduced a large number of instruments of soft regulation that are expected to contribute to safe work with nanomaterials in the context of uncertain risks.

How regulators cope with uncertain risks of nanomaterials

In technology regulation, industry has been involved from the very beginning in the 19th century (Kloepfer, 2002). Knowing the limits of their technological knowledge, governments have built on private standard setting and private oversight activities. Vice versa, industries have often welcomed regulatory collaboration because of the stability, certainty and property protection public regulation is expected to provide. Nanotechnological regulation combines existing 'hard' regulation (e.g. legislation) with various forms of 'soft' regulation (amongst which codes of conduct, voluntary reporting schemes, standards and benchmarks).[6] Hard regulation is based on legal authority, while soft regulation does not have legally binding force. The latter is called *soft* because it is not backed by legal sanctions that build on the state's monopoly of violence. Soft regulation can be set by private and public regulators. It has an autonomous steering role, but also the roles of preparing the ground for hard regulation and contributing to the interpretation and implementation of hard regulation (Senden, 2004, p.112-114).

With regard to the assessment and management of OHS risks of nanomaterials, various regulatory instruments have been introduced: safety data sheets, standards, guidelines and exposure limits. It is

[5] Various scientists even claim that definite answers on the risks of nanomaterials might be years away, only emerging on a case-by-case basis (e.g. Wiesner et al., 2006, p. 4343).
[6] See, note 2. By regulation we understand sustainable rules of conduct which serve to achieve certain policy goals, and which are based on certain (private or public) regulatory authority. Regulation refers to the activities of standard-setting, implementation, monitoring and enforcement (Scott, 2002, p.60; Dorbeck-Jung et al. 2010, p. 156).

striking that most of these instruments are voluntary and non-legally binding, for instance, the EDV-DuPont *NanoRisk Framework* (2007), EU *Project NanoSafe2* (2008), ICON *GoodNanoGuide* (2009), Austrian Federal Ministry of Labour, Social Affairs and Consumer Protection Labour Inspectorate *Leitfaden für das Risikomanagement beim Umgang mit Nanomaterialien am Arbeitsplatz* (2010). This raises the question what advantages of soft regulation regulators expect in the context of compliance with the employers' legal duty to care for occupational health and safety when risks are uncertain.

Generally, advantages of soft regulation are said to lie in its capacity for openness, flexibility and simplicity, which is expected to foster the coherence, unification, stability and diversity of rules of conduct, as well as the speed of regulation, empirical legitimacy and low negotiation costs (Aalders & Wilthagen 1997; Sinclair 1997; Abbot & Snidal, 2000; Webb 2004; Trubek et al. 2006). Regarding the regulatory challenges of nanotechnological development, soft regulation seems to be well equipped to cope with the uncertainty, complexity and ambiguity of nanotechnological risk problems because it allows for reflective learning processes. Unlike hard regulation, soft regulation seems to be capable of facilitating constant experimentation and adjustment of regulation in response to new insights into nanotechnological risks (Dorbeck-Jung & Van Amerom, 2008; Bowman & Hodge 2009; Meili & Widmer, 2010). In the discussion of nano-specific soft regulation the advantage of less resource intensive regulation is emphasized (Bowman & Hodge, 2009, p. 147). It is assumed that soft instruments can be implemented quicker than legislation because lengthy political discussions are avoided. According to Meili and Widmer, regulatory speed is of particular importance with regard to the commercial exploitation of manufactured nanomaterials, which is far ahead of their inclusion in the regulatory system (Meili & Widmer, 2010, pp. 455-456). As Bowman and Hodge put it: "(…) innovative consent-based governance regimes can be developed and implemented by institutions despite the fast –moving pace of technologies" (Bowman & Hodge, 2009, p. 159).

However, in scientific debates on soft regulation, its presumed benefits have been countered and contrasted with particular deficiencies. Opponents argue that soft regulation is deficient in providing acceptability, effectiveness and efficiency of regulation because of its unpredictability, unreliability due to poor process and accountability facilities, as well as low level of safeguards and high transaction costs (Dorbeck-Jung & Van Amerom, 2008, p. 134). Regarding nano-specific soft regulation it is criticized that it may serve the interests of industry primarily and not those of society, that it lacks the legitimacy and accountability of hard regulation and that it has variable standards of enforcement (Bowman & Hodge, 2009, p. 147). Despite these critical comments and compliance problems with the nano-specific voluntary reporting, notification and assessment schemes, stewardship programs and codes of conduct, soft regulation is still regarded as an answer to the criticism on traditional command and control regulation of having inadequate enforcement, being reactive, slow, inflexible and overall formal (Bowman & Hodge, 2009, p. 146). Soft regulation is still widely promoted because of the trust-building and reputational advantages that are expected (Nash & Ehrenfeld, 1997; Sethi & Emelianova, 2006). Since soft instruments seem to stay in nanotechnological regulation, special attention should be paid to the conditions of rule compliance.[7]

[7] Since soft regulation is prominent in risk assessment and risk management the focus lies on soft OHS instruments. The compliance conditions that are discussed in the next section generally apply to soft and hard regulation.

Rule compliance conditions – the missing link of technological factors

In regulatory theory compliance is understood as 'rule-following behavior' (Griffiths, 1999), as acting in conformity with the rules (Hutter 1997, p. 12). Rule compliance emerges in a process of interaction between the regulators and the regulated. It can be regarded as the outcome of processes in which regulators and the regulated parties use certain rules in interaction with each other. Rule compliance generally depends on whether (1) the regulated parties can follow the rules ('capacity to comply') and (2) whether they are willing to use them (Griffiths, 1999; 2003; Havinga, 2006; Karlsson-Vinkhuyzen & Vihma, 2009, p. 405). Specific conditions regarding the capacity and willingness to comply have been explored in numerous studies on the effects of hard regulation (e.g. Baldwin & Black, 2008; Braithwaite, 1995; Braithwaite et al., 1994; Coglianese & Mendelson, 2010; Gunningham, 2010; Kagan & Scholz, 1984; Vogel, 2009), soft regulation (e.g. Havinga, 2006; Karlsson-Vinkhuyzen & Vihma, 2009) and hybrid regulation that combines hard and soft regulation (Halpern, 2008; Dorbeck-Jung et al., 2010).

With regard to the capacity of rule following, a crucial prerequisite is that regulated parties know and understand the rules. Furthermore, the capacity to follow the rules may depend on financial resources (Coglianese & Mendelson, 2010, p. 161; Gunningham, 2010, p. 141), as well as on certain 'obstacles' the regulated parties may encounter in practice. Whether the regulated parties are willing to comply relies on their attitudes or motivational stances towards compliance (Kagan & Scholz 1984; Braithwaite 1995; Gunningham, Kagan & Thornton 2002; Baldwin & Black 2008). This article focuses on technology-related conditions on which the capacity to comply depends. Technology-related 'obstacles' to comply with soft and hard regulation have not yet been explored in socio-legal studies. Black, an influential commentator in regulatory theory, admits that any ability to control is either hampered or facilitated by technology, depending on whether one has or has not the necessary technological capacity and depending on the inherent characteristics of this technology (Black, 2002, p. 14). However, Black does not further specify how such a systematic exploration could look like. She only states that technology is "(…) something that needs to be explored more systematically (…)" (Black, 2002 p. 14). In the next section specific technological conditions to the regulated parties' capacity to comply will be discussed in the context of OHS soft regulation. When technological devices and methods are involved in rule following, the capacity to comply depends on the availability of the devices. It relies also on the appropriateness of the devices and methods. When contested devices and methods are used the policy goals of occupational health and safety may not be achieved. Furthermore, the capacity to comply depends on the technological expertise to use the technology and to apply the methods.

Technological factors – examples of OHS nano-specific soft regulation

Technological devices and methods form an essential part in soft instruments that control occupational health and safety of nanomaterials. This section focuses on three examples of these soft instruments: the Recommendation of the Dutch Minister of Social Affairs and Employment on *Nano Reference Values*, the nano-specific guideline of the chemical company BASF and the guidance by the German Federal Institute for Occupational Safety and Health (Baua) which was developed in co-operation with the German Chemical Industry Association (VCI).[8]

In 2010, the Dutch Minister of Social Affairs and Employment recommended to use a particular system of Nano Reference Values (NRVs).[9] In his letter to Parliament the Minister stated that this system is provisionally regarded as part of the current state of science. Since NRVs do not guarantee that exposures below the values are safe the Minister emphasized that they are pragmatic benchmark levels that have to be accompanied by additional measures to minimize exposure. NRVs have been developed by analogy with other substances such as asbestos or fine-dust particles and they are considered benchmarks, that is 'warning levels'. They are a provisional alternative for health-based recommended occupational exposure limits (HBR-OELs) or derived no-effect levels (DNELs), based on a precautionary approach. When these levels are exceeded measures are required to identify the source and if possible minimize exposure (Dekkers & De Heer, 2010, p.17). To measure the level of exposure, a specific measuring device is recommended for use: the NanoTracer by Philips, which considers a range between 10 and 300nm (Philips, 2011).

The *BASF Code of Conduct Nanotechnology* (2004) consists of four principles that are attracted at acting responsibly towards the company's employees.[10] In one of the principles BASF commits itself to identify sources of risk for employees by using 'the appropriate measures'; this general concern is put into the practice by the company's *Guide for safe manufacture and for activities involving nanoparticles at workplaces in BASF AG*. The guide mentions specific protective measures, including workplace exposure measurement of nanoparticles. In the context of measurement BASF advocates to use a specific technique to determine the number of particles and the particle size distribution in a range between 5 to 1110 nm. It refers to the scanning mobility particle size measuring technique with the GRIMM SMPS + C technological device (BASF, n.d., p. 2; Grimm Aerosoal Technik, n.d.).

The Baua and VCI *Guidance for Handling and Use of Nanomaterials at the Workplace* provides an overview of the legal frame, the nano-related terminology, as well as of the available exposure measurement and protective measures. The guidance includes a manual to assess (potential) risks. It provides an evaluation of the latest scientific state of the exposure measurement methods and devices for nanoparticles. In this context the guidance identifies one group of devices, the Scanning Mobility Particle Sizers (SMPS), to be more suited than other instruments for exposure measurements in work areas (Baua & VCI, 2007, pp. 7-8). The SMPS devices consider a particle size distribution in a range between 3 and 800 nm.

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[8] These examples of soft regulation were selected because compliance relies on different technical devices and because they cover a variety of regulators (public, private and public/private). The Dutch *Recommendation on Nano Reference Values* is an interesting example of soft regulation because the NRVs are part of a current discussion of international relevance on the topic of exposure values for working with nanomaterials (e.g. by the British Standard Institution or the German Institute for Occupational Safety and Health of the German Social Accident Insurance). The *BASF guideline* is particular interesting because BASF is a worldwide leading company in the chemical industry, which is involved in various private and public projects on the safety of nanomaterials. The Baua and VCI *Guidance for Handling and Use of Nanomaterials at the Workplace* (2007) is very informative. It is co-regulated with the German Chemical Industry Association.

[9] Ministry of Social Affairs and Employment, Letter from 10 August 2010 (G&VW/GW/2010/14925).

[10] The first principle refers to the manufacture of new products containing nanoscale materials of enhanced properties, the second principle deals with identifying potential environmental and health risks of nanotechnologies. The third principle addresses the future usage of nanotechnology by BASF and, lastly, the company commits to engage in open dialogue with society related to activities with nanotechnology. For details concerning the four principles of the BASF Code see http://www.basf.com/group/corporate/en/function/conversions:/publish/content/sustainability/dialogue/in-dialogue-with-politics/nanotechnology/images/BASF_Code_of_Conduct_Nanotechnology.pdf.

Availability of technological devices and methods

To comply with soft regulation that has been introduced to implement the legal duty to care for occupational health and safety, employers must have technical devices of measurement and acknowledged methods for OHS measures at their disposal. The three examples indicate that measurement equipment and methods are on the market. With regard to the capacity to comply (in the sense to measure exposure and to take measures) a crucial prerequisite is that employers are able to purchase the devices. What are the costs of measurement and can companies afford to buy it? According to a report of the EU project NanoSafe2, the indicative costs for measuring equipment for nanoparticle exposure vary between 7 and 75,000€ (NanoSafe, 2008, p.4). For example, the portable NanoTracer is likely to be relatively cheaper than the stationary version of the GRIMM SMPS + C. Large companies can afford expensive risk assessment and risk management. An interesting example is the health-based occupational exposure limit for Carbon Nanotubes (‘Baytubes’) that has been developed for approximately a million Euro (Pauluhn, 2009).[11] By contrast, start-ups, small and medium sized companies (SMEs) which do not have the financial resources may not be able to purchase expensive equipment. They may tend to buy the cheaper devices and not the better equipment if this is more expensive. With regard to the methods for OHS measures, financial resources do not seem to be an obstacle to compliance. A couple of manuals and checklists are available on the Internet (Swiss Federal Office of Public Health & Federal Office for the Environment, 2011; Dutch Ministry of Social Affairs and Employment, 2011). One example is the Baua/VCI guidance.

Appropriate technological devices and methods

When measurement devices and OHS methods are on the market and employers can buy them, a further condition is that the devices are acknowledged. When devices and methods are contested and not regarded as the latest state of science the policy goals of OHS may not be achieved. With regard to nanoparticles, to date, there is still a lack of validated measurement techniques, and there is no standard procedure yet that is broadly agreed upon (Abbott & Maynard, 2010). It is said that the existing techniques s do not allow for ‘simple’ technical monitoring, which could be employed in routine operations of workplaces The available devices, like the NanoTracer,,deliver real time information on the average particle diameter and the number concentration of nano particles per cm^3 (Philips, 2011). The problem is that measurement results include also nanoparticles from the environmental background. The workplace air is likely to be polluted with nanoparticles that are generated by engines at the workplace or by nanoparticles that are diffused from the environmental background, originating from natural sources; at workplaces rapid agglomeration processes of these different kinds of nanoparticles take place, thereby forming complex agglomerates with manufactured nanomaterials. In measurement the sources of the particles remain unclear. In the example of the NRVs a problem arises when the benchmarks are exceeded. In this case it is required to distinguish manufactured nanomaterials from other nanomaterials that are not considered in the scope of the NRVs (Van Broekhuizen & Dorbeck-Jung, 2012). Regarding these difficulties to measure manufactured nanoparticles many companies and their associations rely on the experience with risk

[11] This sum was mentioned in the interviews that were held in the Dutch Pilot NRV (see, Van Broekhuizen & Dorbeck-Jung, 2012).

management of ultrafine dust (Van Broekhuizen & Dorbeck-Jung, 2012). They tend to take the same or at least similar OHS measures.

A further point of critique refers to the determination of the chemical composition of the nanoparticles, which is an important aspect of nano-specific OHS. According to the Baua/VCI guidance, the Condensation Particle Counters (CPSs), as mentioned in the BASF Guide, do not allow for measuring the chemical composition of nanoparticles (Baua & VCI, 2007, p. 7).[12] Critique concerns also the exposure levels. For example, the German Institute for Occupational Safety and Health of the German Social Accident Insurance (IFA) has argued that the BSI benchmark exposure levels[13], which are based on a particle number concentration of over five orders of magnitude, cannot be covered by currently existing measuring devices. To derive exposure limits that are actually measurable with existing instruments, IFA suggests the classification criteria of size and density of nanoparticles (Van Broekhuizen & Dorbeck-Jung, 2012). To determine the morphology and particle structure, the Baua and VCI guidance refers to electron microscopy (TEM/SEM). However, the guidance concedes that this method is highly complex and that it allows only for semi-quantitative analysis (p. 8). Contested measurement of nanoparticles was one of the reasons why the Baua and VCI rejected the concept of NRVs and why they proposed a more holistic approach in which exposure measurement is less prominent.

Technological Expertise

When validated technical devices and methods are on the market, a further condition is that the regulated parties have the expertise to use them properly. Expertise includes particular technological know-how to perform measurement and know-how to analyze the retrieved data and to embed the measurement results into the organization's general risk analysis and assessment strategy. Noteworthy in this respect is that large firms often have an already integrated policy of safety within their company culture (Van Broekhuizen & Dorbeck-Jung, 2012). Hence these firms can embed new instruments, such as the NRVs, into an already established OHS policy whereas small firms have to establish this structure first. Large firms with an OHS tradition are more likely to have the expertise at hand to conduct and assess measurements than SMEs. When companies have validated technical devices and methods the employees, who conduct the measurements, must be knowledgeable. In this regard a prerequisite is sufficient instruction on the proper use of the equipment. Proper use may be difficult when devices and methods are complicated. Complex equipment requires a high level of expertise that often cannot be reached in practice. According to Baua, proper use of complex methods is limited (Baua, 2007, p. 7). More specifically, Baua refers to the high level of metrological complexity of the SMPS technique which requires in-depth technical knowledge and experience (Baua, 2007, p.7). [14]

[12] The same critique has been made on the NanoTracer (TNO, 2011, p. 62).
[13] British Standard on a Guide to safe handling and disposal of manufactured nanomaterials (BSi PD 6699-2:2007, Nanotechnologies – Part 2).
[14] The BASF guideline which advocates the GRIMM SMPS + C's detection system relies on this method.

Conclusion and Discussion

This paper seeks answers to the question how compliance with soft regulation can be enhanced when technical devices and other technology-related factors are involved. More specifically, the paper discusses the availability and validity of technological devices and methods, as well as the required expertise of the regulated parties. The discussion focuses on three examples of soft regulation which play an important role in nano-specific OHS regulation (the Dutch Recommendation on Nano Reference Values, the BASF Guide and the Baua and VCI Guidance). The exploration shows that a variety of measurement devices and methods is on the market. It indicates that the costs to measure exposure to nanoparticles at the workplace may be very high. SMEs may have financial difficulties to purchase certain measurement devices. As a consequence, they may not be able to comply with the OHS regulation. In this case compliance could be enhanced by financial support of the industry's associations and governments. However, even when financial resources are sufficient the question arises whether a focus on measuring the exposure to nanoparticles is adequate to provide occupational health and safety. The exploration indicates that all measurement devices and methods are contested. Technological expertise to apply them seems to be inadequate. A focus on exposure measurement that is recommended by authoritative regulators may as well create a false sense of certainty. Employers may not seek for additional OHS measures because they feel that they are on the safe side. As a consequence, even a proper use of the available technique may not contribute to occupational health and safety.

The fundamental critique raises the question whether it would make sense to enhance the compliance with soft regulation that relies on contested risk assessment devices and that is confronted with problems of technical expertise that are difficult to solve. It seems that soft regulation that is based on a more holistic approach like the Baua and VCI guidance, in which measurement is less prominent, is more promising to achieve occupational health and safety. The exploration of the required technological expertise indicates that appropriate equipment and methods should not be complicated to use. Compliance with OHS regulation can be enhanced by offered training facilities to companies.

The discussion of the three examples of soft regulation shows how strongly the capacity to comply with (soft) regulation depends on technological factors when technical devices and methods are involved. It indicates that deficient devices and methods question the use of certain regulatory instruments. This paper could not pay attention to the willingness to comply which is essential for high compliance rates. The brief discussion of the analytical frame suggests that capacity and willingness to comply are interconnected. The exploration indicates that when the regulated parties are willing to comply, but do not have the appropriate technical devices, methods and expertise compliance may not contribute to achieve occupational health and safety. Vice versa, compliance rates will be low when regulatees are capable, but not willing to use validated technical devices, methods and guidance. Further research is required to provide more refined knowledge on compliance with regulation that serves to achieve occupational health and safety. It can be expected that compliance investigations on technological regulation will extend the theoretical frames that have been proposed in regulatory governance research.

References

1. Austrian Federal Ministry of Labour, Social Affairs and Consumer Protection: Labour Inspectorate (2010). *Leitfaden für das Risikomanagement beim Umgang mit Nanomaterialien am Arbeitsplatz*. Retrieved on April 2, 2012 from http://www.arbeitsinspektion.gv.at/NR/rdonlyres/6C01F836-C1B1-4142-B6F2-0ED672D27A69/0/Nano_Leitfaden_2010.pdf.
2. Aalders, M., Wilthagen, T. (1997). Moving Beyond Command-and-Control: Reflexivity in the Regulation of Occupational Safety and Health and the Environment. *Law & Policy* 19, pp. 415-443.
3. Abbott, L.C. & Maynard, A.D. (2010). Exposure Assessment Approaches for Engineered Nanomaterials. Risk Analysis 30, pp. 1634 – 1644.
4. Abbott, K.W. & Snidal, D. (2000). Hard and Soft Law in International Governance. *International Organization* 54(3), pp. 421-456.
5. BASF (2004). *Code of Conduct for Nanotechnology.* Retrieved on 15 March 2012 from http://www.basf.com/group/corporate/en/sustainability/dialogue/in-dialogue-with-politics/nanotechnology/code-of-conduct.
6. BASF (n.d.). *Guide for safe manufacture and for activities involving nanoparticles at workplaces in BASF AG*. Retrieved on April 2, 2012 from http://basf.com/group/corporate/de/function/conversions:/publish/content/sustainability/dialogue/in-dialogue-with-politics/nanotechnology/images/BASF_Guide_to_safe_manufacture_and_for_activities_involving_nanoparticles.pdf.
7. Bundesanstalt für Arbeitsschutz und Arbeitsmedizin (Baua) & Verband der Chemischen Industrie (VCI) (2007). *Leitfaden für Tätigkeiten mit Nanomaterialien am Arbeitsplatz*. Retrieved on 12 March, 2012 from http://www.baua.de/de/Themen-von-A-Z/Gefahrstoffe/Nanotechnologie/pdf/Leitfaden-Nanomaterialien.pdf?__blob=publicationFile&v=3.
8. Baldwin, R. & Black, J. (2008). Really Responsive Regulation. *The Modern Law Review* 71, pp. 59-94.
9. Black, J. & Baldwin, R. (2010). Really Responsive Risk-Based Regulation. *Law & Policy* 32 (2), pp. 181-213.
10. Black, J. (2002). *Critical Reflections on Regulation*. London: Centre for Analysis of Risk and Regulation, London School of Economics.
11. Bowman, D.M. & 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.
12. Braithwaite, J. & Fisse, B. (1987). Self-Regulation and the Control of Corporate Crime. In Shearing, C.D. & Stenning, P.C. (Eds.). *Private* Policing. Newbury Park, Calif.: Sage, pp. 221-246.
13. Braithwaite, V. (1995). Games of Engagement: Postures Within the Regulatory Community. *Law & Policy* 17 (3), pp. 225-255.
14. Braithwaite, V., Braithwaite, J., Gibson, D. & Makkai, T. (1994). Regulatory Styles, Motivational Postures and Nursing Home Compliance. *Law & Policy* 16 (4), pp. 363-394.
15. British Standard Institution (2007). *BSi PD 6699-2:2007, Nanotechnologies – Part 2: Guide to safe handling and disposal of manufactured nanomaterials*. BSI.
16. Broekhuizen, P. van & Dorbeck-Jung, B.R. (2012). Exposure limit values for nanomaterials – capacity and willingness of users to apply a precautionary approach*, forthcoming.*
17. Coglianese, C. & Mendelson, E. (2010). Meta-Regulation and Self-Regulation. In Baldwin, R., Cave, M. & Lodge, M. (2010). (Eds.). *The Oxford Handbook of Regulation*. Oxford: Oxford University Press.
18. Department for Environment Food and Rural Affairs (Defra) (2008). *UK Voluntary Reporting*

Scheme for engineered nanoscale materials. Retrieved on May 10, 2012 from http://archive.defra.gov.uk/environment/quality/nanotech/documents/vrs-nanoscale.pdf/.
19. Dekkers, S. & Heer, C. de (2010). *Tijdelijke nano-referentiewaarden. RIVM Rapport 601044001*. Retrieved on April 2, 2012 from http://docs.minszw.nl/pdf/190/2010/190_2010_3_14399.pdf.
20. Dorbeck-Jung, B.R. & Amerom, M. van (2008). The hardness of soft law in the United Kingdom: state and non-state regulatory conceptions related to nanotechnological development', in: Verschuren, J. & Schooten-van der Meer, H. (Eds.), *The State Legislature and Non-State Law,* Cheltenham: Edward Elgar, pp. 129-150.
21. Dorbeck-Jung, B.R., Oude Vrielink, M.J., Gosselt, J., van Hof, J. & de Jong, D.T. (2010). Contested hybridization of regulation: Failure of the Dutch regulatory system to protect minors from harmful media. *Regulation & Governance* 4, pp. 154-174.
22. Dutch Ministry of Social Affairs and Employment (2011). *Stoffenmanager Nano Module*. Online tool retrieved on 24 May, 2012 from http://nano.stoffenmanager.nl/.
23. EDV-DuPont (2007). *Nano Risk Framework.* Retrieved on 12 March, 2012 from http://apps.edf.org/documents/6496_nano%20risk%20framework.pdf.
24. Environmental Protection Agency (EPA) (2008). Notice: Nanoscale Materials Stewardship Program. *Federal Register* 37(18), pp. 4861-4866.
25. European Commission of 2 February 2000 Communication from the Commission on the precautionary principle.
26. Griffiths J. (1999) Legal Knowledge and the Social Working of Law: The Case of Euthanasia. In: Schooten H. van (Ed.) *Semiotics and Legislation*, Liverpool: Deborah Charles, pp. 81–108.
27. Griffiths, J. (2003). The Social Working of Legal Rules. *Journal of Legal Pluralism*, No. 48, pp. 1-84.
28. Grimm Aerosol Technik (n.d.). Scanning Mobility Particle Sizer (SMPS+C). Retrieved on April 2, 2012 from http://www.grimm aerosol.com/downloads/datasheets/en/GrimmAerosolTechnik_Nano_SMPS_C.pdf.
29. Gunningham, N. (2010). Enforcement and Compliance Strategies. In Baldwin, R., Cave, M. & Lodge, M. (2010). (Eds.). The Oxford Handbook of Regulation. Oxford: Oxford University Press.
30. Gunningham N, Kagan R, Thornton D. (2002). *Social License and Environmental Protection: Why Business Go Beyond Compliance*. University of California, Berkeley, CA.
31. Halpern S. (2008). Hybrid Design, Systemic Rigidity: Institutional Dynamics in Human Research Oversight. *Regulation & Governance* 2, pp. 85–102.
32. Havinga. T. (2006). Private Regulation of Food Safety by Supermarkets. *Law & Policy*, Vol. 28, No. 4, pp. 515-533.
33. Hodge, G.A., Bowman, D.M. & Maynard, A.D. (Eds.) (2010). International Handbook on Regulating Nanotechnologies. Massachusetts, US: Edward Elgar Publishing.
34. Hutter, B.M. (1997). *Compliance: Regulation and Environment.* Oxford: Clarendon Press Oxford.
35. Institut für Arbeitsschutz der Deutschen Gesetzlichen Unfallversicherung (n.d.). *Maßstäbe zur Beurteilung der Wirksamkeit von Schutzmaßnahmen.*Retrieved on May 10, 2012 from http://www.dguv.de/ifa/de/fac/nanopartikel/beurteilungsmassstaebe/index.jsp
36. International Council on Nanotechnology (2009). *GoodNanoGuide*. Retrieved on April 2, 2012 from http://goodnanoguide.org/HomePage.
37. Institut für Arbeitsschutz der Deutschen Gesetzlichen Unfallversicherung (IFA) (n.d.). *Criteria for assessment of the effectiveness of protective measures*. Retrieved on April 2, 2012 from http://www.dguv.de/ifa/en/fac/nanopartikel/beurteilungsmassstaebe/index.jsp.

38. Kagan, R.A. & Scholz. J.T. (1984). The Criminology of the Cooperation and Regulatory Enforcement Strategies. In Hawkins, K. & Thomas, J.M. (Eds.). *Enforcing Regulation.* Boston: Kluwer/Nijhof Publishing.
39. Karlsson-Vinkhuyzen, S.I. & Vihma, A. (2009). Comparing the legitimacy and effectiveness of global hard and soft law: An analytical framework. *Regulation & Governance* 3, pp. 400-420.
40. Kloepfer, M. (2002). *Technik und Recht im wechselseitigen Werden: Kommunikationsrecht in der Technikgeschichte*, Schriften zum Technikrecht 4. Berlin: Duncker & Humbolt.
41. Meili, C. & Widmer, M. (2010). Voluntary measures in nanotechnology risk governance: the difficulty of holding the wolf by the ears. In Hodge, G.A., Bowman, D.M. & Maynard, A.D. (Eds.). *International Handbook on Regulating Nanotechnologies*. Cheltenham, UK: Edward Elgar.
42. NanoCode (2010). Synthesis Report on Codes of Conduct, Voluntary Measures and PracticesTowards a Responsible Development of N&N. Retrieved on May 5, 2012 from http://www.nanocode.eu.
43. NanoSafe (2008). *Is it possible to easily measure the engineered nanoparticles at workplaces?* Retrieved on April 3, 2012 from http://www.nanosafe.org/scripts/home/publigen/content/templates/show.asp?P=63&L=EN.
44. Nash, J. & Ehrenfeld, J. (1997). Codes of Environmental Management Practice: Assessing Their Potential as a Tool of Change. *Annual Review of Energy and the Environment* 22, pp. 487-535.
45. National Institute for Occupational Health and Safety (NIOSH) (2009). Approaches to Safe Nanotechnology. Atlanta, GA: NIOSH.
46. National Academy of Sciences (NRC) (1983). *Risk Assessment in the Federal Government: Managing Process.* Committee on the Institutional Means for Assessment of Risks to Public Health, Commission on Life Sciences, National Research Council. Washington, D.C.: National Academy Press.
47. Nel, A., Xia, T., Mädler, L. & Li, N. (2006). Toxic Potential of Materials at the Nanolevel. *Science* 311, pp. 622-627.
48. Oberdörster, G., Stone, V. & Donaldson, K. (2007). Toxicology of nanoparticles: a historical perspective. *Nanotoxicology* 1 (1), pp. 2-25.
49. Organisation for Economic Co-operation and Development (OECD). (2012). *Important Issues on Risk Assessment of Manufactured Nanomaterials.* Series on the Safety of Manufactured Nanomaterials No. 33. Paris: Environmental Directorate OECD.
50. Koninklijke Philips Electronics N.V. (Philips) (2011). *NanoTracer*. Retrieved on April 4, 2012 from http://aerasense.com/content/File/Philips%20NanoTracer.pdf.
51. Koutalakis, C., Buzogany, A. & Börzel, T.A. (2010). When soft regulation is not enough: The integrated pollution prevention and control directive of the European Union. *Regulation & Governance* 4, pp. 329-344.
52. National Industrial Chemical Notification and Assessment Scheme (NICNAS) (2008). Industrial Nanomaterials: Voluntary Call for Information 2008. Australian Government Gazette, C 10 -7 October, pp. 25-38.
53. Pauluhn, J. (2009). *Multi-walled Carbon Nanotubes (Baytubes®): Approach for Derivation of Occupational Exposure Limit, Regulatory Toxicology and Pharmacology, DOI: 10.1016/j.yrtph.2009.12.012)*
54. Poland, C.A. et.al (2008). Carbon Nanotubes into the Abdominal Cavity Display Asbestos-like Pathogenic Behaviour in a Pilot Study. *Nature Nanotechnology* 3, pp. 423-428.
55. Ratner, M. & Ratner, D. (2003). *Nanotechnology. A Gentle Introduction to the Next Big Idea.* Upper Saddle River, NJ: Prentice Hall PTR.
56. Safe Work Australia (2009). *Engineered Nanomaterials: Evidence on the Effectiveness of Workplace Controls to Prevent Exposure*. Retrieved on 23 April, 2012 from http://safeworkaustralia.gov.au/AboutSafeWorkAustralia/WhatWeDo/Publications/Docume

nts/312/EngineeredNanomaterials_Evidence_Effectiveness_WorkplaceControlsToPreventExposure_2009_PDF.pdf.

57. Scientific Committee on Emerging and Newly Identified Health Risks (SCENIHR) (2006). *The European Commission's Scientific Committee on Emerging and Newly Identified Health Risks Opinion on the Appropriateness of Existing Methodologies to Assess the Potential Risks Associated with Engineered and Adventitious Products of Nanotechnologies*. Brussels: European Commission.
58. Scott, C. (2002). Private Regulation of the Public Sector: A Neglected Facet of Contemporary Governance. *Journal of Law and Society* 29(1), pp. 56-76.
59. Senden, L. (2004). *Soft Law in European Community Law*. Oxford: Hart Publishing.
60. Sethi, S.P. & Emelianova, O. (2006). A Failed Strategy of Using Voluntary Codes of Conduct by the Global Mining Industry. *Corporate Governance: The International Journal of Effective Board Performance* 6, pp. 226-238.
61. Sinclair, D. (1997). Self-regulation Versus Command and Control? Beyond false Dichotomies. *Law & Policy* 19, pp. 529-559.
62. Swiss Federal Office of Public Health & Federal Office for the Environment (2011). *Vorsorgeraster Nanomaterialien*. Online tool retrieved on 24 May, 2012 from http://www.bag.admin.ch/nanotechnologie/12171/12174/12175/index.html?webgrab_path=aHR0cDovL3d3dy5iYWctYW53LmFkbWluLmNoL25hbm9yYXN0ZXIvcG9ydGFsX2RlLnBocD9tb2Q9YQ%3D%3D&lang=de.
63. TNO (2011). *TNO-rapport V9300. Vervaardiging en gebruik van nano-eindproducten in* Nederland. TNO: Zeist.
64. Trubek, L.G., Cottrell, P. & Nance, N. (2006). Soft law, hard law and EU integration. In Burca, G. de & Scott, J. (Eds.). *Law and New Governance in the EU and the US*. Portland, OR: Hart.
65. Vogel, D. (2009). The Private Regulation of Global Corporate Conduct. In Mattli, W. & Woods, N. (Eds.). *The Politics of Global Regulation*. Princeton, NJ: Princeton University Press.
66. Webb, K. (2004). Understanding the Voluntary Code Phenomenon. In Webb, K. (Ed.) *Voluntary Codes: Private Governance, the Public Interest, and Innovation*. Carleton University, Ottawa, pp. 3-32.
67. Wiesner, M. R., Lowry, G.V., Alvarez, D., Dionysiou, D. & Biswas, P. (2006). Assessing the risks of manufactured nanomaterials. *Environmental Science and Technology* 15, pp. 4337-4345.