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Discovering Specific Conditions for Compliance with Soft Regulation Related to Work with Nanomaterials

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Abstract At workplaces where nanomaterials are produced or used, risk assessment and risk management are extremely difficult tasks since there is still limited evidence about the risks of nanomaterials. Measurement methods for nanoparticles are contested and safety standards have not yet been developed properly. To support compliance with the legal obligation of the employer to care for safe workplaces a large number of 'soft' regulatory tools have been proposed (e.g. codes of conduct, benchmarks, standards). However, it is not clear whether and under which conditions soft regulation is complied with. This article discusses the potential advantages and drawbacks of soft regulation. It explores compliance issues when exposure measurement devices and other technology-related factors are involved. The exploration of three examples of soft regulation on occupational health and safety (a ministerial recommendation on preliminary exposure benchmarks, a nano-specific guidance of a chemical company and a public–private OHS guideline) shows that the capacity of the regulated parties to comply depends on the availability of appropriate technological devices and methods, technical expertise and other resources. When technological prerequisites are met, compliance is likely to increase.

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Introduction

Worldwide, safe work with nanomaterials has gained attention by policy-makers. Employees produce nanomaterials (e.g. in the chemical industry) or handle them in the process of manufacturing certain products (e.g. tires, coatings, paints, sunscreens). According to the European Directives[1] and the labour law of the member states, employers are legally obliged to care for occupational health and safety (OHS). The legal obligation has its basis in a European Directive, which lays down the specific tasks of the employers' obligation to ensure safety and health of workers; the employer shall: a) be in possession of an assessment of the risks to safety and health at work b) decide on the protective measures and equipment to be taken c) keep a list of occupational accidents d) draw up for the

[1] Council Directive 89/391/EEC of 12 June 1989 on the introduction of measures to encourage improvements in the safety and health of workers at work; Council Directive 98/24/EC of 7 April on the protection of the health and safety of workers from the risks related to chemical agents at work; and Directive 2004/37/EC of the European Parliament and of the Council of 29 April 2004 on the protection of workers from the risks related to exposure to carcinogens or mutagens at work.

responsible authorities on occupational accidents.[2] The employer's obligation to care includes risk assessment and risk management according to the latest state of science.[3] At workplaces where nanomaterials are produced or used, risk assessment and risk management are extremely difficult tasks since there is still limited evidence about the risks of nanomaterials. Measurement methods for nanoparticles are contested and safety standards have not yet been developed properly. This does not mean, however, that regulators can wait and see. For instance, the 2000 Communication of the European Commission on the Precautionary Principle, which is binding on EU institutions, clarifies that scientific uncertainty about technological risks is no reason for regulatory inaction if there might be immense adverse effects [25].

To support compliance with the employer's legal obligation to care for safe workplaces a large number of other regulatory tools have been developed (amongst which are guidelines for safe handling of nanomaterials, benchmarks for exposure limits, standards, reporting schemes and codes of conduct). Regulators have introduced these tools in the context of soft regulation. 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 [58, p. 112]. Policy-makers 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 [13, 43]. In the field of nanotechnologies regulation, studies of regulatory practice show that nanospecific soft regulation face problems of compliance and implementation. For instance, the European Commission's 2008 Nano Code of Conduct has not yet been implemented in the member states [45]. Such 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 [22].

This paper explores specific prerequisites to compliance with soft regulation that serves to support the legal obligation to care for occupational health and safety in the work with nanomaterials. Recent research on benchmarks that have been proposed to limit the exposure to nanoparticles at the workplace points out that technology related conditions and particular motivational postures exert influence on compliance behavior [17]. The importance of technological factors has been mentioned earlier in regulation theory [11, 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 devices and methods, technical expertise and other resources. When technological prerequisites are met, compliance is likely to increase.

Risk Assessment and Risk Management—Regulatory Problems

In the context of the legal obligation 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.[5] 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,

[2] Council Directive 89/391/EEC, section ll, article 9(1).

[3] Directive 98/24/EC; and Regulation (EC) No 1907/2006 of the European Parliament and of the Council of 18 December 2006 concerning the Registration, Evaluation, Authorisation and Restriction of Chemicals (REACH).

[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.

[5] Directive 98/24/EC; and REACH Regulation (EC) No 1907/2006.

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 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 [50, p. 191; 53, p. 14; 55, p. 10]. 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 [33, 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 [49, 51, 52, 56]. In particular the toxicology of most engineered nanomaterials is by no means fully understood. Hence, related risks cannot be articulated precisely [55, p. 17]. According to influential commentators, it will take 5 to 10 years until scientific evidence on the risks of nanomaterials can be provided.[6] Regarding these uncertainties it is extremely difficult to undertake appropriate risk assessment and risk management in order to comply with the legal obligation 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 [8].

How Regulators Cope with Uncertain Risks of Nanomaterials

In technology regulation, industry has been involved from the very beginning in the 19th century [41]. 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).[7] Hard regulation is based on legal authority, while soft regulation does not, in and of themselves, have legally binding force. The latter is called *soft* because it is not backed by legal sanctions. Soft regulation can be set by private and public regulators.[8] 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 [58, p. 112–114].

With regard to the assessment and management of OHS risks of nanomaterials, various regulatory instruments have been introduced in addition to the legally binding measures: safety data sheets, standards, guidelines and exposure limits. As nanotechnology is still emerging and scientific knowledge is limited, most of these instruments are voluntary and non-legally binding, for instance, the EDV-DuPont *NanoRisk Framework* [24], EU *Project NanoSafe2* [46], ICON *GoodNanoGuide* [37], Austrian Federal Ministry of Labour, Social Affairs and Consumer Protection Labour Inspectorate *Leitfaden für das Risikomanagement beim Umgang mit Nanomaterialien am Arbeitsplatz* [5]. This raises the question what advantages of soft regulation regulators expect in the context of compliance with the employers' legal obligation 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,

[6] 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. [67, p. 4343]).

[7] 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 [21, p. 156; 57, p. 60].

[8] Examples of private 'soft' regulation are: codes of conduct, guidelines of private organizations etc. Public regulators are also competent to set non-legally binding regulations. Examples are: recommendations, communications and guidelines.

unification, stability and diversity of rules of conduct, as well as the speed of regulation, empirical legitimacy and low negotiation costs [1, 3, 60, 63, 66]. 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 [12, 20, 44]. In the discussion of nano-specific soft regulation the advantage of less resource intensive regulation is emphasized [12, p. 147]. It is assumed that soft instruments can be implemented more quickly than legislation because lengthy political discussions can apparently be 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 [44, p. 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' [12, 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 [20, 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 [12, 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 [12, p. 146]. Soft regulation is still widely promoted because of the trust-building and reputational advantages that are expected [48, 59]. Since soft instruments seem to stay in nanotechnological regulation, special attention should be paid to the conditions of rule compliance.[9]

Rule Compliance Conditions—the Missing Link of Technological Factors

In regulatory theory compliance is understood as 'rule-following behavior' [26], as acting in conformity with the rules [34, 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 [26, 27, 32, 40, 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. [10, 14, 15, 18, 29, 39, 64]), soft regulation (e.g. [32, 40]) and hybrid regulation that combines hard and soft regulation [21, 31].

With regard to the capacity for 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 [18, p. 161; 29, 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 [10, 14, 30, 39]. 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 [11, p. 14]. However, Black does not further specify how such a systematic exploration could look like. She only states that technology is

[9] 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.

'something that needs to be explored more systematically' [11, 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).[10]

In March 2009 the Social Economic Council (SER) advised the Dutch Minister of Social Affairs and Employment (SZW) to ask the Dutch Health Council to develop reference values (NRVs) for the most commonly used nanoparticles at workplaces. The Minister responded that such reference values cannot be legally binding because they are not health-based therefore would effectively rather lead to confusion. Pressing for a solution in this matter, the Dutch Parliament asked the government to develop reference values that could be used until the Health Council could develop health-based reference values for nanoparticles. In reaction, the Minister asked the National Institute for Public Health and the Environment (RIVM) to investigate the usability of such a concept of NRVs. Based on the resulting report he recommended to use a particular system of Nano Reference Values (NRVs).[11] In his letter to Parliament he 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.[12] To measure the level of exposure, a specific measuring device is recommended: the NanoTracer by Philips, which considers a range between 10 and 300 nm [42]. Compliance with the NRVs is voluntary; there are no legal sanctions for non-compliance.

The *BASF Code of Conduct Nanotechnology* [6] consists of four principles that are attracted at acting responsibly towards the company's employees.[13] 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

[10] 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 Standards Institute [16] or the German Institute for Occupational Safety and Health of the German Social Accident Insurance [8]). 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* [9] is very informative. It is co-regulated with the German Chemical Industry Association.

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

[12] The 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 [19, p. 17].

[13] 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 [6].

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 and 1,110 nm. It refers to the scanning mobility particle size measuring technique with the GRIMM SMPS + C technological device [7, p. 2; 28] Compliance with the Code of Conduct Nanotechnology is binding for BASF employees but compliance appears to not be monitored. Whether or not the BASF Guide by which the Code is implemented is binding or not is not clear.

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 [9, p. 7–8]. The SMPS devices consider a particle size distribution in a range between 3 and 800 nm. Compliance with the Baua guidance is voluntary and non-compliance is not sanctioned.

Availability of Technological Devices and Methods

To comply with soft regulation that has been introduced to implement the employer legal obligation to care for OHS through having risk assessment and management in place, 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€ [46, p. 4]. For instance, the portable NanoTracer costs about 7,000€ but other devices are more expensive than the estimated 75,000€ mentioned by NanoSafe2; according to NanoSafe Australia, the costs for Scanning Mobility Particle Sizers (SMPS) range from 77,000 up to 330,000€ [47, p. 9]. In this light, there are indicators that large companies are able to afford expensive risk assessment and risk management whereas start-ups, small and medium sized companies (SMEs) do not have the financial resources to do so [36, pp. 61,70]. An interesting example is the health-based occupational exposure limit for Carbon Nanotubes (‘Baytubes’) that has been developed for approximately a million Euro [54].[14] SMEs do not seem to be able to absorb the immediate costs for securing OHS in the same way as larger companies can [4, p. 24]. There are even indicators that SMEs tend to buy the cheaper devices and not the better equipment if this is more expensive [36, p. 81].

With regard to the methods for OHS measures, financial resources do not seem to be an obstacle to compliance, since a couple of manuals and checklists are available on the Internet [23, 61]. One example is the Baua/VCI guidance [9].

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 generally accepted to measure what they are supposed to measure. 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 [2]. It is said that the existing techniques do not allow for ‘simple’ technical monitoring, which could be employed in routine operations of workplaces; some even say that the technical development of instrumentation is trailing nanotechnology industry applications [55, p. 56]. 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 [42]. The problem is that measurement results often 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

[14] This sum was mentioned in the interviews that were held in the Dutch Pilot NRV (see, [17]).

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 [17]. Regarding these difficulties to measure manufactured nanoparticles many companies and their associations rely on the experience with risk management of ultrafine dust [17]. They tend to take the same or at least similar OHS measures.

Another problematic aspect with real-time particle monitors is that these are optimized for and calibrated with spherical particles and as a consequence may not correctly measure irregularly-shaped particles with large aspects ratios. Therefore particle number concentration (for instance by using Condensation Particle Counters, CPCs) and size distribution (by using Scanning Mobility Particle Sizers, SMPS) need to be compared directly with confirmation of the morphology of the particles (e.g. by using electron microscopy, TEM) [55, p. 56].

Especially the determination of the chemical composition of the nanoparticles is an important aspect of nano-specific OHS. But according to the Baua/VCI guidance, CPCs as those mentioned in the BASF Guide, do not allow for measuring the chemical composition of nanoparticles [9, p. 7].[15] 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,[16] which are based on a particle number concentration of over five orders of magnitude, cannot be covered by currently existing measuring devices [38]. To derive exposure limits that are actually measurable with existing instruments, IFA suggests the classification criteria of size and density of nanoparticles [17]. 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 [9, 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 only one aspect of a broad OHS strategy.

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. As has been found in an Australian survey that examined enablers and barriers to control hazardous chemicals, especially SMEs perceive lack of in-house expertise as a major barrier to determine and use workplace exposures [4, p. 23]. 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 [17]. By contrast, small firms often have great difficulty to establish safety policies as they lack safety specialists [65]. Larger firms can embed new instruments, such as the NRVs into an already established OHS policy; small firms often have to establish such a structure first [35, p. 2].

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 may not be reached in practice. According to the Baua, proper use of complex methods is limited [9, p. 7]. More specifically, the Baua refers to the high level of metrological complexity of the SMPS technique which requires in-depth technical knowledge and experience [9, p. 7].[17]

In sum. The exploration of technological expertise and the availability of appropriate technological

[15] The same critique has been made on the NanoTracer [62, p. 62].

[16] British Standard on a Guide to safe handling and disposal of manufactured nanomaterials [16].

[17] The BASF guideline which advocates the GRIMM SMPS + C's detection system relies on this method.

devices and methods indicates a couple of compliance problems. What are the tentative conclusions that can be drawn from the evaluation of three examples of OHS nano-specific soft regulation?

Conclusion and Discussion

The exploration of 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) 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.

Probably, the issues of technical contestability and complexity of devices to measure nanoparticle exposure will be not be resolved in the near future. Measuring methods are still in their infancy and in need of improvement. Firms such as BASF have recognized this and are actively involved in the development of 'better' instrumentation. Also government bodies, such as Baua in Germany and the Social Economic Council in the Netherlands, are investing in the improvement of devices to measure nanoparticle exposure. However, for the time being some specific technological related factors are hampering the regulatee's capacity to comply with soft nano-regulation.

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. Aalders M, Wilthagen T (1997) Moving beyond command-and-control: reflexivity in the regulation of occupational safety and health and the environment. Law Policy 19:415–443
2. Abbott LC, Maynard AD (2010) Exposure assessment approaches for engineered nanomaterials. Risk Anal 30:1634–1644
3. Abbott KW, Snidal D (2000) Hard and soft law in international governance. Int Organ 54(3):421–456
4. Australian Safety and Compensation Council (2006) Barriers and Enablers to Control of Hazardous Chemicals

in SMEs. Retrieved on August 4, 2012 from http://www.safeworkaustralia.gov.au/sites/SWA/AboutSafeWorkAustralia/WhatWeDo/Publications/Pages/ACRR200607BarriersAndEnablers.aspx
5. 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
6. 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
7. 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
8. Bundesanstalt für Arbeitsschutz und Arbeitsmedizin (Baua) (2012) *Handlungshilfen für den Umgang mit Nanomaterialien*. Retrieved on August 15, 2012 from http://www.baua.de/de/Themen-von-A-Z/Gefahrstoffe/Nanotechnologie/Links-Beispiele.html;jsessionid=9C75BF0709FFA147BC80D6D37667F330.1_cid253
9. 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
10. Baldwin R, Black J (2008) Really responsive regulation. Mod Law Rev 71:59–94
11. Black J (2002) Critical reflections on regulation. Centre for Analysis of Risk and Regulation, London School of Economics, London
12. Bowman DM, Hodge GA (2009) Counting on codes: an examination of transnational codes as a regulatory governance mechanism for nanotechnologies. Regul Gov 3:145–164
13. Braithwaite J, Fisse B (1987) Self-regulation and the control of corporate crime. In: Shearing CD, Stenning PC (eds) Private policing. Sage, Newbury Park, pp 221–246
14. Braithwaite V (1995) Games of engagement: postures within the regulatory community. Law Policy 17(3):225–255
15. Braithwaite V, Braithwaite J, Gibson D, Makkai T (1994) Regulatory styles, motivational postures and nursing home compliance. Law Policy 16(4):363–394
16. British Standards Institute (2007) BSI published document 6699–2:2007, nanotechnologies – part 2: guide to safe handling and disposal of manufactured nanomaterials. BSI, London
17. Broekhuizen P van, Dorbeck-Jung BR (2012) Exposure limit values for nanomaterials—capacity and willingness of users to apply a precautionary approach, forthcoming
18. Coglianese C, Mendelson E (2010) Meta-regulation and self-regulation. In: Baldwin R, Cave M, Lodge M (eds) The Oxford handbook of regulation. Oxford University Press, Oxford, pp 146–168
19. Dekkers S, de Heer C (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 BR, van Amerom M (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. Edward Elgar, Cheltenham, pp 129–150
21. Dorbeck-Jung BR, Oude Vrielink MJ, Gosselt J, van Hof J, de Jong DT (2010) Contested hybridization of regulation: failure of the Dutch regulatory system to protect minors from harmful media. Regul Gov 4:154–174
22. Dorbeck-Jung BR (2011) Soft regulation and responsible nanotechnological development in the European Union: regulating occupational health and safety in the Netherlands. Eur J Law Technol 2(3):1–14
23. Dutch Ministry of Social Affairs and Employment (2011) Stoffenmanager Nano Module. Online tool retrieved on 24 May, 2012 from http://nano.stoffenmanager.nl/
24. EDV-DuPont (2007) Nano Risk Framework. Retrieved on 12 March, 2012 from http://apps.edf.org/documents/6496_nano%20risk%20framework.pdf
25. European Commission, Communication from the Commission on the precautionary principle COM (2000) 1 final
26. Griffiths J (1999) Legal knowledge and the social working of law: the case of euthanasia. In: van Schooten H (ed) Semiotics and legislation. Deborah Charles, Liverpool, pp 81–108
27. Griffiths J (2003) The social working of legal rules. J Leg Plur 48:1–84
28. Grimm Aerosol Technik (n.d.) Scanning Mobility Particle Sizer (SMPS + C). Retrieved on April 2, 2012 from http://www.grimmaerosol.com/downloads/datasheets/en/GrimmAerosolTechnik_Nano_SMPS_C.pdf
29. Gunningham N (2010) Enforcement and compliance strategies. In: Baldwin R, Cave M, Lodge M (eds) The Oxford handbook of regulation. Oxford University Press, Oxford, pp 120–145
30. Gunningham N, Kagan R, Thornton D (2002) Social license and environmental protection: why business go beyond compliance. University of California, Berkeley
31. Halpern S (2008) Hybrid design, systemic rigidity: institutional dynamics in human research oversight. Regul Gov 2:85–102
32. Havinga T (2006) Private regulation of food safety by supermarkets. Law Policy 28(4):515–533
33. Hodge GA, Bowman DM, Maynard AD (eds) (2010) International handbook on regulating nanotechnologies. Edward Elgar Publishing, Cheltenham
34. Hutter BM (1997) Compliance: regulation and environment. Clarendon Press Oxford, Oxford
35. International Council of Chemical Associations (ICCA) (2011) Global Product Strategy. ICCA Guidance on Chemical Risk Assessment. Retrieved on July 19, 2012 from http://www.icca-chem.org/ICCADocs/ICCA_GPS%20July2011_LowResWEB.pdf

36. International Council on Nanotechnology (ICON) (2006) A Review of Current Practices in the Nanotechnology Industry. Retrieved on June 27, 2012 from http://www.icon.rice.edu/projects.cfm?doc_id=4388
37. International Council on Nanotechnology (ICON) (2009) GoodNanoGuide. Retrieved on April 2, 2012 from http://goodnanoguide.org/HomePage
38. Institut für Arbeitsschutz der Deutschen Gesetzlichen Unfallversicherung (IFA) (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
39. Kagan RA, Scholz JT (1984) The criminology of the cooperation and regulatory enforcement strategies. In: Hawkins K, Thomas JM (eds) Enforcing regulation. Kluwer/Nijhof Publishing, Boston
40. Karlsson-Vinkhuyzen SI, Vihma A (2009) Comparing the legitimacy and effectiveness of global hard and soft law: an analytical framework. Regul Gov 3:400–420
41. Kloepfer M (2002) Technik und Recht im wechselseitigen Werden: Kommunikationsrecht in der Technikgeschicht*e*, Schriften zum Technikrecht 4. Duncker & Humbolt, Berlin
42. Koninklijke Philips Electronics N.V. (Philips) (2011) NanoTracer. Retrieved on April 4, 2012 from http://aerasense.com/content/File/Philips%20NanoTracer.pdf
43. Koutalakis C, Buzogany A, Börzel TA (2010) When soft regulation is not enough: the integrated pollution prevention and control directive of the European Union. Regul Gov 4:329–344
44. Meili C, Widmer M (2010) Voluntary measures in nanotechnology risk governance: the difficulty of holding the wolf by the ears. In: Hodge GA, Bowman DM, Maynard AD (eds) International handbook on regulating nanotechnologies. Edward Elgar, Cheltenham
45. NanoCode (2010) Synthesis Report on Codes of Conduct, Voluntary Measures and Practices Towards a Responsible Development of N&N. Retrieved on May 5, 2012 from http://www.nanocode.eu
46. 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
47. NanoSafe Australia (2007) Current OHS Best Practices for the Australian Nanotechnology Industry. A Position Paper by the NanoSafe Australia Network. Retrieved on August 2, 2012 from http://mams.rmit.edu.au/72nuxiavskpg.pdf
48. Nash J, Ehrenfeld J (1997) Codes of environmental management practice: assessing their potential as a tool of change. Ann Rev Energy Environ 22:487–535
49. National Institute for Occupational Health and Safety (NIOSH) (2009) Approaches to safe nanotechnology. NIOSH, Atlanta
50. 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. National Academy Press, Washington, D.C.
51. Nel A, Xia T, Mädler L, Li N (2006) Toxic potential of materials at the nanolevel. Science 311:622–627
52. Oberdörster G, Stone V, Donaldson K (2007) Toxicology of nanoparticles: a historical perspective. Nanotoxicology 1(1):2–25
53. 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. Environmental Directorate OECD, Paris
54. Pauluhn J (2009) Multi-walled carbon nanotubes (Baytubes®): approach for derivation of occupational exposure limit. Regul Toxicol Pharmacol. doi:10.1016/j.yrtph.2009.12.012
55. 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/Documents/312/EngineeredNanomaterials_Evidence_Effectiveness_WorkplaceControlsToPreventExposure_2009_PDF.pdf
56. 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. European Commission, Brussels
57. Scott C (2002) Private regulation of the public sector: a neglected facet of contemporary governance. J Law Soc 29(1):56–76
58. Senden L (2004) Soft law in European Community law. Hart Publishing, Oxford
59. Sethi SP, Emelianova O (2006) A failed strategy of using voluntary codes of conduct by the global mining industry. Corp Gov 6(3):226–238
60. Sinclair D (1997) Self-regulation versus command and control? Beyond false dichotomies. Law Policy 19:529–559
61. 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
62. TNO (2011) TNO-rapport V9300. Vervaardiging en gebruik van nano-eindproducten in Nederland. TNO, Zeist
63. Trubek LG, Cottrell P, Nance N (2006) Soft law, hard law and EU integration. In: de Burca G, Scott J (eds) Law and new governance in the EU and the US. Hart, Portland
64. Vogel D (2009) The private regulation of global corporate conduct. In: Mattli W, Woods N (eds) The politics of global regulation. Princeton University Press, Princeton
65. Warmerdam J et al (1993) Arbozorg in Het Midden- en Kleinbedrijf. Ministerie van Sociale Zaken en Werkgelegenheid, The Hague
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 MR, Lowry GV, Alvarez D, Dionysiou D, Biswas P (2006) Assessing the risks of manufactured nanomaterials. Environ Sci Technol 15:4337–4345