Effective Regulation under Conditions of Scientific Uncertainty

How Collaborative Networks Contribute to Occupational Health and Safety Regulation for Nanomaterials

Aline Reichow

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HOW COLLABORATIVE NETWORKS CONTRIBUTE TO OCCUPATIONAL HEALTH AND SAFETY REGULATION FOR NANOMATERIALS

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Summary

This thesis argues that business associations in the German and United States (US) chemical sector contribute to effective nanomaterials occupational health and safety (OHS) regulation. Since 2003 until today (March 2015), business associations worldwide have been actively participating in the regulatory debate on nanomaterials that are handled in workplaces albeit to varying degrees. It is argued that business associations may play a crucial role in making available, and extending, scientific data in collaboration with regulators.

On this basis associations can develop guidance material (i.e., soft regulation), based on the latest state of science, in order to support their members companies in conducting risk assessment for nanomaterials. This is important in view of legal obligations of employers, anchored in OHS legislation in the US and Europe (EU), to protect workers from the potential health risks of nanomaterials by conducting risk assessment. Applying the traditional risk assessment approach to nanomaterials–and thereby complying with existing OHS legislation–is currently challenging due to fundamental scientific data gaps regarding exposure, hazard, and toxicity of certain nanomaterials.

Thus, this thesis argues that business associations can prepare compliance for companies with the legal obligation to conduct risk assessment for nanomaterials. The question of how business associations, in practice, prepare compliance for companies is important in regard to the notion of effective regulation.

In the field of regulation and governance numerous studies on effective regulation have focused on the outcome of rule compliant behavior. Here, the degree to which policy goals (e.g., OHS) have been achieved through the rule compliant behavior of the regulated parties determines whether, or not, we speak of "effective regulation". This approach is not useful when conditions of scientific uncertainty exist, as in the case of nanomaterials. Put simply this is because we do not know whether existing rules are evidently adequate to reach the legislative and policy goal. More specifically, in the case of nanomaterials OHS, the risk endpoints of certain nanomaterials are largely unknown. Therefore it is unclear whether the existing employer obligation to conduct risk assessment for nanomaterials protects, from a scientific point of view, the health and safety of employees who handle nanomaterials.

By investigating processes of preparing rule compliance through learning among business associations and regulators rather than focusing on the outcome of rule compliance this thesis differs from most studies on effective regulation. This notion of process effectiveness is an underresearched issue.

This thesis adds to the research on learning processes in collaborative activities that involve private and public actors aimed at contributing to effective regulation. Contributing to effective regulation can be achieved through activities that prepare compliance, including, for example information provision and/or generation and development of soft regulation. Such activities may also have an influence on rule-making, including, for example when developed soft regulation is used by regulators in order to specify existing regulation.

A theoretical framework is proposed for the study of three types of learning processes: substantive learning (generation of new scientific facts), strategic learning (development of trust among the collaborators), and institutional learning (development of rules). Conditions under which these learning types develop are identified and used to analyze and compare business association contributions to effective nanomaterials OHS regulation in two case studies: the American Chemistry Council's Nano Panel (ACC Nano Panel) and the German Chemical Industry Association (VCI). These associations arguably are most actively involved in the regulatory debate on nanomaterials OHS.

Association collaborative activities are investigated through 38 qualitative, semi-structured interviews with involved stakeholders from the two associations, industry, regulators, (federal) research institutes, academia, non-governmental organizations (NGOs), consultancies, and labor unions. Data from publicly available (policy) documents supporting association activities was investigated.

The results of the empirical analysis indicate that the two associations have facilitated learning–to varying levels–relevant for preparing compliance of companies with existing OHS legislation. Overall, the VCI activities facilitated strong learning, i.e., many conditions for the development of all three learning type are met. In comparison, the ACC Nano Panel facilitated limited learning, i.e., only a few conditions for the development of trust among collaborators and the development of rules have been met while strong learning in regard to the generation of new scientific facts is observed.

This thesis finds that trust among collaborators (strategic learning) is a pre-condition for knowledge generation (substantive learning), and rule development (institutional learning). More precisely, *limited trust* among collaborators appears sufficient for these actors to exchange nanomaterials knowledge and data among each other and also, on this basis, to generate new scientific facts. *Strong trust* among collaborators seems to facilitate the exchange of valuable knowledge and the generation of many new scientific facts. Furthermore, *limited trust* among collaborators combined with *strong scientific expertise* appears not sufficient for these actors to engage in rule development. Rather, *strong trust* among collaborators, combined with *strong scientific expertise*, facilitates the process of joint rule development among collaborators. These findings are an important step towards building a theory on learning in collaborative networks that can support regulatory process effectiveness under circumstances of scientific uncertainty.

In order to facilitate trust among collaborators it is recommended that repetitive, non-public meetings are held and that an independent body, responsible for identifying and communicating the goals of the involved actors, oversees the collaboration. While trust is important for the development of new scientific facts, it is also recommended that a heterogeneous set of actors be involved in the collaborative process since this can also support the generation of new facts.

Samenvatting

Deze dissertatie betoogt dat brancheverenigingen in de Amerikaanse en Duitse chemische industrie bijdragen aan effectieve regelgeving op het gebied van veiligheid en gezondheid op het werk met betrekking tot nanomaterialen. Vanaf 2003 tot en met nu (maart 2015) hebben brancheverenigingen wereldwijd actief deelgenomen aan de discussie over regelgeving rondom de omgang met nanomaterialen op de werkvloer, zij het met verschillende bijdragen. Brancheverenigingen kunnen een cruciale rol spelen in het beschikbaar maken en vergroten van wetenschappelijke informatie in samenwerking met beleidsmakers.

Zij kunnen richtlijnen (zachte regels, soft regulation) ontwikkelen gebaseerd op de meest recente wetenschappelijke kennis om hun leden (chemische bedrijven) te ondersteunen bij hun risico analyses van nanomaterialen. Dit is belangrijk vanwege de wettelijke verplichtingen (vastgelegd in arbowetgeving zowel in de VS als in de EU) die werkgevers hebben om, door middel van risicoanalyses, hun personeel te beschermen tegen mogelijke gezondheidsrisico's van nanomaterialen. Het toepassen van de traditionele risicoanalyse op nanomaterialien, en daarmee het voldoen aan bestaande arbowetgeving, is lastig vanwege fundamentele hiaten in de wetenschappelijke kennis over blootstelling, gevaar en toxiciteit van bepaalde nanomaterialen.

Daarom betoogt deze dissertatie dat brancheverenigingen bedrijven kunnen helpen bij het zich voorbereiden op het voldoen ann hun wettelijke verplichtingen om een risicoanalyse uit te voeren van de gevolgen van blootstelling aan nanomaterialen. De vraag hoe brancheverenigingen dit in de praktijk doen is belangrijk met het oog op de effectiviteit van de regelgeving.

Studies naar effectieve regulering focussen zich doorgaans op de uitkomst van nakoming van de regels. Hierin bepaalt de mate waarin de regels worden nagekomen de effectiviteit van de regelgeving. In omstandigheden waarin wetenschappelijke onzekerheid bestaat, zoals in het geval van nanomaterialen, is deze aanpak niet geschikt omdat het onduidelijk is of bestaande regulering adequaat is om haar doeleinden te bereiken. In het geval van veiligheid en gezondheid rondom nanomaterialen is dit probleem vooral evident omdat de risico-eindpunten van bepaalde nanomaterialen grotendeels onbekend zijn. Daarom is het, vanuit wetenschappelijk oogpunt, onbekend of de huidige verplichtingen van de werkgever om risicoanalyses uit te voeren, de veiligheid en gezondheid van werknemers die met nanomaterialen te maken hebben, werkelijk beschermen.

Door het proces van leren door brancheverenigingen en beleidsmakers in hun voorbereidingen op het nakomen van regels te analyseren, in plaats van te kijken naar het nakomen van de regels, onderscheidt deze dissertatie zich van de meeste andere studies naar effectieve regelgeving. Het concept van proceseffectiviteit is weinig onderzocht.

Deze dissertatie draagt bij aan de systematische studie van leerprocessen in samenwerkingsverbanden tussen publieke en private actoren die kunnen bijdragen aan effectieve regelgeving. Effectieve regelgeving kan worden bereikt door activiteiten die het nakomen van deze regelgeving voorbereiden, bijvoorbeeld door het verstrekken van informatie en/of de creatie en ontwikkeling van zachte regels. Zulke activiteiten kunnen ook van invloed zijn op het bepalen van beleid, bijvoorbeeld wanneer beleidsmakers de ontwikkelde zachte regels gebruiken om bestaande wetten te specificeren.

In deze dissertatie wordt een theoretisch raamwerk voorgesteld om drie typen leerprocessen te bestuderen: substantief leren (het genereren van nieuwe wetenschappelijke feiten), strategisch leren (ontwikkeling van vertrouwen tussen de samenwerkende partijen) en institutioneel leren (ontwikkeling van regels/beleid). Omstandigheden waaronder deze typen leerprocessen zich ontwikkelen zijn geïdentificeerd en gebruikt voor de analyse van de bijdragen van brancheverenigingen aan effectieve arboregels met betrekking tot

nanomaterialen. In deze studie wordt een vergelijking gemaakt tussen het Nano Panel van de American Chemistry Council (ACC Nano Panel) en de Duitse branchevereniging voor de chemie (VCI). Deze brancheverenigingen zijn het meest actief betrokken bij de debatten aangaande de Arbowetgeving met betrekking tot nanomaterialen.

Samenwerkingsactiviteiten van de brancheverenigingen zijn onderzocht middels 38 kwalitatieve, semi-gestructureerde interviews met betrokkenen van de beide verenigingen, de industrie, beleidsmakers, (federale) onderzoeksinstituten, de wetenschap, NGO's, consultancies en vakbonden. Daarnaast werd data van publiekelijk beschikbare (beleids-) documenten over de activiteiten van de brancheverenigingen onderzocht.

De resultaten van de empirische analyse laten zien dat beide brancheverenigingen leerprocessen voor de voorbereiding op het nakomen van arboregulering gefaciliteerd hebben, maar in verschillende mate. De VCI heeft vooral 'strong learning' gefaciliteerd; dat wil zeggen dat aan vele condities voor de ontwikkeling van alle drie de typen leerprocessen werd voldaan. De ACC Nano Panel heeft vooral 'limited learning' gefaciliteerd; dat wil zeggen dat voor de ontwikkeling van vertrouwen tussen de samenwerkende partijen en voor de ontwikkeling van regelgeving slechts aan enkele voorwaarden werd voldaan, terwijl 'strong learning' kon worden geobserveerd met betrekking tot de ontwikkeling van nieuwe wetenschappelijke feiten.

De dissertatie concludeert dat vertrouwen tussen de samenwerkende partijen (strategisch leren) een voorwaarde is voor de productie van kennis (substantief leren) en de ontwikkeling van regelgeving (institutioneel leren). Meer in detail: *limited trust* (beperkt vertrouwen) tussen de samenwerkende partijen lijkt voldoende voor de actoren om kennis over nanomaterialen te delen en, op basis hiervan, nieuwe wetenschappelijke feiten te genereren. *Strong trust* (sterk vertrouwen) lijkt de uitwisseling van waardevolle kennis te faciliteren en daarmee bij te dragen aan de ontwikkeling van vele nieuwe wetenschappelijke feiten. Bovendien blijkt *limited trust* in combinatie met *strong scientific expertise* (sterke wetenschappelijke expertise) onvoldoende voor deze actoren om zich bezig te houden met het ontwikkelen van regelgeving. *Strong trust* gecombineerd met *strong scientific expertise* faciliteert gezamenlijke ontwikkeling van regelgeving. Deze bevindingen vormen een belangrijke stap voor de ontwikkeling van een theorie over leerprocessen in collaboratieve netwerken die kunnen bijdragen aan effectieve regelgeving onder omstandigheden van wetenschappelijke onzekerheid.

Om vertrouwen tussen samenwerkende partijen te faciliteren is het aan te raden regelmatig besloten bijeenkomsten te organiseren en om een onafhankelijke partij in het leven te roepen die de doelen van de verschillende actoren identificeert en communiceert. Hoewel vertrouwen belangrijk is voor de ontwikkeling van nieuwe wetenschappelijke feiten, is het ook aan te raden dat een heterogene groep van actoren samenwerkt, omdat ook dit de ontwikkeling van nieuwe feiten ondersteunt.

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Table of Contents

List of abbreviations

ACC	American Chemistry Council
ACTU	Australian Council of Trade Unions
AGS	Committee on Hazardous Substances (Germany)
ALARP/ALARA	As low as reasonably practicable/achievable
ArbSchG	Safety and Health at Work Act (Germany)
BAuA	Federal Institute for Occupational Safety and Health (Germany)
BDI	Federation of German Industries
BfR	Federal Institute for Risk Assessment (Germany)
BIAC	Business and Industry Advisory Committee
BMAS	Federal Ministry of Labour and Social Affairs (Germany)
BMBF	Federal Ministry of Education and Research (Germany)
BMUB	Federal Ministry for the Environment, Nature Conservation, Building and Nuclear Safety (Germany)
BSE	Bovine Spongiforme Enzephalopathie (mad cow disease)
BSI	British Standardization Institute
BUND	Friends of the Earth Germany
CBI	Confidential Business Information
CEFIC	European Chemical Industry Council
CIA	Chemical Industries Association (United Kingdom)
CIB	Current Intelligence Bulletin
CLP	Classification, Labeling and Packaging Regulation
CNTs	Carbon nanotubes
DaNa	Data and Knowledge on Nanomaterials
DECHEMA	Society for Chemical Engineering and Biotechnology
DEFRA	Department for Environment, Food and Rural Affairs (United Kingdom)
DG	Directorate General
DGB	Confederation of German Trade Unions
DGUV	German Social Accidence Insurance
DIN	German Institute for Standardization
DSL	Dynamic Light Scattering
EAN	European ALARA Network
EC	European Commission
ECHA	European Chemicals Agency
EDF	Environmental Defense Fund
EP	European Parliament
EPA	Environmental Protection Agency (United States)
EU	European Union
EU-OSHA	European Agency for Safety and Health at Work
GefStoffV	Hazardous Substances Ordinance (Germany)
GMOs	Genetically Modified Organisms
HSE	Health and Safety Executive (United Kingdom)
ICCA	International Council of Chemical Associations
IFA	Institute for Occupational Safety and Health of the German Social Accident Insurance
IG BCE	Labor Union Mining, Chemistry and Energy (Germany)
ILSI	International Life Sciences Institute

IP	Intellectual Property
ISO	International Organization for Standardization
IUTA	Institute of Energy and Environmental Technology
KIT	Karlsruhe Institute of Technology
MIT	Massachusetts Institute of Technology
MSDS	Material Safety Data Sheet
MWCNTs	Multi-Walled Carbon Nanotubes
NGOs	Non-Governmental Organizations
NIA	Nanotechnology Industries Association
NICNAS	National Industrial Chemicals Notification and Assessment Scheme (Australia)
NIOSH	National Institute for Occupational Safety and Health (United States)
NNCO	National Nanotechnology Coordination Office (United States)
NNI	National Nanotechnology Initiative (United States)
NRC	National Research Council (United States)
NRVs	Nano Reference Values (Netherlands)
OECD	Organization for Economic Cooperation and Development
OEL	Occupational Exposure Limit
OHS	Occupational Health and Safety
OSHA	Occupational Health and Safety Agency (United States)
OSHAct	Occupational Health and Safety Act (United States)
PEL	Permissible Exposure Limit
PIBF	Association of Danish Process Industries
RCEP	Royal Commission on Environmental Pollution (United Kingdom)
RCP	Responsible Care Program
REACH	Registration, Evaluation, Authorization and Restriction of Chemicals Regulation
REL	Recommended Exposure Limit
RPaUoN	Responsible Production and Use of Nanomaterials Working Group
RS-RAE	Royal Society and Royal Academy of Engineering (United Kingdom)
SCENIHR	Scientific Committee on Emerging and Newly Identified Health Risks (European Union)
SEM	Scanning Electron Microscopy
SiO_2	Silicon Dioxide
SMEs	Small and Medium-sized Enterprises
SNURs	Significant New Use Rules (United States)
SNUN	Significant New Use Notification (United States)
SOPs	Standard Operating Procedures
SRU	Advisory Council of the Environment (Germany)
SWA	Safe Work Australia
SZW	Ministry of Social Affairs and Employment (Netherlands)
TEM	Transmission Electron Microscopy
TiO_2	Titanium Dioxide
TRGS	Technical Rules for Hazardous Substances (Germany)
TSCA	Toxic Substances Control Act (United States)
UBA	Federal Environment Agency (Germany)

UIC	Association of the Chemical Industry (France)
US(A)	United States
VCI	German Chemical Industry Association
VDI	Association of German Engineers
VNCI	Association of the Dutch Chemical Industry
VZBV	Consumer Organization Verbraucherzentrale Bundesverband (Germany)
WPMN	Working Party on Manufactured Nanomaterials
ZnO	Zinc Oxide

Chapter 1

Introduction

This chapter introduces the thesis. To this end, in section 1.1, specific regulatory challenges related to the handling of engineered nanomaterials in workplaces are described in order to provide a brief compendium of the main challenges in the protection of workers who handle nanomaterials at workplaces. In section 1.2, these challenges are placed in the context of the essential problems of, and proposed solutions to, effective regulation discussed in the regulatory literature. Against this context, in section 1.3, the chapter spells out the research aim and questions underpinning the thesis. The chapter concludes by providing an outline of the structure of the thesis.

1.1 Problem situation

Engineered nanomaterials have been heralded for their economic potential in many industrial sectors (Hett 2004). Nanomaterials are expected to help address global problems pertaining to energy, pollution, transportation, food and health (National Institute for Occupational Safety and Health (NIOSH) 2012). By incorporating nanomaterials into conventional products, consumer products may be made lighter, stronger, less expensive, more efficient, and/or more precise (Lövestam et al. 2010). Today nanomaterials are used in many applications and consumer end-products in areas such as pharmaceuticals (Ehmann et al. 2013; Sosnik 2013), medicine (European Technology Platform Nanomedicine (ETPN) 2013; Giljohann et al. 2010), electronics and computer (Lövestam et al. 2010), and cosmetics (The Woodrow Wilson International Center for Scholars 2013).

The number of nano-products and methods of use has increased steadily (Kaluza et al. 2009). The most common manufactured nanomaterials are nanoscale forms of metal oxides (e.g. titanium dioxide, TiO_2) and metals (e.g. gold), but nanoscale silver and silica are also common (NIOSH 2013a). But it is important to note that some materials now considered as nanomaterials have been incorporated into products and are available on the market for decades (e.g. window glass, paints). Carbon black has widely been used in car tire production since 1915, and other commonly used nanomaterials in commercial production are fumed silica (a form of silicon dioxide, SiO_2), TiO_2, zinc oxide (ZnO) and, more recently, silver nanoparticles (Lövestam et al. 2010).

Since 2004 the prevention and control of potential risks related to engineered nanomaterials that are handled at workplaces is a subject of particular concern among various policy-makers worldwide (Royal Society and Royal Academy of Engineering (RS-RAE) 2004). For instance, in 2005 the German Federal Ministry for the Environment, Nature Conservation, Building and Nuclear Safety (BMUB) stated that nanomaterials may pose risks to the environment and health (BMUB 2005). In 2006 the Australian Senate Community Affairs References Committee questioned the adequacy of traditional occupational health and safety (OHS) instruments for nanomaterials (Australian Senate Community Affairs References Committee 2006). Following this concern, the New South Wales (NSW) Standing Committee on State Development has explicated that health and safety issues related to the potential toxicity of nanomaterials in the workplace require specific and immediate attention (NSW 2008). In 2007, the United States (US) Environmental Protection Agency (EPA) stated in its Nanotechnology White Paper that some nanomaterials may pose hazards to humans and the environment (EPA 2007). In April 2009 the European Parliament (EP), in a non-binding resolution, asked for higher controls on nanomaterials in the area of occupational health and workers safety (EP 2009). One year later, the Netherlands Ministry of Social Affairs and Employment (SZW) raised concern over the potential human health impact of nanomaterials (SZW 2010).

Whether nanomaterials pose risks to human health cannot be articulated precisely as the toxicology of most engineered nanomaterials is not fully understood (Meili 2013; Safe Work Australia (SWA) 2009). However, some information is available for certain types of nanomaterials, such as carbon nanotubes (CNTs) (Sargent et al. 2014; EPA 2012a), nanoscale TiO_2 (National Industrial Chemicals Notification and Assessment Scheme (NICNAS) 2013; Organisation for Economic Co-operation and Development (OECD) 2007) and nanoscale silver (EPA 2012b; OECD 2007). For instance, studies indicate that certain types of CNTs produce inflammations and inflammatory lesions (Bonner et al. 2013) and tumors (Sargent et al. 2014) in lungs of mice that are exposed to CNTs under laboratory conditions. But it will still take years until comprehensive scientific studies can determine if, and which, nanomaterials pose risks to human health.

Therefore, regulatory scholars speak of the 'known unknowns' of nanotechnologies (Black 2010) and signify their regulation as a 'wicked' public policy problem (Dorbeck-Jung 2010; Hodge et al. 2010).

The term 'wicked problem' was first mentioned in theories of urban planning. As Rittel and Webber (1973: 160) argued, modern social or policy problems are often 'ill-defined' and, rather than relying on scientific certainty, they rely on political judgments. In this respect, many public policy problems are wicked, i.e. they are inherently resistant to a clear and agreed solution and there even might not be a 'solution' in the sense of a definite and objective answer (Rittel & Weber 1973: 155). Building on this notion, Harmon and Mayer (1986) characterize wicked problems as having no clear solutions, but merely imperfect, temporary resolutions. Therefore, as scholars in the field of network governance postulate, dealing with wicked problems requires continuous collaboration among a multiplicity of actors (O'Toole 1997; McGuire 2006). Actors typically show an interest but also inability to agree on the exact nature of the 'problem' (to the degree that it exists at all), and/or on the most desirable solution to be applied (Koppenjan & Klijn 2004). Usually, wicked problems build on an insufficient knowledge base, which makes it difficult to interpret and solve these problems appropriately (Klijn 2008).

Referring to the features of wicked problems, the issue of nanomaterials OHS is characterized as a wicked problem in this thesis. The affected actors broadly disagree on the nature of the problem and on the most desirable solution to secure safety and health at workplaces where nanomaterials are handled.

In this context of uncertainty, employers in most countries, including the two key-manufacturing jurisdictions Germany and US, are by default legally obliged to protect the health of their employees who handle nanomaterials at workplaces. This is achieved, ideally through having risk assessment and management processes in place. But since scientifically sound risk data on particular nanomaterials such as single and multi walled CNTs are still scarce, it is challenging to apply risk assessment to nanomaterials and to know whether existing health and safety frameworks and methodologies are evidently effective in protecting employee health.

To gain insights into the appropriateness of existing regulation, regulatory scholars have called upon regulators to cooperate with companies producing nanomaterials for purposes of risk uncovering and avoidance (Coglianese 2010; Bartis & Landree 2006). There is a need for, for example, fundamental data on certain nanomaterials. This has been illustrated by mandatory data calls of regulators worldwide including the California Department of Toxic Substances Control (January 2009) and the French Government (January 2013). Equally apparent is an EU-wide effort to develop so-called nano-registries. France was the first European country to require manufacturers to identify the use of produced, imported, distributed, or formulated nanomaterials; the reporting scheme took effect on 1 January 2013 (Ministère de L'Écologie du Développment durable et de L'Énergie 2013). On 4 July 2013, the Belgian Federal Public Service for Health, Food Chain Safety, and Environment informed the EC of a draft decree to create a nano-register. On 7 February 2014, the Belgian Council of Ministers agreed on a royal decree to require manufacturers to register substances (from 1 January 2016) and mixtures (from January 2017) containing nanomaterials (Résidence Palace 2014). On 4 July 2013, the Danish Environmental Protection Agency started a public consultation on a draft for a nanomaterials register (Høring Portalen 2013). On 18 June 2014 the order for a nano-products registry entered into force (Høring Portalen 2014). While Sweden and Italy may possibly create nano-registries in the coming years, 10 EU Member States (plus Croatia) sent a letter to the EC in which they asked for the creation of a nano-database at the EU level (Nanotechnology Industries Association (NIA) n.d.a).

On 21 June 2013, the EC Directorate General (DG) Enterprise and Industry called for tenders to assist in the development for a nanomaterials registry parallel to the obligations under the Registration, Evaluation, Authorization and Restriction of Chemicals (REACH) Regulation and the Classification, Labeling, and Packaging (CLP) Regulation (EC DG Enterprise & Industry 2013).

In the US similar activities appear to be underway. On 3 July 2013 the US Environmental Protection Agency (EPA) posted in its Regulatory Agenda that it is developing a proposal to establish reporting requirements for chemical substances processed as nanoscale materials (EPA 2013a). The same proposal was posted again by EPA on 23 May 2014; to date (January 2015) it is still in the proposed rule stage (EPA 2014).

Likewise industry has been asked by occupational health scientists to engage in global networking for the purpose of sharing scientific data and knowledge, which would allow learning how to improve current (traditional) risk assessment frameworks in the context of nanomaterials (Savolainen et al. 2013: 188). By contributing to scientific progress in this area, industry may potentially mitigate concerns regarding worker health and safety and may be able to demonstrate–if harm would be proven in the future–that workers have been protected according to the latest state of science, i.e. industry cannot be accused of neglect.

Business associations in some jurisdictions–that are those in the EU and US–have become actively involved in these discussions around nanomaterials. Business associations appear to collaborate with public policy-makers in an effort to exchange knowledge and thereby push forward nanomaterial characterization, risk specification and regulation. On this basis, associations initiate other activities, for instance, in form of developing OHS guidance material that is based on the latest state of science and technology, to support their member firms to comply with existing legislation when the risks of some nanomaterials are largely uncertain. The practical contribution of business association activities, and on this basis their specific role in the regulation of nanomaterials OHS, is however unclear. It is important to shed light on the involvement of business associations in the context of nanomaterials OHS to understand their role in, and impact on, the regulation of nanomaterials in workplace contexts.

1.2 Context of effective regulation and co-regulation

Regulation refers to sets of interconnected activities that can be conceived of as rule setting, implementation, and enforcement (Black & Baldwin 2010; Levi-Faur 2010; Scott 2010; Black 2002; Scott 2002). Rule setting is the establishment of standards while implementation refers to the communication of rules to the regulated parties and their compliance with the rules. Enforcement is the detection of unwanted behavior by the regulated parties, enforcement of tools and strategies in relation to a performance assessment and, if necessary, modification of these strategies (Black & Baldwin 2010).

Effective regulation, broadly in the field of public administration, is most often defined as the degree to which policy goals have been achieved through the rule compliant behavior of the regulated parties (Opschoor & Turner 1994). In the sociology of law, effective regulation is defined as the outcome of rule-following behavior, i.e. whether the regulated parties comply with rules (Griffith 2003). Rule compliance depends on the willingness (or motivation) and the capacity of regulated parties to follow rules (Coglianese & Mendelson 2010; Gunningham 2010; Karlsson-Vinkhuyzen & Vihma 2009; Vogel 2009; Baldwin & Black 2008; Braithwaite 1995; Braithwaite et al. 1994; Kagan & Scholz 1984). From this perspective the focus is thus on the *outcome* of rule compliant behavior.

In the context of nanomaterial OHS, one desired outcome of rule compliant behavior is the protection of employee health. However, since the risk endpoints of certain nanomaterials are largely unknown, one cannot know whether the quality of rules designed to mitigate such risks is sufficient. Or, in other words, one cannot know whether these rules are evidently protecting employee health from a scientific point of view.[1] When there is no one scientific standard a focus on the outcome of rule compliant behavior becomes problematic, making it less useful to research effectiveness from a traditional regulatory perspective. Therefore, instead of focusing on the outcome of rule compliant behavior, it becomes more useful to investigate a preliminary, or preparatory, step of compliance; namely the practice by which the regulated parties give meaning to, or try to understand and 'translate', the rules they are supposed to follow into their specific practice to discern how they can become rule-compliant.

Business associations can facilitate the process of 'giving meaning' to rules that need to be complied with through initiating activities such as knowledge exchange and collection, as well as the generation of new knowledge. Based on these activities learning may take place which may enable the development of specific guidance material (soft regulation) that can support rule compliance under certain circumstances.

Thus, in this thesis, we investigate effective nanomaterials OHS regulation focused on *processes* of compliance. More specifically, we look at the activities preparing rule compliance with the employer legal obligation to provide safe workplaces through conducting risk assessment for nanomaterials. These preparatory activities are the first step towards effective regulation of nanomaterials OHS.

It can be assumed that not only regulatees, i.e. employers and workers, participate in these processes (in order to achieve compliance); regulators are likely also participating because they can benefit from the knowledge on the health risks of nanomaterials that is generated by using this new knowledge to ensure that OHS rules are evidently protecting the

[1] Such a situation can be described as a typical 'technology control dilemma': too little knowledge on new or emerging technologies is available to be able to develop evidently effective regulatory controls. Moreover, when problems with such technologies emerge, regulatory control becomes difficult as the technology is fixed or settled in society already and cannot be changed without significant disruptions (Collingridge 1980). The control dilemma, as suggested by the Royal Commission on Environmental Pollution (RCEP), states that such new technologies require a governance framework that is adaptive, having the capability to develop and grow when dangers to human health become apparent over time (RCEP 2008: 8).

health and safety of workers. Accordingly, regulators may specify existing rules or develop new rules.

Such a process-oriented perspective on effective regulation directs the attention to collaboration among key actors, i.e., whether, and how, business associations, companies, and public policy-makers cooperate in activities designed to support the provision of safe workplaces. When collaborators learn how to improve risk assessment frameworks for nanomaterials that are critical for complying with OHS regulations, activities aimed at supporting nanomaterials OHS are more likely rendered effective.[2]

The practice of policy-makers appealing to private firms for purposes of collaboration and support is not new. Since the 19th century governments have worked together with industry in order to establish standards for the regulation of technologies such as steam machines and buildings (Dorbeck-Jung 2011). Companies have an interest to ensure the longevity of their economic sector and as they possess expertise in their specific field that policy-makers lack (Héritier & Eckert 2007), firms are asked to share their knowledge in exchange for legal certainty and stability (Abbot 2012). While industry supports government with a crucial resource, 'knowledge', it also remains critical to government (Kloepfer 2002).

In the 1980s a stream of international research started to investigate the role of business associations in politics (Coleman 1990; Jacek 1987; Schmitter & Streeck 1981). Two themes appeared to be of particular interest to scholars:

1. the extent to which political structures shape business association characteristics and,
2. the degree to which business associations extend their traditional role of lobbying in political processes (Bell 1995).

Around the same time regulatory scholars also started to address the involvement of private bodies in driving regulation (Bardach & Kagan 1982).

The traditional view of regulation dominant during the 1960s and 1970s conceived the state to regulate in form of a "command-and-control" approach, using legal rules that impose standards backed by sanctions (Baldwin 1997). The force of law was used to levy fixed standards directly and to prohibit activities that do not conform to these standards (Baldwin et al. 2012). Regulation was perceived as 'centred' by assuming that states have the 'capacity to command and control, to be the only commander and controller, and to be potentially effective in commanding and controlling' (Black 2002: 2). Thus, from a top-down instrumentalist viewpoint, the connection between a rule in the hands of a policy-maker and its social effects in form of changed behavior was perceived as a straightforward, causal one (Griffiths 2003:13); it has even been called deterministic (Von Benda-Beckmann 1989).

From the 1980s various weaknesses of the command-and-control approach to regulation were voiced by regulatory scholars (e.g. Bardach & Kagan 1982; Viscusi & Zeckhauser 1979). They argued that government agencies oftentimes have insufficient knowledge to be able to pinpoint the causes of problems, design appropriate solutions, detect non-compliance and implement regulation (Black 2002). As Bardach and Kagan (1982) argued, such command and control regulation led to redundantly complex and inflexible rules, producing "over-regulation" and constraints on businesses and economic vitality more broadly; under these circumstances regulatees were often less willing to comply with rules.

In the light of such criticism, regulators and regulatory scholars called for the introduction of "soft-law" approaches, i.e. 'less-restrictive' controls that pay attention to

[2] Based on this process-oriented perspective on effectiveness, the specific conditions that constitute successful collaboration and effectiveness are formulated in chapter 4 (theoretical framework).

alternative modes of influence and that stress the need to adopt a minimal level of self-regulatory controls within corporations (Baldwin et al. 2010). As Levi-Faur and Comaneshter (2007) stressed, command and control can only be utilized when regulators know how to exactly define regulatory problems and solutions *a priori*, thereby being able to develop rules to mandate response. In their view, such traditional approaches do not work when specific knowledge is unavailable and/or unknown, as in the regulation of new and emerging technologies (e.g. Genetically Modified Organisms (GMOs), nanomaterials).

Against this background regulatory scholars began to emphasize the increasing multilevel character of regulation (Black 2001; Hancher & Moran 1989), the need for a transition from more hands-on, interventionist style of government to ‘governing at distance’ (Howlett & Rayner 2004), and a move from government to *governance* (Hutter & Jones 2007). By this they were referring to ‘steering’ without presuming the presence of hierarchy (Rosenau 1992). But governance regarding public policy goals is said to still require a ‘shadow of hierarchy’, i.e. governmental intervention to ensure the efficacy of regulatory efforts (Héritier & Eckert 2007). Proponents of “smart regulation”–broadly defined as the use of regulatory instrument combinations, rather than individual instruments, to be matched by policy-makers depending on a particular situation–emphasized that governments, in place of directing expensive and possibly ineffective bureaucracy, could achieve public purposes by steering collaboration among public and private actors (Gunningham et al. 1998).

In such systems of *co-regulation*, government agencies retreat from direct intervention and use third parties like companies as ‘surrogate regulators’; it is third parties who decide by themselves how best to regulate certain activities (Gunningham et al. 1999). The government, meanwhile, continues to provide legal backing to enforce such arrangements.[3] When both state and private actors contribute to regulation one can speak of co-produced regulation (Bowman & Gilligan 2010). Some authors emphasize the role of industry in co-regulation by using the term ‘industry co-regulation’ (e.g. Aalders & Wilthagen 1997; Gunningham & Rees 1997), and some refer more specifically to ‘industry association co-regulation’ (e.g. Ayres & Braithwaite 1992). Collaboration between business associations, firms and government may offer mutual benefits to involved parties (Sethi 2005; Gunningham & Rees 1997) and takes shape most prominently through the development and implementation of non-legally binding “soft” instruments[4] aimed at achieving public policy goals (Sethi & Emelianova 2006; Trubek et al. 2006; Webb 2004; Abbot & Snidal 2000; Gunningham & Rees 1997; Nash & Ehrenfeld 1997; Sinclair 1997; Braithwaite 1982). Co-regulation is not restricted to industry; non-governmental organizations (NGOs) as well as insurers may be involved. Therefore co-regulation must be understood in the broader framework of decentralized regulation.

At the conceptual core of a decentered understanding of regulation lay notions of complexity, fragmentation, ‘ungovernability’, interdependencies, and the rejection of a clear distinction between public and private (Black 2002). *Complexity* denotes causal complexity and complexity in interactions between actors and/or systems with diverse identities in society that are in constant tension between stability and change (Rose 2000). *Fragmentation* refers both to the fragmentation of knowledge in society–no single actor has all knowledge to solve complex problems and there is no ‘objective truth’, as knowledge is socially constructed (DiMaggio & Powell 1991)–and to the fragmentation of power and control, such as that distributed between social actors and the state, whereby governments do not have a monopoly on the execution of power and control (Rose & Miller 1992). *Ungovernability* connects to the autonomy of actors or systems in that they continue to act and develop in the absence of

[3] Instead of referring to ‘regulatory arrangements’ some authors refer to the term ‘self-regulation’ (e.g. Ayres & Braithwaite 1992).

[4] Soft regulation instruments comprise voluntary reporting schemes, voluntary risk management systems and benchmarks, codes of conducts, guidelines and auxiliaries (Meili & Widmer 2010) and they might be established by public as well as private organizations (Zumbansen 2011).

intervention. As such, "[a]ctors or systems are self regulating, and regulation cannot take their behavior as a constant" (Black 2002: 4).

This understanding implies that regulation also results in unintended behavioral changes and that the form of regulation should vary depending on the stance of the regulatee towards compliance (Grabosky 1995). Moreover, no one single actor can dominate regulation unilaterally since all actors can be restricted by the autonomy of others as well as by their own knowledge (Kooiman 1993). Therefore actors are, to a certain extent, unreceptive to external regulation. *Interdependencies* and interactions refer to the co-production of regulation through mutual relationships between government and elements of society, each exhibiting certain problems and needs, solutions and capacities (Black 2002: 5). Lastly, a decentered perspective states that regulation 'happens' in the absence of formal legal sanctions, being the product of interactions, and not of the exercise of the formal, constitutionally recognized authority of government (Black 2002: 6). Against this background, governmental and non-governmental actors are conceived of as interacting in 'hybrid' organizations or governance arrangements (Dorbeck-Jung et al. 2010).

Regulation, in the context of a decentered understanding, is defined by Black as "the sustained and focused attempt to alter the behavior of others according to defined standards or purposes with the intention of producing a broadly identified outcome, which may involve mechanisms of standard-setting, information-gathering and behavioural-modification" (Black 2002: 20). Black's influential definition of regulation has been adopted broadly in this thesis. Taking up her conceptualization of regulation implies the view that rules do not only emanate from the state alone, but also emerge from processes of problem-solving that involve non-governmental actors, having available a set of instruments based on written or unwritten norms, without the use of legally binding force.

Taking such a perspective is useful for studying the regulation of nanotechnology (Bowman & Hodge 2008). This approach assumes that successful regulation of nanomaterials derives from a range of broader issues that cross the borders of society, policy and science, forming an 'emerging governance landscape of nanotechnology' (Kearnes & Rip 2009: 3). In that way nanotechnology is conceived as being co-regulated by a multiplicity of private and public actors and at multiple governance levels. On a more general level business associations are identified as having a meaningful position, particularly in the regulation of OHS risks (Aalders & Wilthagen 1997).

To date, we lack a comprehensive account of how business associations are engaged in contributing to the regulation of potential OHS risks in workplaces. Research in this area is important as leading chemical associations worldwide, e.g. in the US and the EU, have made nanomaterial OHS a priority. In the US and the EU these associations have entered into intensive discussion with public policy-makers on the scope and direction of regulatory approaches to nanomaterial OHS. In Europe, the German Chemical Industry Association (VCI) has been engaged most intensively in the topic of workplace health and safety regarding nanomaterials since 2003 (see Society for Chemical Engineering and Biotechnology (DECHEMA) & VCI 2007); in the US the American Chemistry Council (ACC) started action on this matter in 2005. This thesis focuses on these two business associations in Germany and the US, which currently display comparable employer legal provisions on safe workplaces, to assess the emergence of co-productive regulatory approaches under conditions of risk uncertainty.

The rationale for a focus on the US and Germany is their forefront position in the manufacturing of nanomaterials; although there is few and conflicting data about the actual amounts of nanomaterials produced, surveys have estimated that overall production quantities of engineered nanomaterials are highest in the US, followed by Europe and Asia (Piccinno 2012; Roco et al 2011). As believed, within Europe, Germany accounts for the highest (documented) number of firms that produce nanomaterials (Invernizzi 2011). Even though the US and Germany are, thus, comparable it shall need to be acknowledged that, while clear statements can be made about Germany–i.e. a (federal) nation state–this is not necessarily possible for "the US" as a federation of states. Even though OHS is regulated in the US at the federal level, the eleven circuit courts may well differ in their opinion on what constitutes acceptable OHS measures and instruments.[5]

1.3 Research questions and aim

This thesis seeks to find conditions, including relations between them, under which collaborative activities initiated by business associations within the US and Germany, and involving regulators, contribute to effective nanomaterials OHS regulation through learning processes. A number of business associations are actively engaged in the OHS debate and may possess resources crucial for the protection of health and safety at workplaces where employees handle nanomaterials. At the same time, little is known as to what such activities contribute to effective OHS regulation. Therefore the main research question underpinning this thesis is:

What can be learned from the activities by business associations, in the US and Germany, aimed at contributing to effective nanomaterials OHS regulation?

Answering this question requires us to answer a range of subordinate questions. In this line, first it is necessary to identify and describe the OHS laws applicable to nanomaterials in the US and Germany. Since Germany is an EU member country it is necessary to identify and describe EU legislation including its translation into German legislation. How to handle chemical substances and related risks at workplaces is grounded in various pieces of general OHS legislation and employer obligations that also apply to nanomaterials. These obligations are connected to the scientific debate on nanomaterials and related challenges as to the formulation of risks. In this respect, the first subordinate question to be answered is:

1. What are the specific challenges of nanomaterials and how are they related to legal obligations with regard to OHS in the US and EU?

Second, there is a need to examine the nano-related activities by business associations that are aimed at contributing to effective nanomaterials OHS regulation because regulatory activities are embedded in those activities. To this end, activities by business associations are approached in the light of a broader rational of association existence, as depicted in the regulatory literature. This discussion sets the context in which collaborative association activities are investigated. Therefore, the question to be answered is:

2. How can we *describe* the activities by business associations directed at effective nanomaterials OHS regulation?

[5] Some US states have taken a more, or less, proactive approach to nanomaterials; e.g. in December 2006 Berkeley, California amended its hazardous material ordinance and required manufacturers and users of nanomaterials shall disclose toxicity data of their reported materials and how the materials will be safely handled (Monica et al. 2014).

Third, since business association activities will be analyzed in terms of their level of collaboration and effectiveness, a theoretical framework and analytical categories need to be developed that consider regulatory effectiveness as a process. In this respect the question to be answered is:

3. How can business association activities as a process towards effective nanomaterials OHS regulation be *evaluated*?

Fourth, the theoretical framework will be applied to analyze business association collaborative activities in the US and Germany, which are directed at nanomaterials OHS regulation. The related question to be answered is,

4. How do collaborative activities of US and German business associations contribute to effective nanomaterials OHS regulation *in practice*?

This thesis refers to collaborative activities, initiated and sustained by business associations, which are directed at contributing to nanomaterials OHS regulation. In this relation, a total number of 40 association activities are described and analyzed over a period from 2003 to 2014. Collaborative business association activities may show certain commonalities and/or differences in the US and German regulatory context. Comparing business association activities in the US and Germany can provide useful insights on conditions of effective nanomaterials OHS regulation. In this context, the question to be answered is:

5. What are the *commonalities and differences* between US and German collaborative business association activities with regard to effective nanomaterials OHS regulation?

The main research question will be answered and lessons are drawn for the effective regulation of nanomaterials OHS. Key insights from the answers to the five subordinate research questions are conveyed in order to contribute to our understanding of the role of various policy actors in developing regulatory approaches, in certain jurisdictions, under conditions of scientific uncertainty.

1.4 Outline of the thesis

Chapter 2 concerns the broader problem definition and contextualization of the thesis's topic and answers subordinate question 1. The multiple scientific issues regarding nanomaterials are described and related to the employee legal obligation to care for safe workplaces within the US and EU (respectively the German) regulatory context. The process of risk assessment at workplaces is described as posing challenges, and uncertainty, to employers.

Chapter 3 addresses subordinate question 2. Business association activities directed at contributing to effective nanomaterials OHS regulation are described in view of collective and individual goods.

Chapter 4 provides the analytical framework for the investigation of business association activities and thereby answers subordinate question 3. Drawing on the network governance literature, key conceptualizations and building blocks for the analysis of effective nanomaterials OHS regulation through collaboration by private and public actors are developed. Based on this discussion, selective analytical categories are established, which allow for the investigation of business association activities.

Chapter 5 identifies, and discusses, the method underlying this thesis. To that end the case study method is chosen and critically discussed. The case selection strategy is explicated and appropriate techniques for empirical data generation and analysis are identified.

In chapters 6 and 7 empirical answers to subordinate question 4 are provided. In this respect two case studies of business associations, one within the US and one within Germany, are subject to in-depth study. Chapter 6 investigates the US business association that initiates collaborative activities directed at contributing to OHS in work with nanomaterials. In chapter 7 collaborative business association activities by a German association are investigated.

Chapter 8 reflects on the main findings from chapters 6 and 7 by answering subordinate question 5. Comparing activities by two business associations in different regulatory contexts provides a rich set of experiences as to the effective regulation of nanomaterials OHS.

Lastly, chapter 9 answers the main research question and draws lessons for effective nanomaterials OHS regulation. The limits and opportunities of co-regulation for nanomaterials OHS are fleshed out and a tentative outlook for future research is provided, which points to interesting new research directions.

Chapter 2

The problem of nanomaterials OHS under conditions of scientific uncertainty

This chapter answers subordinate research question 1, *What are the specific challenges of nanomaterials and how are they related to legal obligations with regard to OHS in the US and EU?* To answer the question, challenges related to assessing the toxicity and risks of nanomaterials are identified, in section 2.1, by reviewing the scientific literature. The aim is to deliver an informed background to which, in section 2.2, we can relate US and EU OHS legislation that sets out general employer obligations applicable to nanomaterials at workplaces. In this respect, challenges for employers to comply with their obligation to protect the health and safety of employees, who handle nanomaterials at workplaces through conducting risk assessment, are identified. Against this background, in section 2.3, specific activities related to nanomaterials at workplaces are identified that aim at contributing to nanomaterials OHS under conditions of uncertainty.

2.1 Overview of nanomaterials: Toxicology, risks, and risk assessment

In scientific terms 'nano' refers to one billionth, thus one nanometer (1nm) is 1/1,000 000 000 of a meter, or 10^{-9} (Ratner & Ratner 2003). 'Nanotechnology' refers not to a single technology, but rather to an umbrella term that denotes specific activities, or ways of doing things; namely to manipulate matter at the nanoscale (usually 1-100nm), which allows reconfiguring the chemical, physical and biological characteristics of materials to create systems or materials that have new properties or functions (Mandel 2008; Maynard 2007).

Materials on the nanoscale, or materials containing nanoscale structures (internally or on their surface), are 'nanomaterials' (see, for a graphical overview, Figure 2.1). They can include naturally occurring nanoparticles like volcanic ash, sea-air or mineral composites as well as manufactured nano-objects (e.g. nanoparticles, nanotubes, nanoplates[6]) (NNI n.d.a). While nanomaterials may originate from sources such as open fire, diesel engine exhaust or welding fumes, they can also be engineered intentionally in order to create specific novel properties that differ from non-nanoscale materials. It is uncertain whether, and under which circumstances, these engineered nanomaterials create human health risks. Therefore this thesis focuses on engineered nanomaterials.

[6] Nanoparticles are part of materials in which all three dimensions are within the nanoscale. Nanotubes can be several hundred nanometers long but have a diameter in the nanoscale. Nanoplates can be large in two dimensions but have a thickness at the nanoscale (NNI n.d.a).

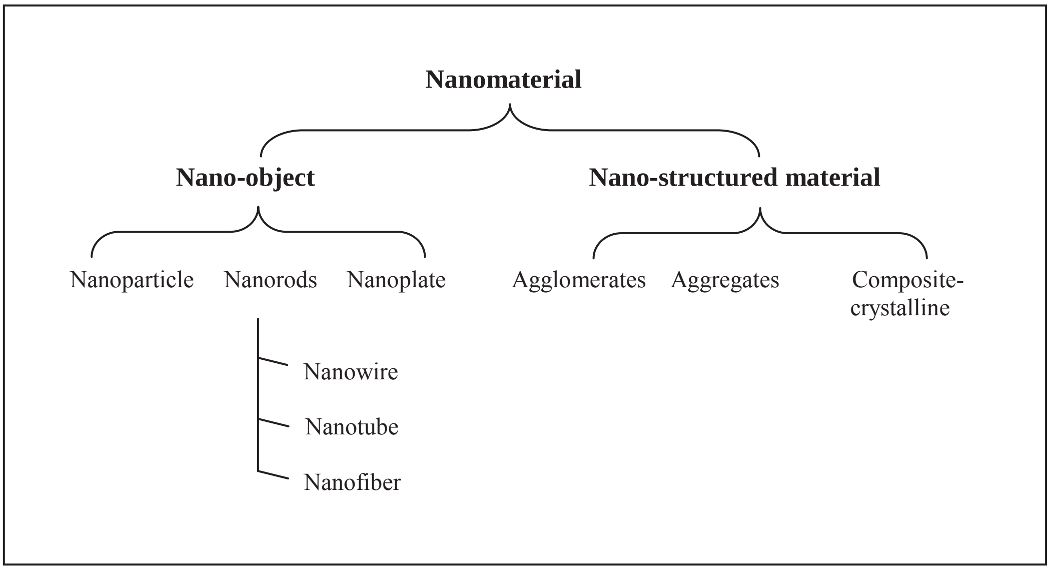

Figure 2.1. Overview nanomaterials (adopted from Packroff 2012).

At the nanoscale matter, such as solids, liquids, or gases, may exhibit properties that essentially differ from their physical, chemical, and biological properties compared to those of bulk materials, atoms, or molecules. Certain materials, for instance graphene nanoplates, have a higher thermal and electrical conductivity (Data and Knowledge on Nanomaterials (DaNa) 2.0 2012), or gold nanoparticles are known for high durability and resistance (Giljohann et al. 2010). TiO_2 particles change from white colour into coloureless as particle size decreases below 50nm (European Agency for Safety and Health at Work (EU-OSHA) 2009).

While some information on certain types of nanomaterials is available–including, for example, single and multi walled CNTs (Sargent et al. 2014; NIOSH 2013b; EPA 2012a; Nakanishi 2011a; Poland et al. 2008; OECD 2007), nanoscale TiO_2 (NICNAS 2013, NIOSH 2011, EPA 2010; OECD 2007), nanoscale silver (Massachusetts Institute of Technology (MIT) 2014; EPA 2012b, OECD 2007), and fullerene (Nakanishi 2011b; Fujitani et al. 2008)–the potential risks of many nanomaterials outside the laboratory environment are largely unknown. For instance, with regard to nanosilver concerns about the human health effects have been raised and studies have indicated that inhaled nanosilver particles lead to inflammatory responses in the lungs of rats (Sung et al. 2008). Other studies have indicated that CNTs should be used with caution (Maynard 2014; Kuempel et al. 2012) as certain CNTs, under specific conditions, have the potential to cause asbestos-like diseases or acute toxicity (Safe Work Australia (SWA) 2012).

The analogy between asbestos fibres and long and thin multiwalled CNTs was made since 2004 (Poland et al. 2008; Takagi et al. 2008; RS-RAE 2004). Especially the Australian Government was cautioned about this analogy given the legacy of mesothelioma and asbestosis in Australia, combined with other workplace dust diseases (Australian Council of Trade Unions (ACTU) 2009). Australia has, according to Mullins (2009), the worst record worldwide for asbestos-related diseases caused by inhalation or ingestion of asbestos particles in workplaces. To avoid another 'asbestos-like tragedy' the Australian Government regarded precautionary measures for the protection of workers as essential ingredient of pursuing nanotechnology; for instance, SWA stated that multi-walled CNTs should be considered hazardous unless scientific data indicate otherwise (SWA 2012).

Concern has been voiced within Europe and the US as to the health effects of CNTs, and other nanomaterials, with many research projects having been initiated to better understand potential health risks (e.g. in the EU, NanoSafe 1/NanoSafe2, Particle Risk, CarboSafe, NanoReTox, and in the US research under the lead of NIOSH and the National Nanotechnology Initiative (NNI)). Although these projects have yielded much required information, it has been suggested that additional studies are necessary to better understand the toxic effects of certain nanomaterials (NIOSH 2013b).

Engineered nanomaterials are complex as result of their physio-chemical characteristics, their behavior and interaction with living systems (Savolainen et al. 2013). Nanomaterials have a high surface area-to-mass ratio and their composition possibly presents specific concerns related to toxicity. The issue of particle surface is particularly important (Oberdörster et al. 2005a). When particle size is reduced, "the proportion of atoms found at the surface related to the atoms in the interior of the particle increases and, as consequence, the nanoscale particles are more reactive. From a health effects perspective, reactive groups on a particle surface can modify the toxicological properties" (Oberdörster et al. 2005b) (see Figure 2.2. for a graphical overview of the effect of increased surface area of nanomaterials).

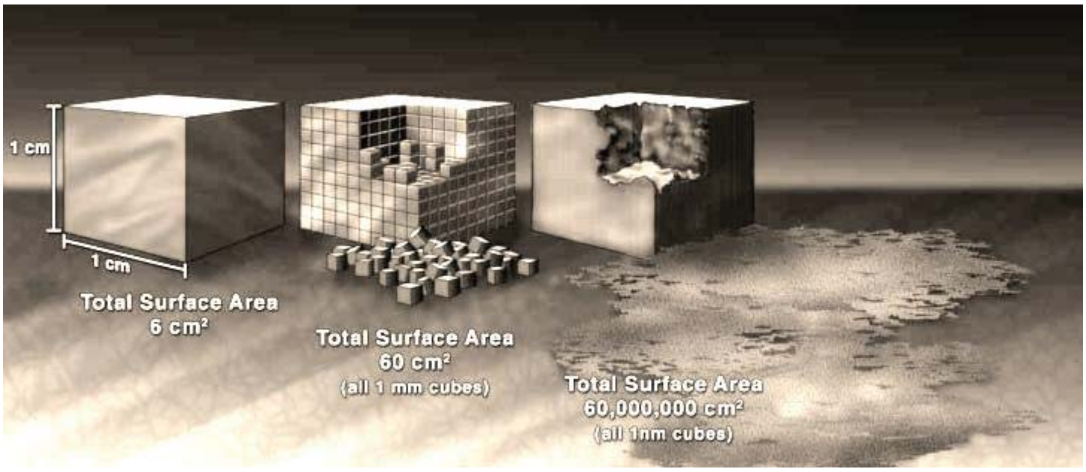

Figure 2.2. Effect of increased surface area of nanomaterials (Retrieved from NNI n.d.b).

Toxicity concerns may arise when nanoparticles enter the human organism through inhalation, dermal penetration or ingestion (Oberdörster et al. 2005a). Currently most attention by scientists (and regulators) has been paid to the effects of inhalation of free meaning airborne nanoparticles (especially CNTs, fibres and TiO_2) to the human organism (NIOSH 2013b; 2011).

Studies on respirable fine and ultrafine particles have shown that exposure, under certain conditions, can lead to fibrosis and lung tumors in the lungs of rats (Wiessner et al. 1989; Nikula 2000). In determining the carcinogenic potential of these particles it has been found that particle surface in an important factor (Ziemann et al 2010; Oberdörster et al. 2005b). Therefore concerns have been raised for nanoparticles: due to their large surface area compared to their particle mass, nanoparticles may as well be carcinogens in lungs (Pott et al. 2003). But the underlying mechanisms that lead to the development of lung tumors and the contribution of genotoxic effect are still unclear (Ziemann et al. 2011).

To identify whether certain properties of nanomaterials influence, or change, the materials behavior in biological systems like the human body on any level, for instance on a physical or chemical level, toxicologists may analyze nanomaterials *in vivo* (i.e. 'alive' meaning characterizing reactions or processes in living organisms, often rats) or *in vitro* (i.e. 'in the test tube' meaning characterizing reactions outside the organism by using animal/human cell lines) (DaNa 2.0 n.d.a). Various physio-chemical properties of nanomaterials have been identified as being potentially relevant for toxicology:

- size,
- size distribution,
- shape,
- agglomeration/aggregation,
- density,
- surface properties (area (porosity), charge, reactivity, chemistry (coatings, contaminants), defects),
- solubility/solubility rate (lipid, aqueous, in vivo), and
- chrystallinity.

These properties may change depending on the method of production, preparation, process, storage and when introduced to physiological media or an organism. Additionally the epidemiological impacts of nanomaterials–in this research their effects on the health of workers–may need to be evaluated. The key to all parameters is the dose (or concentration), i.e. the dose associated with a specified response, meaning adverse health after a certain exposure time (Oberdörster 2012).

It has been noted that toxicity levels may increase for some substances with decreased particle size and increased particle surface area (EPA 2007). For example, the toxicity of inhaled CNTs, increases as the particles get smaller and the particle surface area-to-size ratio increases (Aitken et al. 2004). However, there are other important parameters than just size: as there is not one single type of CNT their shape, chemical and physical composition, and characteristics differ from one another thereby adding to the complexity of understanding the toxicity of CNTs (NIOSH 2013b). Over the years CNTs have been studied extensively and researchers have shown that under certain circumstances multiwalled CNTs that are fibre-shaped produce length dependent inflammation, which can be comparable to the inflammatory response that long asbestos fibres cause; short multiwalled CNTs did not cause significant inflammation (Bonner et al. 2013; Donaldson et al. 2010; Poland et al. 2008; Takagi et al. 2008).

Against this backdrop, it should be noted that these studies merely refer to one specific type of toxicity, and that different designs of nanomaterials might lead to alternative toxicities. Overall it is difficult to know about biological effects caused by nanomaterials as related to their physio-chemical properties because they are likely to have different effects as compared to fine-sized particle types with similar chemical compositions (Maynard & Aitken 2007). But knowing the physio-chemical properties of nanomaterials, such as particle size distribution, particle composition and surface area, morphology, particle number concentration, particle reactivity and surface chemistry, is important in order to be able to determine risk (Maynard & Aitken 2007). As Maynard suggests, 16 physio-chemical parameters should be considered for the analysis of toxicity of one nanomaterial; in comparison, traditional toxicity analysis requires measuring merely two or three parameters (Maynard 2007). Overall Oberdörster et al. (2007) find, ‘for a full understanding of risk, exposure and toxicokinetic data are both missing, as these are required to combine with hazard data to begin to understand risk’ (p. 11). Typically, risks are identified on the basis of risk assessment.

Risk assessment of nanomaterials

Traditionally, risk assessment follows the process of hazard identification, hazard characterization, exposure assessment and risk characterization (OECD 2012; SWA 2009; National Research Council (NRC) 1983). Risk is understood in terms of a quantitative relationship between am organism'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). The prevention, and control, of risks related to nanomaterials, being potentially hazardous substances at workplaces, is currently challenging. It is difficult to conduct traditional risk assessment for nanomaterials due to uncertainties both in regard to scientifically coherent data relating to hazard and human exposure (comprising potential exposure pathways) and the duration of anticipated levels of exposure (NIOSH 2009a; Poland et al. 2008; Oberdörster et al. 2007; Scientific Committee on Emerging and Newly Identified Health Risks (SCENIHR) 2006; Nel et al. 2006).

For most nanomaterials, the scientific basis of risk assessment suffers from considerable limitations (Savolainen et al. 2013). For instance, conducting risk assessment for nanosilver is not yet feasible due to insufficient data on potential toxicities (Wijnhoven et al. 2009) and ongoing research is needed to help better understand how toxicity is mediated under certain conditions (Foss Hansen et al. 2013; Mikkelsen et al 2011).

Typically the first step in a risk assessment is the identification of hazard. In order to understand potential health impacts of substances in a biological system, e.g. the human body, the potential for a material to cause harm (hazard potential) and the amount of that material to be able to reach target organs in the body (exposure potential) must be known (Maynard 2007). But overall hazard identification for nanomaterials is difficult as 'there is uncertainty about what to measure, and how to measure it' (Shatkin et al 2010). Even though a multitude of variables have been proposed (e.g. size, surface characteristics like chemistry charge, porosity etc.) and validated in regard to specific nanoparticles, it is impossible to derive any generalizing conclusions as regards patterns of particle uptake and effect (Treuel et al. 2013; Oberdörster et al. 2007).

Measurements for the characterization of nanomaterials are further complicated in two aspects:

1. the properties of some nanoparticles may change over time with ambient conditions or other physio-chemical conditions, and
2. usually nanomaterials consist of a mixture of particle sizes and impurities that result in a complexity of factors (Shatkin et al. 2010: 1681).

Even though a variety of physical and chemical parameters for measurement to scale with hazard have been proposed, these units must still be linked, relative to their priorities, with risk characterization (Oberdörster 2005b). So far there is no model to predict hazard solely based on the physicochemical characteristics of nanomaterials which could be used for risk assessment (Oberdörster et al. 2007).

The next step in conducting risk assessment is monitoring occupational or environmental exposure to nanomaterials. In an OHS setting, exposure assessment characterizes the degree and frequency of human worker contact with nanomaterials at the workplace. Human exposure is likely to occur less during manufacturing processes, which are mostly executed in closed systems; however, exposure may occur during conventional activities–e.g. opening the system to remove the manufactured product, cleaning activities, transport, storage or waste treatment–involving nanomaterials as well as during accidental leakage (Van Broekhuizen 2012; Kaluza et al. 2009; Yeganeh et al. 2008; Mazzuckelli et al. 2007). Thus, various exposure paths are possible and must also be considered.

Conducting exposure assessment for nanomaterials brings various difficulties with it. First, traditional exposure assessment does not consider parameters that have been identified as key elements of nanomaterials: typically the mass of a chemical substance is relied upon as the exposure dose, but for nanomaterials other exposure parameters (the surface area and its reactivity) have been identified as potential key elements and shall need to be considered in exposure assessments (Shatkin et al. 2010). A more pragmatic approach to exposure assessment is taken by 'tiered-type' strategies according to which exposure information is collected on successive tiers, starting with basic measurements and information gathering followed by more extensive assessments in the succeeding tiers (Brouwer et al. 2012). On this basis decisions can be taken to either continue or stop data collection (see, for instance, proposed strategies by the British Standard Institution (BSI, 2010), or the VCI (Reuter et al. 2011)).

A second difficulty in exposure assessment is the lack of standard techniques for sampling and analytical methods to measure exposure (NIOSH 2013b; Brouwer et al. 2012). Background exposure to nanomaterials can often only be assessed and characterized by use of highly complex techniques, and distinguishing between engineered and incidentally occurring nanomaterials (e.g., through the operation of machines) requires specific technical expertise (Ramachandran et al. 2011). In this relation, analytical methods such as imaging techniques (scanning electron microscopy (SEM), transmission electron microscopy (TEM), dynamic light scattering (DLS)) may be necessary in order to identify the chemical nature and shape of nanomaterials (Sayes & Santamaria 2014). Many of these specialized techniques are not applicable to routine exposure measurements at workplaces (Abbott & Maynard 2010).

Given these challenges, there is little data on human exposure to nanomaterials (the level as well as the duration of exposure) and, importantly, 'since risk is a function of hazard and exposure, knowledge of both hazard and exposure are necessary to determine a risk' (Oberdörster et al. 2007: 20). While recently the number of exposure assessment studies at workplaces has increased (NIOSH 2013b; Woskie et al. 2010), comprehensive exposure characterization is likely to remain challenging in the near future since exposure situations are diverse as regards the rate at which new nanomaterials enter the market (Brouwer et al. 2012).

The last step in the traditional risk assessment process refers to the characterization of risk. This activity requires relating hazard and exposure potential with toxicological relationships in order to define a level of concern in respect to a nanomaterial (Shatkin et al. 2010). But as noted above, at present there is too little data and too much uncertainty in regard to scientific models and parameters to conduct quantitative assessments for risks associated with most nanomaterials. As Shatkin et al. conclude, "(…) the uncertainty associated with each step of risk analysis culminating with risk characterization raises concerns about unidentified or poorly quantified adverse effects" (2010: 1684). Such uncertainty has led some experts to propose conducting qualitative risk assessments for nanomaterials (e.g. SWA 2009).

An example of qualitative risk assessment for nanomaterials is control banding. Here, a single control technology (e.g. general ventilation) is applied to a defined exposure range (the 'band') of a chemical, which falls in a given hazard group (e.g. harmful by inhalation) (SWA 2010: 27). Following this approach, exposure at workplaces is not actually measured by employers–experts who develop control banding do this–because the tool "(…) includes the estimation of a specific hazard band for which a hazardous substance is assigned, based on risk statements (often from a Material Safety Data Sheet (MSDS)) in combination with other factors, such as the substance's volatility" (SWA 2010: 27). While qualitative risk assessment has its merits, others have identified the quantitative risk assessment framework as adequate for nanomaterials under the premise that 'some amendments' will be necessary (e.g. Shatkin et al. 2010; SCENIHR 2006).

Against this backdrop, when talking about risk assessment and potential health risks of nanomaterials, it shall need to be acknowledged though that, to date, no conclusive harm to humans (Hull & Bowman 2014) and the worker population at large (NIOSH 2013b) has actually been shown. But having no evidence of harm at present may not automatically imply that there will be no harm in the future. Often latency periods of chemicals are long; for instance, harmful effects of exposure to asbestos in form of cancer can have a latency period ranging from approximately 10 to 70 years (Bianchi et al. 1997). Certain types of nanomaterials may have comparably long latency periods (SWA 2009: 23). Therefore, a precautionary approach to certain nanomaterials that are handled at workplaces should be taken until we have more conclusive knowledge (NIOSH 2013b; VCI & German Federal Institute for Occupational Safety and Health (BAuA) 2007).

So far, workers who handle nanomaterials in workplaces are protected by general, non-nano specific OHS legislation in form of employer duties to care for safe workplaces. In the following part these general OHS legal obligations are identified and described in the context of Europe (and specifically Germany) and the US to, later, pinpoint specific challenges for employers seeking to comply with existing OHS legislation in view to nanomaterials.

2.2 Occupational health and safety legislation and regulation

Nanomaterials in workplaces are not regulated specifically, but rather generally as 'chemical substances'. Both EU and US key regulatory bodies such as the EC and the Executive Office of the President render existing chemicals and OHS legislation as adequate for nanomaterials (Holdren et al. 2011; EC 2008) even though regulatory challenges have been identified (Marchant et al. 2007; RS-RAE 2004; Wardak 2003). With regard to OHS practices general obligations and statements rather than precise definitions are used to describe principles and duties of care.

Against a background of fundamental data gaps on the risks of certain nanomaterials and how to conduct risk assessment adequately, employers in the US and EU are legally obliged to care for the safety and health of their employees by having risk assessment for chemicals in place. In case of non-compliance employers may be subject to civil penalty by a legal court of justice.

United States

In the US, the Occupational Health and Safety Act (OSHAct) of 1970 regulates OHS within workplaces. OSHA, an agency of the Department of Labor was established under the OSHAct and still is responsible for setting and enforcing health and safety standards. Specifically section 5(a)(1) requires that each employer "shall furnish . . . a place of employment which is free from recognized hazards that are causing or are likely to cause death or serious physical harm to his employees." Under the OSHAct, one of the main tasks of risk management is to identify, assess and eliminate or reduce risks, which include the prevention or minimization of exposure to hazardous substances.[7] Employers have a duty to provide employees with safe

[7] See, American Occupational Safety and Health Act, 1970, section 5(a)(1).

workplaces 'free from recognized hazards that are causing or are likely to cause death or serious physical harm'[8]. As Howard and Murashov (2009) specify, the use of this general obligation "(…) is limited to cases in which the hazard is shown to be a 'recognized hazard,' that the injuries suffered were linked to the recognized hazard, and that it was feasible for the employer to eliminate the hazard" (p. 1677). In order to show that the hazard is 'recognized' reference to scientific evidence from authoritative sources like documents from the NIOSH, which is charged by the OSHAct to recommend occupational safety and health standards to OSHA, are required. Reference may be made to peer-reviewed scientific papers or industry guidelines.

In addition to general OHS legislation, the Environmental Protection Agency (EPA) regulates (use of) chemicals, based on various statutes, most importantly the Toxic Substances Control Act (TSCA) of 1976.[9] TSCA regulates the use of hazardous chemical substances to ensure protection against health and environmental risks[10]. In this relation, employers are required to provide data on the health effects and (potential) risks of nanomaterials handled at workplaces (TSCA, sections 2 and 4). Under the TSCA the EPA is authorized to prohibit or limit chemical substances on the basis of risk assessment and under the condition that the manufacturing, processing, distribution in commerce, use, or disposal of these substances presents an unreasonable risk of injury to health or the environment.[11] Under the TSCA manufacturers have to record potential adverse effects of chemicals to be reported to EPA timely.

The introduction of risk assessment in federal regulation was signalized with the United States Supreme Court decision in *Industrial Union Department, AFL-CIO v. American Petroleum Institute (the Benzene Case)*, 448 U.S. 607 (1980). The case challenged the OSHA's practice to regulate carcinogens by standards at the lowest technologically feasible level to not harm the viability of the regulated industry. Pursuant to the OSHAct, section 6(b), article 5, where toxic materials or harmful physical agents are concerned, the agency's Secretary shall "set the standard which most adequately assures, to the extent feasible, on the basis of the best available evidence, that no employee will suffer material impairment of health or functional capacity." The OSHA Secretary took the opinion that, where toxic materials or harmful physical agents to be regulated are carcinogens, no safe exposure levels can be established and exposure limits shall be set "at the lowest technologically feasible level that will not impair the viability of the industries regulated".

In the case of benzene, after the Secretary had determined a causal connection between benzene and leukemia, he promulgated a standard that reduced the permissible exposure limit on benzene from the consensus standard (10 parts of benzene per million parts of air, 10 ppm) to 1 ppm. The Fifth Circuit Court of Appeals, on pre-enforcement review, rendered OSHA's standard invalid as it was grounded on findings not supported by the administrative record. The US Supreme Court affirmed the judgment, arguing that,

> "OSHA's rationale for lowering the permissible exposure limit from 10 ppm to 1 ppm was based not on any finding that leukemia has ever been caused by exposure to 10 ppm benzene, and that it will not be caused by exposure to 1 ppm, but rather, on a series of assumptions indicating that some leukemia might result from exposure to 10 ppm, and that the number of cases might be reduced by lowering the exposure level to 1 ppm (Stevens et al.)."[12]

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[8] See, 29 USC 654(a)(1).
[9] The statutes include, next to the TSCA, the Clean Air Act, the Clean Water Act, the Federal Insecticide, Fungicide, and Rodenticide Act and the Resource Conservation and Recovery Act.
[10] Id. §§ 2601-92.
[11] Id. § 2605.
[12] Industrial Union Department, AFL-CIO v. American Petroleum Inst., 448 U.S. 607 (1980). Pp. 448 U. S. 630-638.

Further, the US Supreme Court held that before adopting a health standard OSHA would have to first demonstrate that the workplaces in question are not safe, meaning that significant risks are present. In the aftermath of the Benzene Case OSHA had to conduct a risk assessment specifically for every new toxic agent for which it proposes to set a permissible exposure limit (PEL) (Howard & Murashov 2009).

In 1992 OSHA wanted to revise various 'old' PELs to establish a reduced number of 'new' PELs based on a generic approach. Its efforts, however, were blocked by the 11th Circuit Court of Appeals because the Agency was found not to have conducted the risk assessments properly (i.e. it failed to prove that each separate PEL would reduce a significant risk to employee health).[13] The 11th Circuit Court of Appeals ruling made risk assessment the standard for regulatory agencies, and led to significant political action in terms of the US Congress commissioning the NRC to recommend an explicit risk assessment strategy for government (van Calster 2008). The NRC Risk Assessment in the Federal Government: Managing Process (1983) recommended to clearly distinguish between risk *assessment* (embodying scientific findings and policy judgments) and risk *management* (assessing trade-offs between health consequences of regulatory actions and making value judgments).

With respect to the general employer obligation to conduct risk assessment to create safe workplaces, it has been recommended to use existing OSHA occupational safety and health standards for the protection of workers who handle nanomaterials until feasible risk controls are identified (Davies 2008). While, from a scientific point of view (see section 2.1), exposure to airborne nanomaterials at workplaces is uncertain, calls have been made to take a proactive approach to mitigate exposure (Howard & Murashov 2009). To that end employers could, for instance, apply control strategies in form of Reccomended Exposure Limits (RELs) developed by NIOSH. The Institute has, so far, developed RELs for nano-scaled TiO_2 and CNTs and nanofibres (NIOSH 2013b; 2011).

In line with using general OHS standards for nanomaterials, the EPA approaches nanomaterials in most cases as 'existing' chemicals rather than chemicals with specific new uses. EPA defines a 'chemical substance' in general terms as 'any organic or inorganic substance of a particular molecular identity, including – (i) any combination of such substances occurring in whole or in part as a result of a chemical reaction or occurring in nature and (ii) any element or uncombined radical'.[14] In relation to this definition the EPA states that nanomaterials, which have the same molecular identity as non-nanoscale substances that are considered 'existing chemicals' on the inventory listing under TSCA, may be considered 'existing' despite their differences in regard to particle size and physical and chemical properties (Blaunstein et al. 2014). But when EPA determines that an existing chemical constitutes a 'significant new use', manufacturers of that substance must provide specific information to EPA prior to manufacture ('premanufacture notification'). Whether a chemical is subject to 'significant new use' is determined by various factors[15] with none of these factors being conclusive by themselves (Monica et al. 2014: 288). To date (February 2015), EPA has issued significant new use rules for two nanomaterials–siloxane-modified silica nanoparticles and siloxane-modified alumina nanoparticles–as inhalation and dermal exposure to these substances was not considered under the uses stated in the premanufacure notification (ibid).

[13] American Federation of Labor-Congress of Industrial Organizations v. OSHA., 965 F.2d 962 (11th Cir. 1992).
[14] Id. §2602(2)(A).
[15] See Toxic Substances Control Act, 15 U.S.C. §2604(a)(2).

European Union and Germany

In the EU, one of the most important pieces of legislation with regard to health and safety at work is the Framework 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. It lays down the specific tasks of the employer duty to ensure safety and health of workers; to that end 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, and
d) draw up for the responsible authorities on occupational accidents[16].

Directive 98/24/EC lays down minimum requirements for worker protection from risks to their safety and health which arise, or are likely to arise, from the effects of chemical agents present at the workplace or any activity involving chemical agents (section 1, article 1). Pursuant to section 2, article 4(1), to carry out the obligations of Directive 98/24/EC, the employer shall;

1. Determine whether any hazardous chemical agents are present at workplaces
2. If so, any risk to the safety and health of workers arising from those chemical agents shall be assessed by considering:
    a) their hazardous properties;
    b) information on safety and health provided by the supplier (e.g. relevant safety data sheets in accordance with the provisions of Directive 67/548/EEC or Directive 88/379/EEC);
    c) the level, type and duration of exposure;
    d) the circumstances of work;
    e) any occupational exposure limit values established by Member States;
    f) the effect of preventive measure to be taken;
    g) where available, conclusions to be drawn from health surveillance already undertaken.
3. Further, the employer shall obtain additional information as needed for risk assessment from the supplier or other sources

In regard to risk assessment and management, employers must conduct these tasks according to the latest state of science and *as low as reasonably practicable* (ALARP). This concept involves "(…) weighting a risk against the trouble, time and money needed to control it" (Health and Safety Executive (HSE) n.d.). The concept has been defined in UK case law by the Court of Appeal (in its judgment in *Edwards v. National Coal Board*, [1949] 1 All ER 743[17]):

[16] Framework Directive 89/391/EEC of 12 June 1989, section ll, article 9(1).
[17] In English case law *Edwards v. National Coal Board* was an important case that revolved around the issue whether it is reasonably practicable to, in a coal mine, prevent any possibility of rock falling after Mr. Edwards died when the supporting structure of the mine roadway collapsed. The National Coal Board argued that shoring up all roadways in the mine was too expensive and eventually it was decided that indeed not all roadways needed to be shored up, but only those, which required it.

> "'Reasonably practicable' is a narrower term than 'physically possible' … a computation must be made by the owner in which the quantum of risk is placed on one scale and the sacrifice involved in the measures necessary for averting the risk (whether in money, time or trouble) is placed in the other, and that, if it be shown that there is a gross disproportion between them – the risk being insignificant in relation to the sacrifice – the defendants discharge the onus on them."

While ALARP has emerged in UK common law, it is also rooted in EU (and US) law, under the name ALARA (*as low as reasonably achievable*). In the EU, ALARA is embedded in worker protection from the risks of exposure to ionizing radiation; under Council Directive 96/29/EURATOM (section 6), the Member States shall implement ALARA. Under the patronage of the EC, the European ALARA Network (EAN) broadens the scope of the principle by furthering research and good practices aimed at optimizing all types of occupational exposure in industry and research (EAN n.d.).[18]

Thus, ALARP/ALARA describes the level to which workplace risks are expected to be controlled. However, in reality factors and decisions about risks and their controls may be less obvious and require judgment, which may make the decision whether a risk is ALARP/ALARA challenging (HSE n.d.). Making this decision–as well as complying with the aforementioned provisions of the Directives with regard to risk assessment–appears particularly challenging in situations of scientific uncertainty. Under circumstances of scientific uncertainty guidance materials issued by competent authorities shall be used.

In the context of risk assessment and management it is interesting to note that the EU follows a different approach than the US. As mentioned before, in the US risk *assessment* (embodying scientific findings and policy judgments) is clearly distinguished from risk *management* (assessing trade-offs between health consequences of regulatory actions and making value judgments) (NRC 1983). This approach stands in contrast with the EU approach, in which a clear separation between risk assessment (scientific activity) and management (political activity) was only made in the aftermath of the Bovine Spongiform Encephalopathy (BSE) crisis; with the 2002 Regulation 178/2002 the two activities were distinguished[19].

In addition to the above mentioned OHS legislation that lays down employer obligations to secure the health and safety of workers, chemicals at workplaces are also regulated by various directives that are applicable to nanomaterials and the Registration, Evaluation, Authorisation and Restriction of Chemicals (REACH) Regulation. REACH, partially entered into force in June 2007 and will be fully implemented in 2018, with the aim to progressively replace various directives and regulations applicable to chemicals. REACH, the counterpart to the TSCA in the US, applies broadly to all chemical substances (nanomaterials are not mentioned specifically) (Bowman & van Calster 2007).

Pursuant to Article 6(1) of the REACH Regulation, importers and manufactures must register a chemical substance each calendar year. The registration is volume-based and must consist of a technical dossier and a safety report with information regarding the substances properties together with a safety assessment that includes a hazard characterization and, under

[18] In the US, ALARA is mandated by the Nuclear Regulatory Commission and is defined under the Code of Federal Regulations, title 10, section 20.1003 (10 CFR 20.1003).

[19] See, Regulation (EC) No 178/2002 of the European Parliament and of the Council of 28 January 2002 laying down the general principles and requirements of food law, establishing the European Food Safety Authority and laying down procedures in matters of food safety. Article 3(11) states that 'risk assessment' means a scientifically based process consisting of four steps: hazard identification, hazard characterisation, exposure assessment and risk characterisation. Article 3(12) states that risk management' means the process, distinct from risk assessment, of weighing policy alternatives in consultation with interested parties, considering risk assessment and other legitimate factors, and, if need be, selecting appropriate prevention and control options.

certain circumstances, an exposure assessment and risk characterization.[20] As such, manufacturers and importers shall provide information that ensures their chemicals do not have adverse effects on human health or the environment. Accordingly a registrant shall identify and apply appropriate risk management measures.[21] The dossier, to be send to the European Chemicals Agency (ECHA), must also identify data gaps for specific information requirements applicable to chemical substances.[22]

Companies initially had to register all chemical substances manufactured or imported in the European Union in quantities above 1000 tons per year; when the deadline passed on November 2010 eventually more than 25,000 registration dossiers were submitted (Vencesla 2011). The second deadline for registration was on 31 May 2013, by which time manufacturers and importers had to register all chemical substances above 100 tons per year; more than 9,000 dossiers were submitted (ECHA 2013). The last registration deadline, for chemical substances in quantities above 1 ton per year, is in June 2018.

In addition to the REACH Regulation, today, various directives (still) regulate chemicals at workplaces. The Council Directive 98/24/EC of 7 April 1998 on the protection of the health and safety of workers from the risks related to chemical agents at work applies to any work activity involving chemical agents being likely to expose workers to risk. It is stated in article 5 and 6 that employers have the obligation to conduct risk assessments of any hazardous chemical agent present at the workplace and to identify and implement preventive measures to ensure a safe work environment. Other applicable directives are mentioned in Table 2.1.

Table 2.1. Overview EU Directives that regulate chemicals at workplaces.

Directives regulating chemicals at workplaces	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
	Council Directive 98/24/EC of 7 April 1998 on the protection of the health and safety of workers from the risks related to chemical agents at work
	Council Directive 89/655/EEC of 30 November 1989 concerning the minimum safety and health requirements for the use of work equipment by workers at work
	Council Directive 89/656/EEC of 30 November 1989 on the minimum health and safety requirements for the use of personal protective equipment at the workplace
	Directive 1999/92/EC of the European Parliament and of the Council of 16 December 1999 on minimum requirements for improving the safety and health protection of workers potentially at risk from explosive atmospheres

EU Member States are responsible for the accurate and timely implementation of OHS and chemicals legislation and they have to ensure that their legislation complies with EU law. Since this thesis is concerned with OHS practices in Germany, the implementation of EU directives in German legislation are explained briefly.

Framework Directive 89/391/EEC is implemented in German legislation with the Safety and Health at Work Act or the ‘Arbeitsschutzgesetz’ (ArbSchG). Pursuant to section 2, article 5(1), employers must ensure, and improve, health and safety at workplaces through conducting risk assessment for (under more) chemicals that may involve a risk and that are handled at workplaces. The results of the risk assessment serve to inform the choice for health

[20] See, Regulation (EC) No 1907/2006 of the European Parliament and of the Council of 18 December 2006, Articles 6 and 14.

[21] See, Regulation (EC) No 1907/2006 of the European Parliament and of the Council of 18 December 2006, Article 14.

[22] See, Regulation (EC) No 1907/2006 of the European Parliament and of the Council of 18 December 2006, Annex 6.

and safety measures. The employer must document the results of the risk assessment and the measures that have been taken to ensure the health and safety of workers (ArbSchG, article 6).

Next to the ArbSchG, the Hazardous Substances Ordinance of 26 November 2010 (BGBl. I p. 1643) ('Gefahrstoffverordnung', GefStoffV) is relevant for OHS and serves to implement Council Directive 98/24/EC. Pursuant to section 3, article 6(1) of the GefStoffV employers are required–on the basis of the results from risk assessment–to establish whether workers perform activities involving hazardous substances, or whether hazardous substances may arise, or be released during workplace activities. If this is the case, all risks to the health and safety of workers need to be assessed in respect to the following aspects:

1. Hazardous substances of the substances/preparations including their physico-chemical effects,
2. Information of the manufacturer/legal entity responsible for placing the substance on the market (specifically information from safety data sheets),
3. Nature and extent of exposure taking into account all exposure routes,
4. Possibilities of substitution,
5. Working conditions and processes,
6. Occupational exposure limits (OELs)[23] and biological limit values,
7. Effectiveness of protective measures taken, or to be taken, and
8. Knowledge gained from preventative medical examinations.

In addition, risk assessment and measures to ensure, or improve, health and safety at workplaces shall be in accordance with various Technical Rules for Hazardous Substances ('Technische Regeln für Gefahrstoffe', TRGS) if available through the BAuA. TRGS are determined and adapted by the Hazardous Substances Committee ('Auschuss für Gefahrenstoffe', AGS) of the Federal Ministry of Labour and Social Affairs and reflect the state of the art technology, science, and occupational health related to work with hazardous substances.

While the AGS has not (yet) developed a TRGS for nanomaterials, the body has developed a guidance document for employees in order to help ensure nanomaterials OHS and conduct risk assessment for nanomaterials. This document is based on the latest state of science and technology. In its Announcement 527 'Manufactured nanomaterials' the AGS provides concrete advice to employers (AGS 2013). When employers adopt the suggested approaches and measures compliance with existing legislation is supported.

Employers in Germany and the US are also advised to apply a precautionary approach in situations where substances with potentially hazardous properties, such as some nanomaterials, are handled at workplaces. In a communication on the precautionary principle, the EC outlined when and how to use the principle (EC 2000).[24] Accordingly, the EC states that the precautionary principle should be taken into considerations when scientific evidence

[23] OELs are a major tool for preventing occupational disease and serve as quantitative targets to designing controls. Airborne OELs are developed through establishing relationships between magnitude and duration of exposure to a chemical substance and the magnitude and nature of the response of employees with the goal to limit exposure to a concentration below which there is no significant threat to employee health (Schulte & Kuempel 2012).

[24] Within the EU, there are only two explicit references to the precautionary principle: One reference is made in Article 191 (environment) of the Treaty on the Funcioning of the European Union, but it is not defined there. Another reference is made in the Regulation (EC) No 1223/2009 of the European Parliament and of the Council of 30 November 2009, but also here no definition is provided. At international level, the precautionary principle was mentioned at the 1992 Rio Conference on the Environment and Development; the Rio Declaration, principle 15 states: "(…) to protect the environment, the precautionary approach shall be widely applied by States according to their capability. Where there are threats of serious or irreversible damage, lack of full scientific certainty shall not be used as a reason for postponing cost-effective measures to prevent environmental degradation".

is uncertain and there are indications through preliminary scientific evaluation that there are reasonable grounds for concern that potential hazards may affect the environment or human, animal or plant health (EC 2000: 9-10). The global reinsurance company Swiss Re was the first to call explicitely upon the precautionary principle in the context of nanotechnology (Swiss Re 2004: 47). Against this backdrop, according to the general European and US OHS regulatory regime, exposure to (potentially) hazardous chemicals that may lead to adverse health effects should be avoided, or minimized, by employing a hierarchy of controls following a precautionary approach (Federal Ministry of Labour and Social Affairs (BMAS) 2009; NIOSH n.d.). This hierarchy can be summarized as follows:

1. Elimination or substitution (e.g. by use of less hazardous substances)
2. Engineering controls (e.g. closed systems)
3. Organizational or administrative controls (e.g. worker training and education), and
4. Personal protective equipment (e.g. gloves, respiratory protection)

The hierarchy of controls is based on the idea that the control method at the top is most efficient in reducing a (potential) hazard, those at the bottom are less efficient. At the same time it is also more difficult to implement the method at the top; where it is not possible to eliminate or substitute a (potentially) hazardous substance, the second best method in the hierarchy (i.e. engineering controls) should be employed and so forth. Typically, when hazards are not well controlled, administrative controls and personal protective equipment are often employed (NIOSH n.d.).

At this moment it cannot be ensured that exposure to some nanomaterials does not lead to adverse health effects. Therefore the hierarchy of controls should be applied as a precautionary approach to ensure health and safety at workplaces (VCI & BAuA 2012). Applying this strategy to nanomaterials may result for instance in the following measures:

1. Use of nanomaterials that are bound in a matrix rather than using nanomaterials in form of powders or liquids
2. Use of closed systems or exhaust ventilation at the source of (potential) exposure
3. Only specially educated people are allowed access to the production site, indicate such workplaces at which nanomaterials are used/manufactured, which have (partly) unknown properties by use of a label, and
4. Use of certain types of respiratory protection (ibid).

In addition to the range of regulatory activities, a great number of both private and public stakeholders have become active in an effort to support OHS in work with nanomaterials.

2.3 Specific activities related to nanomaterials in workplaces

The limitations of the scientific state-of-the-art on potential human risks and the environment posed by nanomaterials have been well acknowledged by the research community and other relevant stakeholders (NIOSH 2013a; Reuter et al. 2011; Federal Ministry of Education and Research (BMBF) 2009a). Concerns have, indeed, been raised by commentators for over ten years now. It can be argued that the catalyst for much of today’s research into the health effects of nanomaterials is associated with the publication of the 2004 RS-RAE report Nanoscience and Nanotechnologies: Opportunities and Uncertainties. A select working group of over 200 experts summarized the then current state of knowledge on nanoscience and nanotechnologies to identify what health and safety implications might emerge that require consideration by policy-makers. The RS-RAE emphasized "(…) there are uncertainties about the risks of nanoparticulates currently in production that need to be addressed *immediately* to safeguard workers and consumers and support regulatory decisions" (RS-RAE 2004: 81; emphasis added).

As Maynard (2014) has suggested, despite the report's broad remit to evaluate both the opportunities and uncertainties of nanotechnologies, it in fact focused almost exclusively on its potential risks and uncertainties. Even more so, it gave urgency to the issue of OHS within workplaces where nanomaterials are manufactured and/or handled. In effect the global research and regulation community started to follow a path in which "(…) the speculation of possible risk has developed into an assumption of as-yet-to-be-discovered risks" (ibid: 160).

It could be argued that despite being focused on the United Kingdom (UK) and the EU, the RS-RAE report provided the catalyst for global action into examining, and addressing, the adequacy of arrangements for adequately handling nanomaterials at workplaces.

Within the international sphere, action and activity has been focused in the hallways of the OECD, an international organization that provides a forum for governments of 34 countries to collaborate on common (policy) problems. The body provides a forum for the governments to coordinate policies through setting international standards, under more on the safety of chemicals. Since 2004 the OECD has initiated a number of activities related to manufactured nanomaterials (see Table 2.2).

Table 2.2. Overview OECD activities related to nanotechnologies (based on OECD 2013, 2012, 2006).

Year	Parties	Action
2004	OECD Chemicals Committee & Environmental Policy Committee Working Party on Chemicals, Pesticides and Biotechnology (the Joint Meeting)	Start internal consideration of potential challenges posed by manufactured nanomaterials
2005	Joint Meeting between the Chemical Committee and the Environment Policy Committee Working Party on Chemicals, Pesticides and Biotechnology	Workshop on the Safety of Manufactured Nanomaterials
2006	OECD Council	Establishment of the Working Party on Manufactured Nanomaterials (WPMN)
2007	OECD's Business and Industry Advisory Committee (BIAC), EC, OECD member countries	Establishment Sponsorship Programme for Testing of Manufactured Nanomaterials in order to analyze the safety of a priority list of nanomaterials and amend, where necessary the existing, general chemical's test methods and guidelines

In concert with OECD actions, industry and governments developed distinct approaches to nanomaterials in the area of health and safety at workplaces. Industry has, for example, developed various voluntary instruments ranging from principle-based codes of conduct–BASF Code of Conduct Nanotechnology (2004), and Bayer Code of Good Practice for Nanomaterials (2007)–to more substantive guidelines. These include, for example, BASF's Guide to safe manufacture and for activities involving nanoparticles at workplaces (BASF n.d.). The expectation of such voluntary instruments is that they can be adapted easily as more knowledge and certainty on the risks of particular nanomaterials become available. In short, they offer substantial flexibility, not found in legislative approaches.

In addition to these industry activities a number of national governments have developed approaches to deal with the scientific uncertainty of nanomaterials. In Europe, the German government initiated the so-called NanoDialog (2006-08, and 2009-11). The NanoDialog provided a platform to enable, early in the development of nanotechnologies, a broad stakeholder debate on nanomaterials including health and safety aspects (Ökopol 2010a).

Government activity within the US has similarly involved active engagement on all aspects of nanotechnologies, including nanomaterial production and commercialization. The National Nanotechnology Initiative (NNI), a federal research and development (R&D) initiative involving (as of today) 20 departments and independent agencies, was launched by President Clinton in his FY2001 budget request to Congress (NNI n.d.c). The NNI formulated nanotechnology-related Environmental, Health, and Safety research needs and defined goals and accordingly organized a series of workshops on the Environmental, Health, and Safety (EHS) aspects of nanomaterials (Sargent 2011).

Despite widespread concern about the potential health impacts of certain nanomaterials generally, and the worker population more specifically (RS-RAE 2004), there is concern among some stakeholders that existing OHS measures may fail to protect the health and safety of those who manufacturer or work with free manufactured nanomaterials. Why? Because at present we simply do not know enough about what constitutes the most appropriate safety response to nanomaterials.

The state-of-the-art scientific knowledge on the potential risks of nanomaterials in relation to the legal requirements under the relevant EU Directives, REACH and OSHAct suggest challenges for employers seeking to comply with the obligation to have risk assessment and management for nanomaterials in place. It is difficult to apply traditional risk assessment to nanomaterials due to 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 2009a; Poland et al 2008; Oberdörster et al. 2007; Nel et al. 2006; SCENIHR 2006).

In response to this situation of insufficient risk knowledge, and against a background of legislation that seems to be difficult to comply with, policy-makers stress greater collaboration with producers and the need to acquire more scientifically coherent data on nanomaterials risks.[25]

It has been proposed to approach nanomaterials OHS as 'wicked problem'[26] that requires coordination and collaboration among a wide range of stakeholders each holding specifically relevant insights. These could best be leveraged by merging and extending the individual expert knowledge collectively to make available a multifarious knowledge base (Mandel 2008). When actors share their knowledge in collaborative activities, i.e. deliberate on this broad knowledge base in joint effort, possibilities increase for finding innovative solutions to the problem of nanomaterials OHS as characterized by complex uncertainty.

One important actor group in such a governance landscape is supposedly business associations because, typically, they possess scientific data and knowledge that would facilitate making traditional risk assessment applicable to nanomaterials. As has been proposed in section 1.2, associations are expected to fill this data void by actively

[25] See, e.g. initiated information collection and disclosure programs by in the UK Department for Environment, Food and Rural Affairs (Defra) (2008) on a Voluntary Reporting Scheme for Engineered Nanoscale Materials or, in the US, The EPA's (2008) Nanoscale Materials Stewardship Program.

[26] See section 1.1 (p. 16).

collaborating with public policy-makers. Next, chapter 3 will review the literature on business associations to discuss how and by means of which activities associations would typically collaborate. On this basis an analytical framework will be developed in chapter 4.

Chapter 3

Business associations

This chapter answers subordinate research question 2, *How can we describe the activities by business associations directed at effective nanomaterials OHS regulation?* The question is answered by reviewing the literature on business associations. In section 3.1, general types and activities of associations are characterized to provide a rationale for their existence in a complex system of interests in which collaboration with regulators shall need to be conceived. Building on this discussion, in section 3.2, business associations in Germany and the US are delineated and compared as to their structure, organization and activities. Against this backdrop, associations in these jurisdictions that are involved in the debate on nanomaterials OHS and their activities are identified.

3.1 Association types, collective and selective goods

All often companies are members of business associations, the latter of which can possess crucial data and knowledge for the understanding of the potential risks of nanomaterials in workplaces. However, as will be shown in this section, business association activities must always be understood in regard to a certain rationale for association existence and self-sustainability, since such associations and individual companies within them are profit-oriented organizations (Gunningham & Rees 1997). Before going into details of association activities, the forms of business associations must be distinguished since specific types of associations have particular interests and in this line deliver certain activities relevant for regulation.

The most comprehensive discussion on forms of business associations is provided by Bennett (2000).[27] He captures six forms of business associations distinguished by their types of members (see, Table 3.1, for an overview):

1. *Associations of companies* with mainly large companies as members,
2. *Associations of owner-managers* with chiefly small companies as members,
3. *Associations of (self-employed) professionals* with predominantly individuals as members,
4. *Professional associations of individuals* with employees from various kinds of companies as members,
5. *Mixed associations*, and
6. *Federations* which are associations of associations (in the literature they are often termed ‘peak associations’).

[27] In this thesis Bennett’s (2000; 1999; 1998) definition of ‘business associations’ is followed broadly. It shall be noted that other scholars might use the term ‘industry associations’ interchangeably.

It is useful to distinguish associations by the types of their members as this provides a first understanding of specificities of association activities and dynamics reflected in their demand orientation and their decision-making structures (Bennett 1999), as well as their potential for influence in public policy (Boleat 2000).

Table 3.1. Business association types (based on Bennett 2000).

Business association type	**Membership**	**Decision making**	**Example**
Companies	Predominantly large companies (›200 employees)	Several managers (senior/middle level)	American Chemistry Council (ACC), German Chemical Industry Association (VCI)
Owner managers	Predominantly small companies (2-10 employees)	Individual owner manager(s)	German Verband Chemiehandel (VCH)
(Self-employed) professionals	Predominantly individuals	Individual	National Association for the Self-Employed (NASE)
Individuals	Predominantly employees (across all classes of companies)	Individual	German Association of Nanotechnology (DV Nanotechnologie)
Mixed	Mixed (small and/or large companies, owner managers, self-employed, individuals)	Mixed	Society for Chemical Engineering and Biotechnology (DECHEMA)
Federations	Other associations	Mixed (several executives in board structure)	International Council of Chemical Associations (ICCA)

Before identifying the type of business association most prominent in the context of nanomaterials OHS a broader discussion of association rationale, or 'logic', of existence is provided. Later association activities are described generally, and specifically in regard to nanomaterials OHS.

Business association activities center around the provision of collective and selective goods to their members within a particular industry or sector (Czada & Windhoff-Heritier 1991; Van Waarden 1991; Schmitter & Streeck 1985). The nature of collective action implies that, while member businesses receive reputational benefits through association activities, other non-member businesses are not entirely excluded from any broader collective goods (e.g. information) generated by the association. Rather, such non-member firms essentially free ride on the benefits provided to others (Lenox 2006; Howard et al. 1999). To minimize the effects of the 'free-rider problem' associations provide, next to collective goods, selective goods through which they assign benefits, which may only be requested by association members (Bennett 2000). Members then benefit from improved ability to maintain higher quality in the sector as they differentiate themselves from other (lower quality) firms in the sector (Lenox 2006; Bennett 2000). Another means to resolve free riding is to have forces of strong associability or commitment among members towards the association in place, importantly through a culture of support and trust (Unger & van Waarden 1999; Olson 1971).

Associations need to balance the provisions of collective and selective goods in form of activities: they need to fulfill the individual needs and demands of their members in order to 'survive' in terms of generating income through member fees. To prove their worth to their members, associations need to establish good relations with relevant government actors in order to increase their involvement and influence in policy processes (Bennett 1997a). From the perspective of individual firms, membership in business associations imposes transaction costs, starting with membership fees and extending to investments in time and manpower. Thus, attending meetings or engaging in voluntary management positions within associations imposes some burdens on firms, which naturally expect such costs to be offset by benefits. Firms, especially SMEs often cannot, or do not want to, bear such costs (Getz 1993). Therefore they only become member in business associations when the advantages of this arrangement–for instance, enhanced capacity to survive (Uzzi 1994)–outweigh the costs necessary for maintaining the membership including potential loss of decision autonomy and operation (Provan & Milward 1995).

In this light, associations are structured around a complex system of interests. In fact, business associations wear many hats. They have 'multiple selves' or even contradictory commitments to economic rationality, law abidingness and business responsibility in different contexts and moments (Gunningham & Rees 1997). Acknowledging such contradictory interests, overall associations are more influential in their sector when they gain government encouragement and recognition (Crouch & Traxler 1995; Lamoreaux 1985). Van Schendelen (1993) argues that the greater the involvement of government, the better a sectoral association will be organized. But the impact of associations on regulation is also determined by an association's history of working relationships with regulators as well as their reputation (Grossmann 2012a). Overall, business associations have been particularly influential in areas of energy, finance, macroeconomics, science and technology, and transportation (Grossmann 2012a: 180-181).

In the regulatory literature, association activities have mostly been discussed by reference to associations of companies (often called trade associations) in the context of the chemical sector. This stream of literature puts a focus on the discussion of collective goods.

A well-known and widely discussed form of business association activity is the protection of business *reputation and representation* (see, Table 3.2, for an overview of typical business association activities). Especially in dangerous industries like the nuclear industry (Coglianese & Mendelson 2010), or the chemical industry, companies are 'hostages to each other' (Rees 1996); the major accident occurring company usually damages the reputation of the rest thereby prompting new government legislation applicable to the sector as a whole (Coglianese 2010; King et al. 2001).

But business associations do not simply represent the interests of their members. They aggregate viewpoints (Bailey & Rupp 2006) and redefine them in such a way that renders possible their collective representation (Lane & Bachman 1997). Through the representation of interests, acceptable ways of business behavior or ethics may be defined and member expectations are synchronized (Lane & Bachmann 1997: 240).

Another important collective good of business associations is advocacy, generally known as *lobbying* (Bailey & Rupp 2006). Through lobbying, associations aim at supplementing or complementing government policy or regulation (Gupta & Lawrence 1983), or minimizing the impacts of unfavorable regulation through bargaining or manipulating information and publicity (Veljanovski 2010). One of the most famous examples of lobbying within the US comes from the tobacco industry, which during the 1960s through to the 1980s set up a program to 'bend science' by controlling and covering up research on the health effects of nicotine and to encourage only scientific inquiry that was likely to favor the position of the industry (McGarity & Wagner 2008; Redish 2001). In effect of these (and other) efforts, the tobacco industry succeeded in preventing the passage of many tobacco control policies in the US (Givel & Glantz 2001).

Associations may forestall (more stringent) government legislation by developing and implementing sector-wide non-legally binding *soft regulation*, such as codes of conducts, guidelines, and technical standards. Thereby associations can facilitate the collective improvement of performance within a certain industry (Lenox & Nash 2003). Through formulating collective actions and strategies, associations may reduce the costs of political action for individual firms (Levy & Prakash 2003).

While some forms of soft regulation are independent of the state, common hybrid forms (e.g. enforced soft or self-regulation) comprise state as well as corporate regulatory efforts (Coglianese & Lazer 2003; Rees 1997; Gunningham 1995). The adoption of soft regulation may provide a signal to stakeholders about the quality or social responsibility of firms in a given sector and in turn stakeholders are likely to reward firms for participation (Lenox 2006). Often soft regulation is developed by associations themselves in the assumption that the demands they will place on their member businesses will be less burdensome and costly than government regulation (Coglianese 2010) as well as liability as result of externalities, like fatal accidents or emission of toxic pollutants, with consequences not only for individual but all companies in an industry (Lenox & Nash 2003). Soft regulation can play an important risk management role by providing education and information to member businesses or by interacting with government over the best ways to achieve required (risk) standards (Hutter 2011; Hutter & Jones 2007; Gunningham 2002; Henson & Heasman 1998). Associations communicate such standards to businesses collectively and in that way coordinate a standard of behavior (Bailey & Rupp 2006).

A widely discussed example of soft regulation is the chemical industry's Responsible Care Program (RCP). The program was launched in 1988 by the Chemical Manufacturers Association (CMA), which today is called American Chemistry Council (ACC) (Prakash 2000). In a climate of steadily eroding public confidence in the chemical industry, due to accidents and spills, the RCP was initiated to improve the environmental performance of chemical companies and demonstrate improved performance among stakeholders and critics (Howard et al. 1999; Rees 1997). The RCP contains six codes with more than 100 specific management practices involving ten underlying principles for the members of chemical associations to proactively deal with environmental and occupational issues relevant in processes of manufacturing, distribution and transportation (King & Lenox 2000). The program has been criticized as it merely required members to annually self-assess the implementation of its principles and therefore would have no real effect, but merely being a marketing strategy "(…) to convince society of the potential harmonious coexistence of the chemical industry with the natural environment" (Evangelinos et al. 2010: 823). Citizens have voiced concern and distrust as to the usefulness of the RCP (Heath & Palenchar 2009). In light of such criticism, the program has been overhauled and now requires member companies to go beyond self-assessment and adopt verification processes to be carried out by associations, government bodies, or external organizations (International Council of Chemical Associations (ICCA) 2012). It has been suggested that this approach resulted in increased transparency and accountability of RCP members (Li et al. 2014).

Another collective good provided by industry associations is general *knowledge exchange* (Coglianese 2010) through circulars, newsletters, websites (Izushi, 2002) or analysis of market information and commentary on policy (Boleat 2000). In that way businesses can keep themselves updated on the latest scientific and technological developments in a sector. Based on knowledge exchange associations also clarify and simplify regulatory agreements and/or regulation and they may develop soft regulation to support firms in developing adequate implementation strategies (Bailey & Rupp 2006).

Next to the provision of collective goods, to minimize the effects of the free-rider problem and to obtain income through membership fees (mentioned above), associations need to provide selective goods. In this relation, associations often establish *specific member statuses* through which they assign benefits resulting from association collective action. Other examples of selective goods are specific *business advice* or targeted *marketing support*, which serve as incentives for association membership. Also *technical standards* can be selective goods if they are provided only to member companies. The example of technical standards demonstrates that determining whether we label certain association goods as selective, or collective goods, depends on the specific conditions under which these goods are provided.

Table 3.2. Typical activities of business associations.

Collective goods	**Selective goods**
Reputation and representation	Specific member status
Lobbying	Business advice
Soft regulation	Marketing support
Knowledge exchange (scientific/technical/political)	Technical standards

Providing individual goods allows associations to obtain income from membership fees and other sources so as to support their collective activities (Bennett 2000). However, such goods can only be accessed if firms are willing, and able, to afford paying association membership fees. This exchange of money for services (pay-to-play principle) may be problematic for certain small and medium-sized enterprises (SMEs) due to their limited resources, which can create informational disadvantages and entry barriers to associations (Mattli & Büthe 2003). Although, often associations have tiered fee structures in place that lower entry barriers.

Before turning to business associations specifically in the context of the US and Germany, we should acknowledge that business associations have often been positioned in opposition to the interest of the general public because they represent demands that are often by no means the most popular (Hansen 1991). Associations may be more oriented towards profit making at the expense of public health and safety and the environment (McGarity & Wagner 2008). Associations know about the importance of considering public perception and aligning their activities accordingly. For example, during the 'Tobacco Wars' (1960s-1990s), one important reason why the US tobacco industry was successful in preventing stricter state tobacco control laws and state tobacco policies was because they surveyed public attitudes and used the results to develop targeted advertisements that put the tobacco industry in a favorable light (Givel & Glantz 2001).

The next part of this chapter, since this thesis is concerned with the comparison of German and US business associations in the chemical sector, will point to key differences regarding association structure, organization and types of activities across the two legal jurisdictions before describing association activities related to nanomaterials OHS.

3.2 Business associations in Germany and the US: structure, organization, activities

Describing and discussing key differences among German and US business associations regarding their structure, organization, and types of activities is important in order to understand what these associations can be expected to contribute to effective regulation generally, and specifically in view to nanomaterials OHS.

In Germany, by 2009 approximately 2,100 associations with political interests exist (Pötzsch 2009). Overall, a tradition of economic self-organization nourishes the collective organization of business interests significantly (Lane & Bachmann 1997). German associations have been, and constantly are, an important feature of economic life that is independent from changes in political regimes through forming a highly centralized and hierarchical system of organization (Federation of German Industries (BDI) 2012; Henneberger 1993; Rampelt 1979). In this sense, industrial sectors are largely represented by one or a few chief business associations that are themselves represented by an umbrella or peak association; in this case the BDI. Usually associations are structured into special subject groups (Fachgemeinschaften) that are organized via sectoral or product subsections as well as through geographically dispersed sub-groups, which represent regional and local industry interests (Abromeit 1993). In fact, "[t]he BDI's strong sense of purpose has made it a powerful representative of German manufacturing industry" (Lane & Bachmann 1997: 236). German associations are strong in representing member interests through being 'interlocutors of government'; they are acknowledged as bodies for legal consultation and assistance and frequently being asked to implement public policy or even their own sectoral policy (Lane & Bachmann 1997). Associations are granted a role by government and have large memberships.

In the US, in 2012 about 7,800 trade and professional associations exist (Anders et al. 2012). US business associations, in contrast to the German system, are said to be pluralistic and lacking unity and common purpose (Lane & Bachmann 1997: 236). US associations are typically not integrated into policymaking with no coherent government policy in order to deal with associations (Bennett 1997a). Support of government importantly influences the ability of an association to develop and flourish (Young 2010). But in the US, relations between government and industry provide little financial and logistical support for sustained industry organization due to a political system of divided government, i.e. two-party system (Newman & Bach 2004). Confirming the latter, Martin and Swank (2008) find that two-party systems–where (nearly) all elected officials belong to one of two major parties that dominate politics–tend to support the formation of more fragmented groups.

Multi-party systems in many EU countries, for example in Germany and Denmark, tend to reinforce business cooperation and enable their development into social corporatist organizations (Martin & Swank 2008). Or, in other words, private and public sectors generally appear to consider each other as partners that aim to agree on a joint course of action rather than aiming to avoid government involvement (Newman & Bach 2004).

How can we explain these fundamental differences? Various scholars point to historical and institutional explanatory factors.

In Germany, the legacy of the pre-industrial guild system with its traditions for economic cooperation and coordination and high-skill production with an organized workforce have played a role in the evolution of business associations (Martin & Swank 2004). Elements of this system have predated the industrial revolution and the formation of nations states in Germany (Newman & Bach 2004; Hofstede 1993). Through the legacy of handicraft guilds educational and training systems directed the organization of work and distribution of knowledge and skills in a different way as compared to the US: through vocational education, training, and certification practices workers and employers developed (with the support of state mediation) a mutual interest in the development of a system that directly linked vocational programs and certificates to the economy; in contrast, vocational educational programs in the US were weak and had a low status (Hansen 1997). One facet that gave rise to this difference is that, even though many American employers were interested to develop institutions to foster the development of skills and cooperation with labor, others followed a low-wage strategy, which established sectional differences in the various parts of the economy. These differences were augmented by the dynamics of the two-party system in hindering the emergence of corporatist business associations in the US (Martin & Swank 2008).

The organizational and structural differences among German and US business associations are also reflected in the activities these bodies pursue. Generally associations are characterized by a strong practice of collective knowledge exchange and a 'culture of support' (Lane & Bachmann 1997). Especially the problem-oriented working groups are "(…) arenas to exchange experience and interests which promotes cooperation in other areas" (ibid: 242). Furthermore through such collaborative activities member expectations are harmonized which provides the basis for a common level of trust among association members, despite their competitive orientation (ibid).

Next to the allocation of collective goods, German business associations offer to their members a range of selective goods, including research and development services and the provision of individual (business) advice and consultancy services (Bailey & Rupp 2006). A particularly meaningful selective good offered by German associations are technical standards. Looking back in history, both the production and the implementation of technical norms have been important association activities all throughout the 19th century (Weber 1987). By offering technical standards–under more for the protection of workers–some associations gained nearly a monopoly position in their industry, which secured generally high levels of membership (Henneberger 1993; Weber 1987). Many German companies even render their membership as compulsory (Bennett 1997b). In result, German associations possess a high degree of authority to create rules of behavior common to a particular industry.

Where German associations offer a mixture of collective and selective goods, US associations tend to mainly offer collective goods (Bailey & Rupp 2006). Amongst those collective goods, association activities in form of lobbying are most common (Grossmann 2012a) and overall US associations are said to follow a strong tradition for lobbying (Woll & Artigas 2007; Berry 1989). Looking closer at these lobbying activities, Baumgartner et al. (2009) find that business associations are disproportionately likely to lobby against, rather than support, policy changes. Likewise, US regulators typically denounce the influence of associations on policy; during presidential elections political candidates frequently vow to reduce the influence of 'the special interests' through reforming bills (Grossmann 2012b: 2). As US associations mostly offer collective activities of the type lobbying, they are likely to attract less members compared to German associations.

Many German associations operate separate businesses through which income can be generated independent from membership (Weber 1987). Their relatively healthy financial situation enables German associations to establish and maintain a high level of professionalization. Typically they employ qualified staff with graduate and postgraduate education (Lane & Bachmann 1997: 237; Abromeit 1993: 550). Well-resourced associations are said to have advantages over those that are not: they can lower administrative costs, improve compliance with regulation, apply knowledge more efficiently and they can facilitate immediate response of regulations to technical and market developments in the light of new knowledge (Izushi 2002; Bennett 1998).

While collaboration between associations, policy-makers and regulators can be beneficial in respect to the development of effective regulation (as described in section 1.2), it has also been acknowledged that this kind of collaboration may foster 'capture'.[28] Business associations might capture regulators who then no longer act in the public interest. Capture and corruption is fostered by the very same conditions that foster cooperation, namely through

[28] The concept of regulatory capture has been coined by US economist Stigler (1971).

ongoing relationships between businesses and regulators, and through regular repetition of encounters with the same regulators. Under these conditions, to secure the advantages of cooperation while avoiding capture may require a form of tri-partism (Ayres and Braithwaite 1991). Tri-partism refers to the empowerment of public interest groups (e.g. NGOs) and ensuring their access to information on regulatory deals, even granting them the ability to punish regulators failing to punish non-compliant firms (Axelrod 1986), and punishing firms themselves (Ayres & Braithwaite 1991).

However, it can be argued that capture, to some extent, is 'natural' because the affiliations and jobs of people often change over time making it difficult to act in the interest of merely one party. Not uncommonly, industry representatives move into government and regulators move from regulatory agencies into industry. The idea that regulators are either drawn from, or returning to, industry refers to the notion of the 'revolving door'. As Coglianese et al. (2004) hold though, this practice can also be advantageous: when regulators move from regulatory agencies into industry jobs, future informal contacts between the regulatory agency company or business association are facilitated; likewise, when industry representatives move into government insider knowledge about an industry is delivered to a regulatory agency, which can be used for its advantage. As such, "(…) some cooperation between the regulatory agency and industry actually improves regulator's chances of eliciting data from regulated entities that can help improve overall regulatory performance" (Carrigan & Coglianese 2012: 15).

In this section it has been argued that overall the organization and structure of business associations appears to be highly formalized in Germany in contrast to US associations. Since German associations control a high degree of resources as well as membership they can offer a mixture of collective and selective goods to members while they are direct collaborators to policymaking agencies. For US associations a near opposite picture has been drawn. The question, which will be addressed in the empirical chapters 6 and 7, is in how far such differences across German and American associations are reflected in the nano-specific activities offered by particular associations. Before analyzing such activities, we first need to identify the nano-specific activities provided by these associations.

3.3 Business associations involved in nanomaterials OHS

Leading chemical associations both in the EU and the US have put the topic of nanomaterials OHS on their agenda since 2003 and 2005 respectively. The active participation in the discussion on nanomaterials OHS by these associations goes hand in hand with information on those countries being at the forefront of the manufacturing of nanomaterials. The bulk share of the market for nanomaterials is held by the US, followed by Europe and Asia (Roco et al. 2011; Mandel 2008). Within Europe, Germany accounts for the highest (documented) number of firms that produce engineered nanomaterials (Invernizzi 2011) and invests more than any other country into publicly funded security research on nanotechnologies (VCI 2014a). There are few labor market figures about the actual number of workers involved in the manufacturing of nanomaterials (Invernizzi 2011). For Europe, the European Agency for Safety and Health at Work (EU-OSHA) estimated in 2012 that between 300,000 and 400,000 employees deal directly with nanotechnology whereas nanomaterials probably are handled by many more employees down the supply chain (EU-OSHA 2012). In the US no concrete numbers are available; it has merely been noted that commercial applications of nanomaterials are growing rapidly, and as this growth continues, it is crucial to ensure that employees who may be exposed to nanomaterials are working in safe and healthy environments (NIOSH 2013a).

In both jurisdictions, as will be shown in the remainder of this chapter, most associations active in the area of nanomaterials OHS are of the type 'Companies' (recapture Table 3.1). In the US, the American Chemistry Council (ACC) is the sole chemical industry association. The ACC was founded as the Manufacturing Chemists Association in 1872, was re-named as the Chemical Manufacturers Association (CMA) in 1978; it re-named itself once more as the American Chemistry Council in 2000. The ACC headquarters is situated in Washington, D.C. and its members represent more than 85% of US chemical manufacturing capacity (ACC 2014a). Three membership categories exist: Regular (including Small and Medium-sized Enterprises (SMEs))[29], Affiliate[30], and Associate[31]. Thus, the ACC is an association of the type 'Companies'.

Since 2005 the ACC has been involved in the topic of nanomaterials OHS through the establishment of its Nanotechnology Panel. The Panel advocates for research on potential health effects of nanomaterials and serves as primary forum within the ACC for activities that further the responsible development of nanotechnologies among manufacturers and users (ACC n.d.). For an overview of all ACC activities relevant for nanomaterials OHS that are accompanied by publicly available information (in the time period from 2005 until March 2014), see Table 3.3 below.

[29] Regular members are companies which, as a significant proportion of their business, produce or sell chemical products within the US (ACC 2013b).

[30] Affiliate members are not chemical manufacturers, but value chain partners of the chemical industry including down-stream companies such as retailers (ACC 2013c).

[31] Associate members are 'leaders' from industries other than the chemical industry (e.g. accounting, banking, insurance etc.) and membership is offered on 4 levels: director, executive, chairman and president (ACC 2013d).

Table 3.3. Overview ACC activities related to nanomaterials OHS.

Time	Activity
2005	Establishment of the ACC Nanotechnology Panel (ACC n.d.)
	Publication of a Joint Statement of Principles for nanomaterials (together with the Environmental Defense Fund, EDF) (EDF & ACC 2005)
2006	Issuance of Comments on the EPA Nanotechnology White Paper External Review Draft' (ACC 2006)
2007	Statement before the National Nanotechnology Coordination Office (NNCO) (ACC 2007a)
	Comments on the Draft Environmental Defense/DuPont Nano Risk Framework for Responsible Nanotechnology' (ACC 2007b)
	Comments on the Scientific Opinion of the EC Scientific Committee on Emerging and Newly Identified Health Risks (SCENIHR) on the Technical Guidance Documents of the chemicals legislation, for the risk assessment of nanomaterials (ACC 2007c)
	Conduction of a survey among ACC member companies (ACC 2007d)
2009	Became a member of the Business and Industry Advisory Committee (BIAC) Nanotechnology Committee that advises the OECD Working Party on Manufactured Nanomaterials (WPMN) (OECD 2009)[32]
2011	Comments on the Environmental Health and Safety Strategy of the National Nanotechnology Initiative (NNI) (ACC 2011a)
	Comments on the NIOSH draft Current Intelligence Bulletin (CIB) Occupational Exposure to Carbon Nanotubes and Nanofibres (ACC 2011b)
	Comments on the relevance of the NNI on safe work and use of nanotechnology (ACC 2011c)
	Comments on NIOSH's updated strategic plan for identifying and prioritizing nanotechnology research (ACC 2011d)
	Co-sponsor of the the NanoRelease Consumer Products research project (International Life Sciences Institute (ILSI) 2011)
2012	Comments on the EPA Office of Inspector General's Report on Nanotechnology (ACC 2012a)
	Comments on EPA's proposed significant new use rules (SNURs) (ACC 2012b)
	Organization of a workshop on Strategies for Setting Occupational Exposure Limits for Engineered Nanomaterials' was initiated (ACC 2012c)
2013	Publication of a Comparative assessment of nanomaterial definitions and considerations (ACC 2013e)
	Comments on NIOSH's draft strategic plan for nanotechnology research (ACC 2013f)
	Comments on the draft NNI Strategic Plan 2014 (ACC 2013g)

On the EU level, the overarching umbrella association in the chemical sector is the European Chemical Industry Council (Cefic). The association was founded in 1972 and represents approximately 29,000 large and medium and small chemical companies that cumulatively provide about 1.2 million jobs and represent 21% of chemical production worldwide (Cefic 2014a). Cefic is an association of the type 'Mixed', meaning membership is mixed, with three distinct groups of members–corporate[33], federation[34] and business[35]–as well as three types of partnerships, namely associated companies[36], affiliated associations[37] and partners[38] (Cefic 2014a). 'Federation members' include all national chemical associations of the EU member states. Membership on the level of individual firms is mostly indirect insofar as firms are typically members of the national industry associations in their home country, which, in turn, is a member of Cefic (Cefic 2014a).

Cefic has been publicly involved in the discussion on nanomaterials OHS since 2008 (Cefic 2008) (see Table 3.4 for an overview of these activities).

[32] The ACC Nano Panel has been a member of BIAC at least since March 2009 (OECD 2009); there is no data available from publicly available documents that points to an earlier engagement.
[33] Corporate members are corporations with a production base in Europe and a worldwide turnover in chemicals of more than 1 billion Euros (Cefic 2014a).
[34] Federation members are European national federations and associated EU federations (Cefic 2014a).
[35] Business members are sectoral businesses with a production base in Europe and a worldwide turnover in chemicals of less than 1 billion Euros (Cefic 2014a).
[36] These are companies engaged in the production of chemicals in countries outside Europe (Cefic 2014a).
[37] European associations that represent a specific sector of the chemical industry (Cefic 2014a).
[38] Partners are 'European non-chemical companies working closely with the European chemical industry' (Cefic 2014a).

Table 3.4. Overview Cefic activities related to nanomaterials OHS.

Time	Activity
2008	Organization of a Stakeholder Engagement Workshop Enabling Responsible Innovations of Nanotechnologies (Cefic 2008)
2009	Realization of a Responsible Care Conference (Cefic 2009) related to nanomaterials
2010	Development of the guidance Responsible Production and Use of Nanomaterials: Implementing Responsible Care (Cefic 2010a)
	Issuance of Nano Key Messages (Cefic 2010b) on worker safety
2011	Report on key enabling technologies (including nanomaterials) as part of the High level group (initiated by the EC) (EC 2011)
	Organization of a Nanomaterials and REACH workshop (Cefic 2011a)
	Issuance of a Reaction and criticism of the EC definition of nanomaterials (Cefic 2011b)
	Issuance of a position paper nanomaterials (Cefic 2011c)
2012	Development of a Guidance How to implement Responsible Care regarding production and use of nanomaterials (Cefic 2012a)
	Organization of a REACH Implementation workshop relevant for nanomaterials (Cefic 2012b)
	Publication of an Information on testing and assessment strategies for nanomaterials (Cefic 2012c)
	Development of a Position paper nanomaterials safety and legislation (Cefic 2012d)
	Organization of another REACH Implementation workshop with relevance for nanomaterials (Cefic 2012e)
2013	Publication of a Reaction to the EC Communication on the 2nd Regulatory Review on Nanomaterials (Cefic 2013a)
	Statement on the EC's initiative to launch a public consultation to set an approach for potential adaptation of REACH Annexes and guidance documents to cover nanomaterials (2013b)
2014	Proposition of an approach for the adaptation of the REACG Annexes for nanomaterials to the Commission (Cefic 2014b)

On the level of EU member countries, the German Chemical Industry Association (Verband der Chemischen Industrie, VCI) reflects Germany's role at the forefront of the manufacturing of nanomaterials. It is also the most active (within Germany) in supporting health and safety at workplaces where nanomaterials are handled. The VCI was founded in 1877 under the name 'Verein zur Wahrung der Interessen der Chemischen Industrie Deutschlands'. Today the association has more than 1600 member companies accounting for more than 90% of all German chemical firms (VCI 2014b). Being an association of the type 'Companies', membership in the VCI is possible via two routes: A company may become an ordinary member[39] or an associated member[40] (VCI 2014c). Since 2003 the organization participates in discussions related to nanomaterials OHS. An overview of all VCI activities relevant to nanomaterials OHS in the period from 2003 to March 2014 is provided in Table 3.5.

[39] Ordinary members are typically manufacturers in the chemical industry or a closely related industry (VCI 2014c).
[40] Associated members are companies in the surroundings of the chemical industry as long as their membership is of special interest for the VCI (VCI 2014c).

Table 3.5. Overview VCI activities related to nanomaterials OHS.

Time	Activity
2003	Foundation of the working group Responsible Production and Use of Nanomaterials (RPaUoN) (together with DECHEMA) (DECHEMA & VCI 2007)
2005	Organization of a Workshop Nanomaterials at the workplace I (VCI 2005)
2007	Survey I on occupational health and safety in the handling and use of nanomaterials among VCI member companies (Plitzko & Gierke 2007; Plitzko et al. 2007) (in cooperation with BAuA)
	Comments on the DuPont/Environmental Defense Fund's Nano Risk Framework (DuPont & EDF 2007; VCI 2007a)
	Realization Workshop Nanomaterials at the workplace II (VCI 2007b)
	RPUN issued a Roadmap for Safety Research on Nanomaterials (DECHEMA & VCI 2007)
	Development of a Guidance for Handling and Use of Nanomaterials at the Workplace (in collaboration with BAuA) (VCI & BAuA 2007)
	Issuance of a Strategy Paper of the German Chemical Industry on the Standardization of Nanomaterials (in the context of ISO/TC 229) (VCI 2007c)
2008	Development of guidance Anforderungen der REACH-Verordnung an Stoffe, welche auch als Nanomaterialien hergestellt oder eingeführt werden' (VCI 2008a)
	Development of guidance Tiered Gathering of Hazard Information for the Risk Assessment of Nanomaterials (VCI 2008b)
	Development of guidance Passing on of Information along the Supply Chain in the Handling of Nanomaterials via Safety Data Sheets (VCI 2008c)
	Development of guidance Responsible Use and Production of Nanomaterials (VCI 2008d)
	Development of guidance Umsetzung von Responsible Care® für eine verantwortliche Herstellung und Verwendung von Nanomaterialien (VCI 2008e)
	Organization of the workshop Verantwortlicher Umgang mit Nanomaterialien (in collaboration with the industry association IG Bergbau, Chemie, Energie) (VCI & IG BCE 2008)
2011	Survey II on occupational health and safety in the handling and use of nanomaterials among VCI member companies (Plitzko et al. 2013) (in cooperation with BAuA)
	Co-development of guidance Tiered approach to an Exposure Measurement and Assessment of Nanoscale Aerosols Released from Engineered Nanomaterials in Workplace Operations (IUTA et al. 2011)
	Publication of a reaction to the proposed EC definition of a nanomaterial (VCI 2011a)
	Issuance of a reaction to a report on nanomaterials risks by the German Advisory Council on the Environment (VCI 2011b)
2012	Development of the guidance Empfehlung für die Gefährdungsbeurteilung bei Tätigkeiten mit Nanomaterialien am Arbeitsplatz (revised version of the 2007 guidance) (VCI & BAuA 2012)
	Publication of a Reaction to EC Communication on the 2nd Regulatory Review on Nanomaterials (VCI 2012)
2013	Development of a position paper on the EC REACH report (VCI & VCH 2013)

Other, though much less active, European chemical associations in the area of nanomaterials OHS are situated in the Netherlands, Italy, Britain, France, Denmark and Switzerland (see, Table 3.6, for an overview of the activities of these European associations that are based on publicly available information). These associations are all 'Companies'.

Table 3.6. Overview activities of European associations related to nanomaterials OHS.

Country	Association	Time	Activity
Netherlands	Association of the Dutch Chemical Industry (Vereniging van de Nederlandse Chemische Industrie, VNCI)	2008	Participation in the klankbord 'risico's nanotechnologie since 2008 (VNCI n.d.; Klankbordgroep Risico's Nanotechnologie 2008)
		2010	Development of a guidance for safe work with nanomaterials (in collaboration with The Confederation of Netherlands Industry and Employers) (Cornelissen et al. 2011)
		n.d.	Support of better information exchange on nanomaterials between companies and society by means of various projects[41]
Italy	Federchimica	2008	Co-organization of an annual conference including workshops on nanomaterials in the chemical industry (NanotechItaly 2014)
		n.d.	Establishment of a Task Force Nano Product Stewardship (in collaboration with various ministries (Giovanna 2012)
			Development of a Manual for the responsible management of nanomaterials (Giovanna 2012)
Britain	Chemical Industries Association (CIA)	2010	Foundation of the Nanotechnology-Linking the Supply Chain Forum to shape regulation (CIA 2010)
		2011	Initiation of a survey on the use of nanomaterials (CIA 2011)
France	Association of the Chemical Industry (Union des Industries Chimiques, UIC)	2009	Development of a good practice guide for nanomaterials OHS (UIC 2009a)
			Initiation of a stakeholder debate (UIC 2009b)
Denmark	Association of Danish Process Industries (Procesindustriens Brancheforening, PIBF)	2013	Organization of an information meeting on nanotechnological legislation in the EU and DK context (PIBF 2013)
Switzerland	Scienceindustries	2009	Publication of a position paper on synthetic nanomaterials (Scienceindustries 2009)

An association that has been very active in the area of nanomaterials OHS on a global level, i.e. under more through activities in Europe and the US, is the Nanotechnology Industries Association (NIA). The NIA was established in 2005 by a group of companies from various industry sectors including healthcare, automotive, consumer products, and chemicals in the UK. In 2008 the association opened its international NIA office in Brussels, whilst maintaining an independent UK-national representation through its UK basis (NIA n.d.b). NIA membership includes chemical companies, universities, research consortia and institutes as well as law firms (NIA n.d.c). The association provides support to the nanotechnology industries, to regulators and policymakers as well as to the public and multi-stakeholder audiences through activities ranging from identification, forecasting and roadmapping of unique areas of nanotechnologies to interacting with the media in the representation of nanotechnologies.

This broad spectrum of activities puts the NIA in a unique position compared to the other associations mentioned thus far. Against this backdrop, NIA differs from the other associations in three essential, partly related, ways:

[41] Individual projects are not specified and/or who was involved in such project and at what time they had been realized (see https://www.vnci.nl/themas/overzicht/dossier-detail/subdossier/?dossierid=68354085&title=Stoffen+in+nanovorm).

1. NIA is a sector-independent association in difference to the other associations, which are all associations in the chemical industry
2. NIA has a clear focus on nanotechnologies whereas the other associations are engaged in the area of chemicals more broadly (NIA n.d.b), and
3. Membership in NIA is not restricted to companies, likewise different kinds of not for profit organizations are included (NIA n.d.c)

Due to these important aspects, NIA activities are distinctly different from the activities of the other mentioned EU/US associations and are not comparable in a way that would do justice to the exceptional character of NIA. Therefore, NIA activities are not subject of (in-depth) study within this thesis. However, the general importance of this association in the area of nanotechnology shall be acknowledged.

In this chapter business association activities have been described generally, as well as in the context of the US and German (EU) political systems, and specifically with regard to nanomaterials OHS. In this relation, associations have been delineated and their key activities have been discussed. As has been shown, business associations wear many hats. Even though they might be willing and able to support nanomaterials OHS regulation, at the same time these organizations follow and are organized around multiple and complex interests. Associations exist, and are engaged in certain topics, because businesses in a sector think they are better off by acting collectively rather than individually. With nanomaterials OHS one can clearly identify a collective interest of businesses at large to promote nanomaterials as desirable technology (see Reichow & Dorbeck-Jung 2013a, b). So far nanomaterials have widely been praised for their high innovative potential in a wide range of sectors and related applications and/or products in areas of medicine, cosmetics, and the building sector (see section 1.1). To not lose the innovative and economic potential of nanotechnologies through, for instance, backlash by citizens and non-governmental organizations (as, for instance, has been noted widely in the context of the topic of genetically modified organisms), the chemical industry has an interest to operate collectively rather than individually.

Against this background, for the analysis of complex business association activities, an analytical framework needs to be developed. This framework needs to allow accounting for collaboration among business associations and policy-makers and answering the question what we can learn from such activities aimed at contributing to effective nanomaterials OHS regulation. In the following chapter 4, such a framework will be developed by drawing on the field of network governance.

Chapter 4

Theoretical framework

This chapter reviews relevant literature and develops the theoretical framework and analytical categories for the analysis of business association activities in terms of their contribution to effective nanomaterials OHS regulation. In doing so, this chapter answers the sub-research question 3: *How can collaborative business association activities as a process towards effective nanomaterials OHS regulation be evaluated?* In section 4.1 the perspective on 'effective regulation' of nanomaterials OHS adopted in the scope of this thesis is specified. Next, in section 4.2, by drawing on theories of network governance, key conceptualizations for the analysis of effective regulation of nanomaterials OHS through collaboration and learning across actors are developed. Based on this discussion, in section 4.3, selective analytical categories and conditions are set up to guide the empirical investigations of business association activities.

4.1 Conceptualizing association contribution to effective regulation

The development of new technologies, such as nanotechnologies, typically brings with it an asymmetry in the possession of resources critical to risk governance (e.g. scientific data, expertise, experiences). Non-state actors such as universities and manufacturers usually have more resources than relevant government agencies (Abbot 2012; Coglianese 2007). With this in mind scholars have called for policy-makers and regulators to actively engage with industry for purposes of knowledge sharing that would enable risk uncovering and avoidance (Coglianese 2010). But to date there is limited fundamental understanding of how nanomaterials may interact with the human body. The risk endpoints of certain nanomaterials are unknown (Savolainen et al. 2013).

At the same time this does not mean that there is no knowledge at all; rather, the knowledge base on nanomaterials and their potential risks and toxicity is expanding (see section 2.1). Worldwide, the results of many research projects on nanomaterials are available now and decades of research on ultrafine particles have shown to be relevant for nanomaterials (Ziemann et al. 2010; Oberdörster et al. 2005b; Pott & Roller 2003). While no studies are available that have shown categorical harm to humans (Hull & Bowman 2014) and the worker population at large (NIOSH 2013b), there is no evidence that there will be no harm in the future. Therefore it has been advised to take a precautionary approach to nanomaterials that are handled at workplaces until we have a more conclusive understanding of the risks (NIOSH 2013b; VCI & BAuA 2007; Swiss Re 2004).

In this respect, 'understanding' potential risks means to both collect and deliberate on existing, patchy knowledge on nanomaterials OHS. The aim is to develop a fundamental scientific knowledge base of nanomaterials risks necessary to inform health and safety measures within relevant workplaces. Thus, achieving effective regulation of nanomaterials OHS requires going one step further than merely collecting 'more scientific data'. Namely, data collection should be accompanied by processes of active deliberation on how to make sense of this data in relation to existing risk frameworks that need to be complied with in the context of OHS legislation (Savolainen et al. 2013). To be clear, collecting risk data is but a necessary first step in the development of robust future tools to support OHS in the work with nanomaterials. Needless to say, efforts solely aimed at discovering 'complete' sets of toxicological data do not solve the challenge of specifying potential nanomaterials risks, but merely shift it ad infinitum since one can never be certain whether truly all data has been collected.[42]

Keeping this in mind, as articulated in section 1.2, any evaluation as to the effectiveness of OHS regulation in work with nanomaterials may require a shift in perspective about regulation itself. Traditionally effective regulation refers to the degree to which a policy goal has been achieved through the rule compliant behavior of regulated parties (Opschoor & Turner 1994). In the sociology of law, it is argued that measuring goal achievement is difficult; when the regulated parties follow the rules it can be assumed that a policy goal has been achieved (Griffith 2003). In this respect, effective regulation refers to the outcome of 'rule-following behavior' (Griffiths 1999) or to acting in conformity with the rules (Hutter 1997). Rule compliance generally depends on whether the regulated parties are willing or motivated to follow the rules (willingness to comply), and whether they can follow the rules (capacity to comply) (Karlsson-Vinkhuyzen & Vihma 2009; Havinga 2006; Griffiths 2003). Specific conditions regarding the capacity and willingness to comply have been explored in numerous studies on the effects of hard regulation[43] (Coglianese & Mendelson 2010; Gunningham 2010; Vogel 2009; Baldwin & Black 2008; Braithwaite 1995; Braithwaite et al. 1994; Kagan & Scholz 1984), soft regulation[44] (Karlsson-Vinkhuyzen & Vihma 2009; Havinga 2006) and hybrid regulation that combines hard and soft regulation (Dorbeck-Jung et al. 2010; Halpern 2008). By focusing on compliance, an *outcome-oriented perspective* to effective regulation is adopted. In other words, regulation is effective depending on whether rules are followed, or not.

In the context of regulation of nanomaterials such conceptualizations that focus on the outcome of rule compliant behavior as determining factor for effective regulation are not useful. In nanomaterial's OHS regulation, the desired outcome of rule compliant behavior is the protection of employee health. However, since the risk endpoints of certain nanomaterials are largely unknown, one cannot know whether the quality of rules designed to mitigate such risks is sufficient, or even if these rules are being followed. Thus, from a scientific point of view, we do not know whether these rules are evidently 'working' in protecting workers from the potential harmful health effects of nanomaterials. Therefore, a focus on the outcome of rule compliant behavior is not feasible at this point in time. Rather, in view to effective regulation of nanomaterials OHS it is more useful to consider a preparatory step of rule compliance: the process of giving meaning to, or 'translating', general OHS rules into the specific context of nanomaterials under conditions of scientific uncertainty. In the context of the regulatory process the element of preparing compliance has not received much attention by regulatory scholars and appears largely under-researched. However, preparing compliance is a crucial, first step in the process towards effective regulation.

Certainly, existing OHS regulation with the employer obligation to conduct risk assessment for all chemicals, including those at the nanoscale, must be complied with. The crucial question is how compliance can be achieved by companies, i.e. how risk assessment for nanomaterials can be done. Thus, we need to study those actors who supposedly have scientific expertise, knowledge and data available to make risk assessment applicable for nanomaterials. Likewise we need to study the conditions under which such actors provide

[42] See also the remark earlier in section 1.2 (p. 20) on the impossibility to know 'the objective truth' in a decentered society.
[43] 'Hard regulation' refers to rules (e.g. in legislation) that are based on legally binding force meaning failure to comply is punishable by a Court of Justice.
[44] 'Soft regulation' refers to rules (e.g. in codes of conducts or guidelines) that do not have legally binding force, i.e. is not backed by legal sanctions.

these resources in order to support the clarification and/or specification of the rules that are concerned.

It has been said (in section 1.2) that business associations possess essential knowledge and expertise related to nanomaterials that can facilitate the process of 'giving meaning' to OHS rules that need to be complied with. On this basis, associations can contribute to effective regulation through activities related to knowledge exchange and collection as well as through the generation of new knowledge relevant for making risk assessment applicable to nanomaterials. Such activities can be, for instance, in the form of workshops, seminars, or research projects. On the basis of these activities, guidance material in form of soft regulation may be developed and existing OHS rules may be specified.

Thus, in this thesis, we look at the activities preparing rule compliance with the employer legal obligation to provide safe workplaces through conducting risk assessment for nanomaterials. It can be assumed that not only regulatees business associations participate in these processes (in order to support compliance); regulators are likely also participating because they can benefit from the knowledge on the health risks of nanomaterials that is generated by using this new knowledge to ensure that OHS rules are evidently protecting the health and safety of workers. Accordingly, regulators may specify existing rules or develop new rules.

By evaluating processes of collaboration among business associations and regulators aimed at ensuring rules that provide safe work environments for handling nanomaterials, a *process-oriented perspective* to regulation is taken. Collaboration among business associations and regulators is considered as a contribution to effective regulation when the collaborators learn how to improve traditional risk assessment frameworks for nanomaterials on the basis of newly developed scientific data or knowledge.

Learning how to make traditional risk assessment applicable to certain nanomaterials is crucial. On the one hand, when associations have an increasing knowledge how to conduct risk assessment for certain nanomaterials they can, on this basis, bundle new information and develop soft regulation that support their member companies in complying with existing OHS legislation (i.e. the employer obligation to conduct risk assessment for nanomaterials handled at workplaces). Soft regulation, resulting from learning processes among business associations and policy-makers, may increase the possibility for regulatee compliance regarding future hard regulation. Since regulatees (i.e. industry) were involved fundamentally in the process of rule formulation, their willingness and capacity to comply with rules is likely to be higher. On the other hand, regulators then have an increasing knowledge whether existing OHS rules are adequate for evaluating the health risks of workers when handling nanomaterials and how to, on this basis, protect the health and safety of workers, or whether and which specific adaptations need to be decided.

Hence the focus is on processes of collaboration among business associations and regulators, which induce change in existing knowledge on nanotechnological risks and the assessment and management of these risks.[45] In other words, we investigate collaborative activities of the type knowledge exchange in view of their contribution to enlarging the knowledge on nanotechnological risks, their assessment and management.[46] On the basis of such new insights evidence-based rules of behavior can be ensured that secure health and safety of employees in work environments where nanomaterials are handled. For the purpose of investigating processes of collaboration to solve wicked policy problems such as that of effective nanomaterials OHS regulation,[47] the network governance literature provides useful

[45] In this context, it must be acknowledged that a process-based view on effectiveness does not reject that there is always and inevitably an element of 'outcome' in processes of collaboration; one such element of outcome in nanomaterials OHS as wicked problem is the reduction of uncertainty in risk assessment for nanomaterials.
[46] See section 3.1 (pp. 45-46).
[47] See section 1.1 (p. 16) for an elaboration of nanomaterials OHS regulation as wicked policy problem.

points of entry. In the next section this literature is discussed and key aspects useful for the analysis of collaboration and learning among business associations and regulators are identified.

4.2 Network governance

As will be argued in this section, a network governance approach is particularly suitable for the analysis of collaborative business association activities involving regulators in the area of nanomaterials OHS. The issue of scientific uncertainty, which characterizes the regulation of nanomaterials, is accounted for in this literature and approaches are suggested for analyzing how collaboration can contribute to effective nanomaterials OHS regulation through learning among multiple collaborators. Accordingly, in this section, the problem of effective nanomaterials OHS regulation will be characterized as a network governance problem. Other accounts (e.g. rational choice theories or 'decision theories') that seek to address dilemmas of regulation under uncertainty appear less suitable because they do not consider lack of information in regulation and also do not acknowledge that policy processes can be steered by multiple actors (see, e.g. Klijn 1997; Braybrooke & Lindblom 1963).

Background and main ideas

As various theoretical approaches from the 1970s onwards have shown, public policy results from interaction between many actors who try to influence the process of policymaking in a direction that is favorable to themselves (e.g. Cohen et al. 1972). These approaches look at the dynamics in the process of policy making. In this respect, research on policy networks illustrates an attempt to take up and contextualize the process approach: actors and their preferences, information, and strategies are ambiguous, but are not chance aspects in policy processes because they are connected to an interorganizational network in which these processes take place (Klijn 1997).

Connotations given to the term network were, and are, ambiguous across different research traditions (Kenis & Schneider 1991). The term is also not a neutral one since participation in a network is, to a certain degree, strategic as is the process of networking (Hay & Richards 2000). At its core a network perspective on governance refers to,

> "(…) a decentralized concept of social organization and governance: society is no longer exclusively controlled by a central intelligence (e.g. the State); rather, controlling devices are dispersed and intelligence is distributed among a multiplicity of action (or "processing") units. The coordination of these action units is no longer the result of "central steering" (…) but emerges through the purposeful interaction of individual actors, who themselves are enabled for parallel action by exchanging information and other relevant resources" (Kenis & Schneider 1991: 26).

Importantly, public policymaking and governance is conceived as taking place in networks that consist of multiple actors, organizations, individuals, and coalitions et cetera. While some actors may be more powerful than others, generally no actor alone possesses the sole power to determine strategies of others (Kickert et al. 1997) since all actors are dependent upon each other by their possession of particular crucial resources (e.g. knowledge, expertise, data). Therefore actors come together in specific arenas to exchange resources and negotiate problems (Klijn & Koppenjan 2013). In this light, a network is a specific kind of social organization that is not merely composed of a sum of actors and links, but a network is something that is valuable by itself (O'Toole 1997) and as a 'mechanism of coordination' and cooperation (Provan & Kenis 2007). But networks have also been criticized as as not being transparent and as constituting a threat to the accountability (Milward 1996) and democratic legitimacy of government performance (Marsh & Rhodes 1992).

Research on networks started in the 1960s and has a rich history, including various theoretical traditions[48], which can be distinguished by following two basic approaches:

1. a 'network analytical approach', and
2. a 'network as a form of governance approach' (Provan & Kenis 2007).

Even though the approaches have fundamental differences, some overlap is, of course, possible. Network analytical approaches are chiefly found in the field of sociology. Here scholars traditionally study networks of individuals considering micro-level network features (Moreno 1934) in order to describe, explain or compare a network's structural characteristics and relational configurations (Huxam & Vangen 2005; Agranoff & McGuire 2003; Wassermann & Faust 1994). Broadly speaking a network is conceived of as a set of actors or nodes, which has present or absent relationships among these nodes and therefore networks vary in regard to structural patterns of relations (Provan & Kenis 2007).[49] Accordingly, most often the complete network itself is not analyzed; rather analysis focuses on particular nodes and relations that make up the network (O'Toole & Meier 2006). Studies are typically concerned with the way an actor is embedded in a network and whether this affects network formation and ending of relationships between nodes (Uzzi 1997). A network analytical approach thus helps to address specific network conditions in view to an outcome.

By contrast, network as a form of governance approaches are chiefly found in the field of public administration and political sciences. These approaches focus on the examination of complex societal problems and decision-making that is acceptable to a multiplicity of involved actors (e.g. Sørensen & Torfing 2003; Klijn 2001; Hanf & Scharpf 1978). This approach is more suited to the goals of this thesis since it is concerned with business associations being part of a wider web of relationships with the aim to contribute to solving the policy problem of nanomaterials OHS regulation.

The literature on networks as a form of governance perceives processes of collaboration with the goal to solve complex policy problems as having two general dimensions: On the one hand, due to incomplete knowledge in relation to a certain policy problem there is substantial or content uncertainty across the network as a whole. On the other hand, uncertainty derives from the presence of multiple actors each having own perceptions, goals and strategies in view to the problem definition and its expected solutions (Koppenjan & Klijn 2004: 39). Thus, actor behavior takes shape in complex and unpredictable 'games' of collaboration that are related to broader network structures.

To decrease uncertainty, and provide solutions to policy problems, requires the deployment of various actor key resources such as knowledge, skills, money and decision-making authority (Koppenjan & Klijn 2004: 46). In collaborative processes these resources are exchanged and negotiated depending on general and individual actor strategies. In this

[48] For a historical overview of the development of the different traditions in research on policy networks, see Klijn (2008), who distinguishes between three theoretical traditions: (1) Pluralist theories of political science (Rhodes 1988; Truman 1971; Bentley 1967), (2) organizational science and inter/organizational theory (Agranoff & McGuire 2003; Warren et al. 1975) and, (3) Public Administration (Sørensen & Torfing 2003; Klijn 2001; Hanf & Scharpf 1978).

[49] Concepts of observation are 'centrality', 'structural holes' and 'density'. The unit of analysis is a set of objects termed 'nodes', 'positions' or 'actors' and a set of present or absent relations among these objects (weak, strong, absent) called 'edges', 'ties' or 'links' (Provan & Kenis 2007: 4).

way collaboration among actors is organized around relations of resource dependency[50]. Collaboration brings about exchange of information, perceptions and goals and, if successful, it may create certainties "(…) through mutual perceptions and binding decisions and agreements, that enable common action and joint solutions" (Koppenjan & Klijn 2004: 65). Under these conditions a 'negotiated environment' (Koppenjan & Klijn 2004) or, as regulatory scholars name it, a 'negotiated regulatory framework' (Aalders & Wilthagen 1997) can be developed.

Given that networks do not necessarily have a single central authority or goal, it has been argued that some sort of steering or management might be favorable in order to collaborate meaningfully (Koppenjan & Klijn 2004). The term 'network management' has been defined rather loosely by network governance scholars. For instance, network management is described as "(…) a specific allocation of resources whereby leveraging external opportunities and buffering the system from unwanted shocks supplements hierarchical functions" (McGuire 2006: 39). Network management may be directed at initiating or facilitating interaction among actors (Friend et al. 1974), or it may be directed at creating or changing structures to facilitate improved coordination (Scharpf 1978). As Kickert and Koppenjan (1997) emphasize, besides aiming at influencing interaction processes directly, network management may also improve cooperation indirectly by influencing the institutional context, the values, norms and perceptions within the network.

As such, management from the network perspective is to be distinguished from the traditional intra-organization approach to management; here management is understood as the activity of a 'system controller', a manager who controls an organization or parts of it by top-down activity, based on clearly defined authority structures (Robbins 1980). Instead, from the network perspective management is characterized by divided authority structures with management activities referring to mediating and guiding interaction among actors in view of perceived problems and goals (Kickert et al. 1997). Therefore, network management can be described as an activity that takes place on the meta-level: it is a form of steering, which aims to promote cooperative strategies and finding solutions to joint (policy) problems in networks.

Network management is useful when network actors cannot agree on common goals, or when power is distributed unequally, or when trust-relations cannot be built among actors themselves (McGuire 2006; Goldsmith & Eggers 2004; Huxham 2003). For example, Agranoff (1986), in his empirical study on intergovernmental management in six metropolitan areas, found that interaction processes among network collaborators are characterized by many steps forwards and backwards; steering by a network manager who acts as 'facilitator' for interaction and communication is useful to explore and realize innovative and mutually beneficial solutions. As Provan and Kenis (2007) note, in networks where actors trust each other 'shared governance' as a particular form of network management is most effective; here all organizations that comprise the network govern the network. When little trust among network members prevails, the network should be managed through an external body, or network administrative organization.

The literature on network governance is concerned with investigating processes of interaction among multiple actors, who are connected in a web of relationships, characterized by resource dependency in order to solve a policy problem. The problem of effective nanomaterials OHS regulation can be characterized as a network governance problem: various actors, i.e. representatives from business associations and regulatory agencies collaborate in order to protect the health and safety of workers who handle nanomaterials under conditions of scientific uncertainty. The crucial resources are scientific data and knowledge on

[50] Koppenjan and Klijn's view on dependency among actors is based on Scharpf's (1978) typology, in which he distinguishes two dimensions of dependency, namely the importance of the resource and the substitutability of the resource. Actors are dependent on other actors if the relation to that actor is based on low substitutability and a high level of importance.

nanomaterials as well as decision-making authority. Public and private actors are dependent upon one another in this respect.

Regulators require scientific data and knowledge so as to ensure evidence-based rules for the protection of employee health. Business associations, however, depend on regulators because they have the authority to set (new and possibly stricter) regulation and legislation that businesses need to comply with. When business associations share their scientific data and knowledge on nanomaterials with regulators, win-win situations for both parties can be created: regulators may be able to ensure that OHS rules in form of regulation or legislation is evidence-based; associations may be able to influence such OHS rules in a way favorable to them so that the innovative (market) potential of nanomaterials is not impeded unnecessarily.

In this section we have clarified how collaboration between associations and regulators can be perceived from a network governance perspective. Next, we turn towards general approaches for the analysis of collaborative activities in networks, as suggested in the literature, before more concrete analytical categories are defined.

Approaches for the analysis of collaboration in networks

For the analysis of activities in networks it needs to be acknowledged that networks are not static entities; rather, they are dynamic in character with collaboration on particular issues being an ongoing process. In order to deal with this element of dynamism the network governance literature conceptualizes processes of collaboration to take place in 'rounds' of interaction and negotiation among actors across a certain period of time (Koppenjan & Klijn 2004). Rounds of decision-making start, and end, "(…) with the adoption of a certain combination of a problem definition and a (virtual) solution by one or more actors" (Teisman 2000: 947). Problems and solutions are relevant to the process of negotiation if actors perceive and articulate them as such (Teisman 1998). When actors mutually adjust positions in the process of interaction and deliberation, negotiation paves the way for to decision-making directed at solving a problem.

Rounds of decision-making in networks may be seen as interactive (Scharpf 1997), leading to progress over time (Teisman 2000). The assumption is that decisions by actors are not made on basis of a priori order; it is the task of the researcher to clarify and explain the empirical relation between decisions (Teisman 2000). For that matter the researcher depicts which actors do (or do not) participate at what time, to then demarcate decision-making rounds through determining crucial decisions and conflicts *retrospectively*. Decision-making rounds may be studied by employing three levels of analysis: the actor, the game, and the network (Koppenjan & Klijn 2004) (see Table 4.1).

To conduct an *actor analysis* means to formulate a concrete (though initial) problem identity. This problem identity is based on the identification of the important actors in a network, their positions as to the problem definition and potential solutions, as well as their resource dependencies in relation to the problem situation. In this respect, an actor may be an individual, a group, or an organization active in relation to the problem situation under study (Koppenjan & Klijn 2004: 139). The initial problem identity helps determining the components of the problem situation and, as such, may be rejected or adapted during the course of the actor analysis. By identifying the key actors, their positions in regard to the problem and ideas about solutions we can compare actor interests in the collaboration. Actors frequently serve multiple and conflicting interests simultaneously (Jones et al. 1997; O'Toole 1997). If not all of these interests are taken into consideration it will remain unclear "(…) that the problematic issue in a situation is that both interests are simultaneously at stake and that an adequate approach to the problem must contain an answer to this dilemma" (Koppenjan & Klijn 2004: 143).

Table 4.1. Overview of the three analytical levels and relevant questions (revised form from Koppenjan & Klijn 2004).

CATEGORY	QUESTIONS
ACTOR ANALYSIS	
Actor perceptions and positions	• who are the actors? • which actors have an interest in finding a solution to the problem?
Actor dependencies	• what resources do different actors have at their disposal? • how important are these resources and can they be substituted?
GAME ANALYSIS	
Arenas of negotiation	• where are decisions made? • which actors interact in which context? • which relations do these actors have with each other?
Stagnation	• what is the nature/structure of the game? • is there stagnation/blockades? • how to explain stagnation?
NETWORK ANALYSIS	
Network interaction pattern	• which actors interact frequently/infrequently? • which actors are central & peripheral in network?
Network perception pattern	• what perception do actors hold regarding the problems, solutions, and their environment? • to what degree do those perceptions correspond to those of others?
Network institutional structure	• which soft/hard rules (legislation) apply? • what organizational procedures exist in the network to structure the game?

Once the actor characteristics are mapped, the dependency relations between these actors are determined by comparing the resources that actors control. An actor's degree of dependence is related to the significance an actor ascribes to the resources held by others as well as by the possibility of substituting these resources, or obtaining them, through other actors; this is what Scharpf labels, 'resource substitutability' (Scharpf 1978). In this light, "[t]he degree that one organization is dependent upon another organization is measured by the importance of their resource for the realization of objectives as well as the degree to which it is possible to acquire the resource elsewhere" (Koppenjan & Klijn 2004: 145).

In order to define the resource dependency of a specific actor, the relevance of resources is to be determined in the context of the problem-situation, stated goals, and which 'critical actor' holds them. Furthermore, dependence among actors is influenced by the willingness, or interest, of actors to use their resources. An actor is seen as "dedicated" when that actor has a particular interest in the problem situation/solution or perceives clear costs and benefits in the outcome. In analyzing actor perceptions, objectives and interests similarities and/or differences among actors can be acquired that give information about potential allies, critics, or blockers (Koppenjan & Klijn 2004: 147).

The second, or *game*, level of analysis identifies the grounds, or 'playing fields', where actors make important decisions regarding the problem and its solution(s). It also enables us to understand stagnation in the course of negotiation processes that may prevent collective action (Koppenjan & Klijn 2004: 147). To determine the playing fields where the game takes place provides an overview of the settings where actors form strategies and how decisions do, or do not, relate to each other. It may occur that actors realign their strategies and goals during the process of negotiation as a consequence of stagnation or blockades (Ostrom 1990).

One can speak of stagnation when conflict hinders decision-making, which becomes visible, for instance, through actors' repetition of arguments, decline in interaction or create a hostile atmosphere between critical actors. Stagnation and blockades may have a substantive (knowledge) and a social component. Understanding the cause(s) of asymmetry among actors is important for the development of strategies for overcoming stalemate and continuing collaboration successfully.

In the *network* level of analysis the rules of behavior that structure interactions between actors are investigated to understand the character of collaboration between individual actors and the network (Koppenjan & Klijn 2004: 151).[51] The inventory of interactions is linked to an analysis of actor perceptions and rules in order to explain interaction and provide intervention strategies. The interaction of actors does not take place in a vacuum, so it is important to consider the institutional context by looking at the formal (legal) and informal rules that frame interaction processes (Koppenjan & Klijn 2004: 156) and how these rules might change over time.

In this relation it should be noted that this thesis adopts the terminology of 'soft' and 'hard' rules. Soft rules or regulation concern, most often, rules of behavior that tell actors what ought to be done under certain circumstances and do not have legally binding force. An example of soft regulation that does not concern rules of behavior, but rules to interpret legislation, is the EC Recommendation of 18 October 2011 on the definition of nanomaterial. This Recommendation provides rules on how existing legislation covers nanomaterials specifically.

Actors follow soft rules voluntarily, even if only as a result of social pressure to do so. Both public and private bodies may set soft rules. While state institutions often set soft regulation in form of communications or recommendations, non-state organizations such as business associations frequently set soft rules in form of codes of conduct or guidelines. Soft rules can have an autonomous steering role, but also the roles of preparing the ground for hard regulation–i.e. regulation that is legally binding with non-compliance being backed by sanctions through enforcement agencies and/or the courts–and contributing to the interpretation and implementation of hard regulation (Reichow & Dorbeck-Jung 2013b; Senden 2004: 112-114).

Rather than perceiving soft and hard regulation as dichotomic, this thesis considers gradations in between. As such, we may think of soft and hard regulation on a continuum on which soft rules can 'harden' through processes of formalization (see, below, Figure 4.1). From a sociology of law perspective, formalization can occur through codification of soft rules in legal texts, as well as through their linguistic expression by public authorities. More specifically, sociology of law scholars emphasize that law is closely tied to social realms and practices; law does not merely encompass written texts but as much its application within social realms (Bourdieu 1987[52]). Accordingly, we may speak of 'law-in-books' (i.e. texts of the law such as judicial decisions, commentaries or recommendations that formalize through codification) and 'law-in-action' (i.e. linguistic expressions by legal professionals in social reality that formalize through public authority) (Pound 1910). By taking a pragmatic approach

[51] Originally Koppenjan and Klijn (2004) propose to investigate the frequency and variety of interaction among network actors in order to distinguish central from peripheral actors; in this relation, central actors have many contacts with others and/or a varied contact pattern. However, as mentioned earlier, in the scope of this thesis the aim is not to describe and characterize a network as a whole, but merely key actors. Therefore the frequency of actor interaction is not considered.

[52] It may be arguable whether Bourdieu could be understood as a scholar in the sociology of law; however, his seminal article The Force of Law: Toward a Sociology of the Juridical Field (1987) has been considered as playing an important role in the sociology of law (Dezalay & Madsen 2012).

to this conception, in this thesis, soft rules may become 'hardened' through formalization: namely, written reference in texts of the law and/or oral reference by public authorities. For instance, a guideline for the safe handling of nanomaterials in workplaces, developed by industry, can become hardened through its recommendation for use in a policy brief by a federal OHS agency; or, it may become hardened through oral reference by a representative of a federal OHS agency during a workshop on the safe handling of nanomaterials. In this way rules become more durable and possibly binding. While hardened rules provide certainty that those who follow the rules behave in the best possible way under specific circumstances, hardened rules also level down the playing field, i.e. the regulated parties have less flexibility in deciding how to behave under particular circumstances.

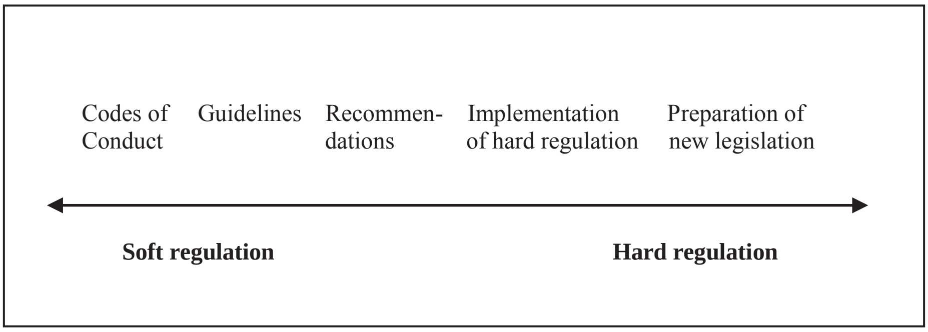

Figure 4.1. Continuum from soft to hard regulation.

In the context of this thesis, the employer legal obligation to provide safe workplaces through having risk assessment and management processes in place is based on legally binding hard rules. To support compliance with this employer obligation in relation to nanomaterials, private and public bodies have developed and/or implemented various forms of soft regulation (Reichow & Dorbeck-Jung 2013a, b). For example, the chemical company DuPont developed the Nano Risk Framework (2007) in collaboration with the NGO Environmental Defense Fund (EDF). Similarly, the VCI together with the German Federal Institute for Occupational Safety and Health (BAuA) developed a guideline to support companies in the risk assessment and management of nanomaterials (VCI & BAuA 2007).

In addition to industry commitment in these soft forms, governments have promoted guidance materials. Due to the uncertainty of the potential impact nanoparticles might have on human health, the Dutch Minister of Social Affairs and Employment (SZW) recommended use of a provisional system of Nano Reference Values (NRVs)[53] to be understood as pragmatic benchmark levels, which have to be accompanied by additional measures to minimize exposure.[54] The expectation of such voluntary instruments is that they can be adapted easily as more knowledge and certainty on the risks of particular nanomaterials become available. In short, these soft rules offer procedural flexibility, not found in legislative approaches.

In this thesis, soft and hard rules that help to address the problem of nanomaterials OHS are named 'problem-oriented rules of behavior'. In contrast, rules that provide broad

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

[54] 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 or derived no-effect levels, 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: 17).

guidance and facilitate interaction and communication among members in a network are called ‘process-oriented rules of behavior’. By analyzing problem-, and process-oriented soft and hard rules, as well as interaction among actors that characterize a network, one can explain why desired interactions are (not) realized or why interaction is hindered.

Following the network governance approach, the study of policy-rounds on three levels of analysis (actor-, game-, and network level) enables us to explain and specify the problem of preparing compliance with OHS regulation in terms of conducting risk assessment for nanomaterials. We can examine how relevant collaborators interact and deliberate in view to solving the problem and possibly develop rules to provide certainty how to behave in view to nanomaterials OHS. Furthermore, this approach helps reasoning whether any kind of network management is, or shall be, in place to facilitate and/or improve deliberation and collaboration processes among actors.

After an explanation of the process of collaboration, the quality of the process shall be evaluated. In the scope of this thesis the quality of processes of deliberation and negotiation is assessed by the criterion of effectiveness. In the next section, three analytical categories for the evaluation of association contribution to effective nanomaterials OHS regulation are developed in relation to the three analytical levels.

4.3 Analytical categories and conditions for effective regulation

Based on the foregoing discussion of the network governance literature and general analytical approaches, we can now distill specific analytical categories that provide us with conditions for the study of learning in collaborative business association activities directed at effective nanomaterials OHS regulation in the workplace. As argued earlier, any evaluation of nanomaterials OHS regulation requires a process- rather than an outcome-oriented perspective on effective regulation. When collaborative activities result in learning, based on new scientific insights that help making traditional risk assessment applicable to nanomaterials an essential pre-condition for compliance is created and these activities have thereby contributed to effective nanomaterials OHS regulation. Our operating assumption is that scientific uncertainty about how best to ensure safe workplaces can be dealt with through collaboration characterized by active deliberation across various actor groups including firms, business associations and public policy-makers, each having specific resources, such as data, expertise, skills and decision-making authority.

Building on network governance theory, the argument underlying this thesis is that actors who share their specific resources during processes of collaboration may mutually learn from each other how to improve existing risk assessment frameworks for nanomaterials. The knowledge that is being generated by the actors is appropriate in the sense that actors at large agree that a certain new scientific ‘fact’ has been established.[55] In this respect, fundamental issues of learning could comprise the decision on which scientific parameters are relevant for nanomaterials risk assessment, how to predict nanomaterial hazard, with which techniques nanomaterial exposure can be measured, and how to characterize nanomaterial risk when both knowledge on hazard and exposure are missing.[56] In this context we must, however, acknowledge that learning among business associations and regulators may be influenced by

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[55] In line with the approach of a decentered society, introduced in section 1.2 (p.20), any positivist conceptualization of ‘correct’ or ‘true’ knowledge is indefensible. Due to the fragmentation of knowledge in society no single actor has all knowledge to solve complex problems and there is no ‘objective truth’, but knowledge is socially constructed (DiMaggio & Powell 1991). This ontological standpoint implies that knowledge is dynamic and open to change over time rather than being a stable absolute.

[56] See section 2.1 on the discussion on the science of nanomaterials.

certain characteristics of the political systems in which collaboration takes place (see section 3.2).

Learning is here defined as the sustainable increase in shared knowledge, insights and methods between various parties. In this thesis, learning is the overarching analytical category for the analysis of collaborative business association activities directed at contributing to effective nanomaterials OHS regulation. This analytical category is broken down into three, more specific analytical categories in the form of three types of learning. As such, learning is differentiated in the areas of content (*substantive learning*[57]), process (*strategic learning*), and network (*institutional learning*) (Koppenjan & Klijn 2004).

While this proposed differentiation is useful we will see that the three types of learning, to a certain extent, appear to build upon each other; the assumed order will be specified after the three learning types, and the conditions under which they develop, have been defined. Further, it needs to be acknowledged that the three learning types are not yet sufficiently operationalized by Koppenjan and Klijn (2004) in order to allow for empirical investigations. Rather, the authors propose overarching conceptualizations relevant for processes of problem solving in collaborative networks. Therefore, in the context of this thesis, Koppenjan and Klijn's (2004) general ideas are used as a starting point for finding conditions under which learning can emerge. By drawing selectively on additional theoretical and (as far as available) empirical studies on networks and the learning types we propose conditions under which learning can emerge and specify them where possible. As such, ideally the empirical analysis to this thesis can be seen as a preliminary step towards building a theory of learning in collaborative networks under circumstances of scientific uncertainty.[58]

Substantive learning[59] refers to gaining increased knowledge and insight about the nature, cause and effects of the problem of nanomaterials risk assessment, potential solutions, and their consequences. During this process multiple actor interests and objectives are negotiated resulting in common agreements. Two forms of substantive learning can be distinguished: joint image building and goal intertwinement (Koppenjan & Klijn 2004). The former is accomplished when interaction and scientific research among companies, business associations and policy-makers lets them agree both on a specific problem related to nanomaterials risk assessment and potential consequences of proposed solutions. When research has been conducted but the key actors do not agree on its meaning and significance, superfluous knowledge emerges: knowledge is generated but does not move forward the process of problem solving and therefore enhances uncertainty (Van de Riet 2003). When actors come to a consensus which is not grounded in scientific knowledge, negotiated nonsense is created (Koppenjan & Klijn 2004). Joint image building requires deliberation and negotiated knowledge, namely the agreement about insights based on research findings that are scientifically defensible. Substantive learning also can be of the type of goal intertwinement. Here, learning refers to innovative agreed-upon solutions, which integrate multiple diverging goals of actors and/or decrease or compensate the costs of negative side-effects (Teisman 1992). The solution that is agreed-upon enables considerable improvement of an existing situation for most actors (Klijn & Koppenjan 2000).

Based on this discussion, for the purpose of this thesis, the key characteristic of substantive learning is *scientific expertise* to be studied by means of four conditions that are assumed to build on each other in the described sequence (see, below, Table 4.2). Substantive learning in regard to making risk assessment applicable for nanomaterials is, first, assumed to

[57] This type of learning is originally termed 'cognitive learning' by Koppenjan and Klijn (2004). In the scope of this thesis the term substantive learning is used instead in order to avoid confusion with previously applied terminology.
[58] These theoretical implications will be reflected on in more detail in chapter 9.
[59] The following conceptualizations of the three types of learning (i.e. substantive-, strategic-, and institutional learning) broadly follow Koppenjan and Klijn (2004). Where the authors do not provide the level of specificity required in this thesis, other relevant network governance literature is consulted.

be possible only when 'relevant actors collaborate'. The principle of resource substitutability (Scharpf 1978) states that actors must bring resources into the collaboration that are essential for solving the policy problem at hand. When these resources cannot easily be substituted by other actors in the network then these actors are 'relevant actors' in the network.

Thus, in this thesis, actors are relevant when they hold the crucial resource scientific (risk) data and knowledge on nanomaterials relevant for solving the problem of risk assessment for nanomaterials. Furthermore, when actors hold the resource decision-making authority they are considered relevant actors because they may decide, which solutions in regard to the problem of nanomaterials OHS are to be implemented into rulemaking (or preparing compliance).[60] Second, when these actors 'exchange their knowledge and (risk) data' with other network collaborators a basis for meaningful deliberation and negotiation of (conflicting) scientific insights in view to conducting risk assessment for nanomaterials can be established. Third, when such deliberations and discussions lead to an 'increased understanding of how to deal with core problems related to nanomaterials risk assessment', another step towards substantial learning is realized. Finally, with the 'generation of novel scientific facts' that help making (aspects of) traditional risk assessment applicable for nanomaterials, substantial learning has been achieved. The actors have a fundamentally better understanding of core problems, as compared to the situation prior to collaboration, and commonly agree on new or innovative 'facts' relevant for nanomaterials risk assessment. Such new scientific facts can relate, for instance, to knowledge increase as to which scientific parameters are relevant for nanomaterials risk assessment, which techniques nanomaterial exposure can be measured, and how risk can be characterized when both knowledge on hazard and exposure is lacking (see Table 4.2 for an overview of the conditions for substantive learning).

Table 4.2. Conditions for substantive learning.

Substantive learning *Scientific expertise*	1. Relevant actors collaborate 2. Exchange of knowledge and (risk) data 3. Increased understanding of how to deal with core problems related to nanomaterials risk assessment, and 4. Generation of novel scientific facts

However, in researching substantive learning in collaborative networks that involve actors from industry, one fundamental restriction in the possibility for knowledge exchange of this actor group needs to be acknowledged. In manufacturing stages of nanomaterials companies are keen on ensuring that the value of their inventions and/or products is protected through intellectual property (IP) legal issues. (Monica et al. 2014). One form of IP–that can be expected to be of special relevance in the context of this thesis–is trade secrets; they concern business information, e.g. scientific data that give an actual or potential economic advantage over others. Such information, when being stamped as trade secret by a company, is prevented from disclosure and can only be accessed by persons other than the holder through setting up confidentiality or non-disclosure agreements. This means that regulators, who receive nanomaterials health and safety data from firms that is stamped as trade secret,

[60] This is not to say that actors who do not hold these two resources are not relevant per se in the discussion on nanomaterials OHS. Rather, they are not of key importance in the context of this research.

can not disclose such information to others. Companies that produce or handle nanomaterials could exchange such data when non-disclosure agreements are set up. Thereby companies could contribute to pushing forward the understanding of nanomaterial toxicity and potential health risks. However, the costs for setting up agreements may hinder knowledge exchange among companies. This aspect shall be considered when talking about knowledge exchange on nanomaterials and learning among industry and regulators.

The second type of learning is *strategic learning*. It refers to the quality of interaction in the process of collaboration evaluated by the key characteristic *trust*. We can speak of strategic learning when network actors develop a growing capacity to collaborate even though they pursue different individual goals (Koppenjan & Klijn 2004). When actors with individually different backgrounds and beliefs work together in view to the common goal of ensuring health and safety at workplaces where nanomaterials are handled, different points of view come together how to reach this goal. Naturally interaction in networks implies that individual actor goals and strategies diverge from each other and from the overall network goal, which may lead to disagreement and conflict in interaction among actors. When such conflict is not addressed and solved, goal divergence can lead to blockades and stagnation in collaboration, visible through actors' repetition of arguments, decline in interaction or a hostile atmosphere (ibid). But when disagreement among actors is addressed openly and solved to the overall satisfaction of collaborators, actors learn that others in the network can be trusted to act in view to the common network goal, even though they may have different individual opinions on specific issues under discussion (ibid). Under these circumstances actors are willing to accept certain risks, in terms of personal loss, because they trust that other actors will refrain from opportunistic behavior where there is an opportunity for such behavior.

When relationships are characterized by trust, exchange of information, knowledge and skills among collaborators is facilitated since actors are more open towards each other; this is said to stimulate learning, enhance problem-solving capacity and the potential for finding innovative solutions to problems and challenges (Edelbos & Klijn 2007; Koppenjan & Klijn 2004; Hajer & Wagenaar 2003; Zand 1972). In the context of finding innovative solutions to complex problems, trust is both necessary and problematic: in innovation uncertainty is high and under uncertainty trust is needed. Trust requires uncertainty regarding the conditions, conduct and results of collaboration because it entails risk of vulnerability to the actions of others. Trust, however, is not totally uniformed, but is based on certain information from observed or reported behavior (Nooteboom 2010).

While Koppenjan and Klijn (2004) acknowledge that trust is important for strategic learning, they do not explain how trust among network collaborators develops and progresses over time in collaborative environments. The literature on trust also does not provide clear answers to this question and is still fragmented. There is no overall theory of trust in interorganizational collaboration and little is known about the conditions under which trust among private and public bodies impact the transfer of knowledge in network collaboration (Becerra et al. 2008; Bachmann & Zaheer 2006). While the issue of trust has received little attention in the public administration literature, mostly by addressing trust of citizens in government (e.g. Van de Walle 2010; Christensen & Laegreid 2005), recently the network governance literature began to address the issue of trust between public and private actors (Klijn et al. 2010; Edelbos & Klijn 2007).

The literature points to three basic characteristics of trust: risk, expectation and vulnerability (Klijn et al. 2010). Trust refers to vulnerability because actors who trust each other put themselves willingly into a vulnerable position. They expect that other actors will refrain from opportunistic behavior even though the opportunity for it may emerge (Sako 1998). As they do not have a guarantee that such opportunistic behavior will not arise, they take a certain risk that other actors do not behave as expected (Deakin &Wilkinson 1998) while having the fundamental believe that actors take other actor's interest into account in the process of collaboration (Nooteboom 2002). In other words, actors trust that other actors (the trustees) will respect their interests as 'trustor' (Nooteboom 2000).

Trust relates to feelings or perceptions (e.g. hope and suspicion) as well as to a rational evaluation or reasoning why and when other people might (not) be trustworthy. Nooteboom (2010) defines trustworthiness as the ability and willingness to not only take into account material self-interest, but also more altruistic motives like loyalty, justice or legitimate conduct. For collaboration to be sustainable or lasting trust is a necessary component (McGuire 2006).

To analyze strategic learning in collaborative networks, six conditions are derived from the trust literature (see Table 4.4). These conditions are assumed to, partly, build upon each other in the order as presented. First, building and maintaining trust among collaborators requires 'meetings over a longer period of time'. Various studies support the idea that trust develops slowly over time because collaborators need to become familiar with each other on the basis of personal interaction and experiences (Edelbos & Klijn 2007; Droege et al. 2003; Sako 1998; Lewicki & Bunker 1996). The literature does not specify what 'meetings over a longer period of time' practically means, but mentions what they are not, namely, 'one-time-only affairs' (Axelrod 1984). Little is known about how much time is necessary for trust to develop and how trust develops over time (i.e. whether it grows stronger or becomes more fragile) and generally "[t]he time issue looms as one of the biggest unexplored aspects of trust empirical work" (McKnight & Chervany 2006: 43).

Second, on the basis of meetings over a longer period of time for trust to develop among collaborators 'intensified actor relations' are required. Actor relations become intensified when collaborators get to know each other better and become familiar with one another. The size of a group of collaborators influences possibilities to become familiar with each other; when a group is made up of a small number of collaborators, possibilities to get to know each other are higher than in large groups. Based on (past) experiences in processes of interaction, trust can develop (Vangen & Huxham 2003; Gulati 1995). Thus, having more information about collaborators available from personal interaction is important for trust to be build. In addition, such information may be derived from impersonal or second-hand information on collaborators, i.e. their reputation based on recommendations or a 'good name' in professional journals (Lewicki & Bunker 1996; Gabarro 1978).

Third, after collaborators have intensified their relationships, 'reliance among collaborators' may develop. Reliance is a sign that trust has begun to emerge. Reliance refers to two elements: predictability and control of other's behavior in a network. In regard to the former aspect, reliance means consistency of other actor's behavior (Gabarro 1978). In this connection actors know each other very well, based on personal experiences, and they believe that others will adhere to agreements that have been made formally or informally (Klijn et al. 2010). But this belief is adaptive: when trust among collaborators is betrayed, behavior becomes less predictable and actors realign relationships towards greater levels of control. While trust and control are substitutes, they also are complements (Klein Woolthuis et al. 2005) since 'complete' trust, i.e. by government that regulatees comply with existing rules, is impossible, and where trust ends control is needed. Conversely, 'complete' control is impossible and where control ends, trust is needed. Concomitantly, more trust allows for less control (Nooteboom 2010).

Fourth, an indicator–rather than the next step in the development of trust after reliance among collaborators has emerged–that collaborators have developed relations of trust is the *realization of common goals* of the network. When actors can coordinate their activities by giving preference to the achievement of common network goals, rather than their own individual goals, trust is present; the collaborators act in this way because they expect that such a situation will not be used against them or will result in opportunistic behavior by other network actors (Koppenjan & Klijn 2004). On the contrary, when certain network actors try to realize their individual goals at all cost and to the disadvantage of the common network goal(s), blockades and conflicts can emerge that hinder collaboration and may even lead to distrust. This situation can be described as ‘goal divergence’ (Koppenjan & Klijn 2004). In this connection it shall be mentioned that ‘individual goals’ may refer to an actor’s own, or personal, goals and/or such goals that emerge from a certain (institutional) background and which an actor adopts as individual goals.

Fifth, trust can grow stronger when *disagreement among collaborators is addressed and solved*. Any kind of disagreement can affect interaction among collaborators. While disagreement can lead to conflicts and blockades in processes of collaboration, such situations can also mark the beginning of improved cooperation (Ostrom 1990). For when conflicts are solved to the broad satisfaction of the network actors, for instance through reaching a consensus that is bearable for most actors, people can develop a strong trust that also future conflict can be handled adequately (Edelbos & Klijn 2007; Koppenjan & Klijn 2004). On the contrary, when conflicts among actors cannot be solved discrepancy is nourished, which feeds stalemate in the process of collaboration as well as distrust among actors.

Sixth, with the *development of additional collaborative activities* trust can grow stronger because temporal continuity ensures stability in collaboration (Zucker 1986). Likewise, it would appear that the organization of new partnership activities indicates that past and present relations are based on overall trust. However, while new activities can strengthen trust relations, we also need to acknowledge that they may result in trust relations becoming fragile or even breaking down when actor expectations are not met or their trust is damaged by opportunistic behavior (Edelbos & Klijn 2007).

Thus, the key characteristic of strategic learning in connection with nanomaterials OHS is *trust*. Knowledge exchange is enhanced when business associations, companies and public policy-makers within networks can realize a common basis of trust in their relations with each other. Knowledge exchange, in turn, can further the development of new scientific facts relevant for making risk assessment applicable to nanomaterials. Trust relationships also help overcome potential clashes among actors in decision-making games (see Table 4.3 for an overview of the conditions for trust as key characteristic of strategic learning).

Table 4.3. Conditions for strategic learning.

Strategic learning *Trust*	1. Meetings over a longer period of time 2. Intensified actor relations 3. Reliance among collaborators 4. Realization of common goals 5. Disagreement among collaborators is addressed and solved, and 6. Development of additional collaborative activities

Lastly, the third type of learning, *institutional learning*, in a network arises when associations, companies and policy-makers develop and communicate agreements and rules of behavior that support interaction and make behavior more predictable (Koppenjan & Klijn 2004). It is assumed when collaborators have developed relationships based on trust, they are more likely supporting the development of agreements and rules because they believe that these will not be detrimental to them. In this context, agreements and rules can be of two types: they can refer to interaction among relevant actors in a network to structure, facilitate and stabilize processes of collaboration so that actors know acceptable ways how to act under certain circumstances (process-oriented agreements/rules). Agreements and rules can also refer to practices on how to handle nanomaterials at workplaces most safely based on the latest state of science and instrumentation (problem-oriented agreements/rules).[61] The precursor of full-fledged rules can be informal or ad hoc agreements developed by key actors during the process of cooperation.

Over time, these agreements can become more durable provisions like soft rules and possibly hard rules that change actor relations in a network. Typically, soft rules play an important role in risk and technology regulation due to their open and flexible character that allows responding quickly to the dynamics of knowledge development and facilitating adaptation to new insights into technological risks (Meili & Widmer 2010; Bowman & Hodge 2009; Black 2002). Under such conditions institutional learning can emerge, which shapes the relations among actors in the network for the long term. As a result, institutional uncertainty in processes of cooperation is reduced because actors and the network become linked through explicit rules that facilitate interaction.

These relatively stable structures enable actors to identify each other and to know about the *modus operandi* of interaction with one another. In other words, actors gain certainty about behavior under specific circumstances (Koppenjan & Klijn 2004). When actors commit to formalized rules a network structure becomes more resistant to conflicts among individual actors and the rules itself become durable (Hood & Jackson 1991).

Based on this discussion, the key characteristic of institutional learning among companies, associations and policy-makers in the context of nanomaterials OHS is *rules*. Rules decrease uncertainty in the network because they provide guidance for actors under specific circumstances. The development of rules can be investigated by means of three conditions, which are assumed to build upon each other in the presented order (see, below, Table 4.4).

First, the 'development of informal agreements' among network actors can provide the foundation, or pre-condition, for formalized rules in the future (Barendrecht et al. 2012). Such informal agreements are based on unwritten agreements that may be tacit, or implicit, meaning collaborators are not aware of them. Nevertheless these informal agreements guide their behavior because network actors have come to converge perceptions and viewpoints over time (Klijn 2001; Termeer 1993). Unwritten agreements can both be problem-, and process-oriented.

Second, informal agreements may provide the foundation for the 'design of soft rules of behavior'. Over time informal agreements among collaborators may be put in writing and develop into soft rules of behavior, which tell actors what ought to be done under certain circumstances. As such, soft rules provide guidance by suggesting appropriate activities (Koppenjan & Klijn 2004) and structures for actor behavior (Scharpf 1997). Soft rules–either process-, or problem-oriented–may take the form of codes of conduct, guidance material or industry standards. Soft rules are flexible, or dynamic, in the sense that they can be changed and adapted easily when actors see a need to do so. Since compliance with soft rules is voluntary, trust is required that network actors actually adhere to these rules (Koppenjan & Klijn 2004).

[61] Note that Koppenjan and Klijn (2004) do not use the terms 'process-oriented' and 'problem-oriented' rules nor do they make this distinction between rules; they merely refer to the notion of rules as providing network actors with anchors in relation to interaction in the network (comparable to the idea of process-oriented rules used in this thesis).

Third, ‘soft rules can become ‘hardened’’ through formalization.[62] Process-oriented soft rules may become hardened through formalization in publicly available documents or formal agreements like contracts. Formalization means that uncertainty as to the proper *modus operandi* among actors in collaborative processes is reduced. Thereby the collaborative network structures are stabilized. In contrast, problem-oriented soft rules may become hardened through oral reference by policy-makers or regulators as well as through written reference in policy documents or legislation. The hardening aspect implies that rules can become more durable over time thereby setting a certain regulatory standard. In effect, uncertainty as to the proper *modus operandi* of regulatees–in this case companies that manufacture nanomaterials–in the application of traditional risk assessment to nanomaterials is reduced. Actors have learned how to apply (specific parts of) risk assessment to nanomaterials. As such, an essential pre-condition for compliance with OHS legislation (i.e. the legal duty to provide safe workplaces through conducting risk assessment for (potentially) hazardous chemicals) is fulfilled.

Thus, the key characteristic of institutional learning is *rules*. When collaborators succeed to make agreements or develop rules, guidance on how to conduct risk assessment for nanomaterials is provided (problem-oriented rules). This is an important step towards decreasing uncertainty in the realization of nanomaterials OHS. But rules may also provide guidance and certainty as to the interaction among actors in processes of collaboration in networks (process-oriented rules). For the investigation of collaborative business association activities directed at nanomaterials OHS it is important to understand which (implicit and explicit) rules steer behavior among actors in the network (see, Table 4.4 for an overview of the conditions for rules as key characteristic of institutional learning).

Table 4.4. Conditions for institutional learning.

Institutional learning *Rules*	1. Development of informal agreements 2. Design of soft rules of behavior, and 3. Soft rules become ‘hardened’

In this chapter the question how we can evaluate collaborative business association activities as process towards effective nanomaterials OHS regulation has been answered by developing an analytical framework that is based on theories and concepts of network governance. Drawing on insights from this field of study provides innovative and enriching approaches to the study of nanomaterials regulation because both scientific uncertainty and need for co-regulation involving private and public actors is accounted for. In this light, categories for the analysis of collaborative network activities initiated by–but not restricted to–business associations have been provided in the form of three types of learning. Below, Table 4.5, offers a graphical overview of the theoretical framework, i.e. the three types of learning that supposedly enable effective nanomaterials OHS regulation with their key characteristics and conditions.

[62] See section 4.2 (pp. 64-65).

Table 4.5. Theoretical framework with analytical categories and conditions for the evaluation of effective nanomaterials OHS regulation.

LEVEL	ANALYTICAL CATEGORY	CONDITIONS
Actor level	**Substantive learning** Characteristic: *Scientific expertise*	1. Relevant actors collaborate 2. Exchange of knowledge and (risk) data 3. Increased understanding of how to deal with core problems related to nanomaterials risk assessment, and 4. Generation of novel scientific facts
Game level	**Strategic learning** Characteristic: *Trust*	1. Meetings over a longer period of time 2. Intensified actor relations 3. Reliance among collaborators 4. Realization of common goals 5. Disagreement among collaborators is addressed and solved, and 6. Development of additional collaborative activities
Network level	**Institutional learning** Characteristic: *Rules*	1. Development of informal agreements 2. Design of soft rules of behavior, and 3. Soft rules become 'hardened'

As indicated in the beginning, and throughout this section, overall to realize effective regulation there is an assumed order in the types of learning. Thus, we assume that strategic learning is a pre-condition, and amplifier, of substantive learning. When relationships among collaborators are characterized by trust, exchange of relevant knowledge and information among collaborators is more likely since actors are ready to take risks and are more open towards each other; the latter is assumed to enhance problem-solving capacity and the potential for finding innovative solutions to problems and generating new knowledge (Edelbos & Klijn 2007; Koppenjan & Klijn 2004; Hajer & Wagenaar 2003; Zand 1972). It is also assumed that strategic learning and substantive learning are pre-conditions for institutional learning. When collaborators trust each other and have generated new knowledge necessary to deal with the policy problem, the development of agreements and rules is facilitated because the collaborators have the necessary knowledge available to develop such rules and they believe that the rules will not be detrimental to them.

Against this background, in the empirical analysis of the three types of learning we will distinguish between 'strong' and 'limited' learning. We speak of strong learning when many, i.e. the majority, of the conditions of a certain type of learning are met in the process of collaboration. We speak of limited learning when only a few, i.e. half or less, of the conditions of a certain type of learning are met. In this respect, when two or three learning types are characterized as 'strong' learning, overall we speak of strong learning in the collaboration. Accordingly, when one learning type is defined as strong but the other two types are limited, we speak of overall limited learning.

Sufficient for now, the analytical foundation has been laid by means of which business association activities can be analyzed empirically and as a retrospective, step-by-step process towards effective nanomaterials OHS regulation. Foregoing this analysis the methodology applied in the context of this thesis needs to be spelled out in the next chapter.

Chapter 5

Method

This dissertation is based on the investigation of case studies of business associations. In this chapter the case study method is discussed critically. In section 5.1, by situating key elements of the foregoing chapters within the case study literature, the scope of research is defined. The implications this brings with it for the selection of case studies are reflected on. After comparative cases of business associations, actively involved in supporting nanomaterials OHS regulation, have been selected for in-depth study in section 5.2, aspects of data collection and analysis will be discussed in section 5.3.

5.1 Case study method and techniques

Typically case studies are a qualitative method for the generation of causal inferences, based on empirical observations. Following the US mainstream approach to case studies (e.g. Mahoney & Rueschemeyer 2003; Gerring 2001; King et al. 1994), a case study can be defined as "(…) the empirical analysis of a small sample of bounded empirical phenomena that are instances of a population of similar phenomena" (Rohlfing 2012: 2). Adopting this perspective to case studies brings with it the ontological premise that empirical relationships are regular, or at least systematic, and that research on a small number of cases can yield valuable insights. In this light, case studies usually focus on empirically regular causal relationships between two components, X (cause) and Y (outcome), which are principally generalizable (Rohlfing 2012). In this relation, case studies can take three forms depending on the main goal of research, to be distinguished as: hypothesis generating, hypothesis testing or modifying an existing hypothesis.

This thesis is concerned with case studies without aiming at hypothesis testing or modifying; rather it is concerned with hypothesis generating. As highlighted in chapter 4, to date, there is no existing theory by means of which a non-speculative hypothesis to this thesis could be formulated. Consequently, this research shall be perceived as being of explorative character.

Studies of largely unexplored phenomena are a characteristic domain for case studies (Gerring 2004). In sections 1.2 and 4.1 the under-researched element of preparing compliance in view of regulatory effectiveness in the context of emerging technologies has been proposed. This element has not received much attention in traditional regulatory studies.[63] An analytical framework has been developed for the study of collaboration among private and public actors in order to prepare compliance. This framework is merely a tentative proposal towards understanding learning processes in collaborative networks. An objective of this research is to contribute to the generation of hypotheses to be tested in future studies, which would support the advancement of a full-fledged theory on process effectiveness of regulation of emerging technologies under conditions of scientific uncertainty.

[63] As has been argued in section 4.1. (pp. 57-58), instead of focusing on the outcome of regulation, it is more useful to evaluate the *process of regulation* in the form of collaboration among business associations and regulators aimed at solving the problem of nanomaterials OHS including risk assessment for nanomaterials.

This thesis draws on two case studies that are analyzed by means of the developed analytical framework. It should be acknowledged that in the past there has been some criticism with regard to the small number of cases (‘small-N analysis’) in case study research related to the issue of generalizability and in how far these analyses provide a useful approach (Collier 1993; Campbell 1975; Lijphart 1971). Even though most scholars agree on the relevance of small-N studies in research (Mahoney 2000), there has been a long-standing dispute as to the viability of this type of research compared to large-N statistical studies (e.g. King et al. 1994; Ragin & Zaret 1983). Scholars disagree whether small-N studies follow one essential approach (Lieberson 1991) or whether they build on different strategies (Mahoney 1999). Typically, small-N case study research is concerned with discovering causal mechanisms–i.e. a system of interlocking parts that transmit causal forces from X to Y (Glennan 2002; Bunge 1997)–to be researched via techniques such as process tracing (see, e.g. Beach & Pedersen 2013; Machamer 2004). However, since this thesis is explorative in character, the goal is not to discover causal mechanisms, i.e. that A causes B thereby producing a certain outcome.

Instead, we want to investigate how actors learn in view to the problem of effective regulation under specific circumstances and which solutions they propose. Thus, we are interested in discovering a multitude of possible social realities that may, or not, influence each other rather than focusing on confirming that X causes Y. Case studies are useful for the analysis of this process since they allow for the in-depth study of a (research) phenomenon in it specific context. But since this study draws on only two case studies, it must be acknowledged that results may not readily be transferable to other cases.

Scope conditions

Scope conditions serve to delineate the population for which research, and later on the results of this research applies (Walker & Cohen 1985). Against this background, scope conditions have the function to create homogeneity across cases thereby making them comparable. There are at least three implications of scope conditions:

1. Every case in the population must meet the scope conditions
2. The more scope conditions, the smaller the population, and
3. The more scope conditions, the more similar cases are (Rohlfing 2012).

In this research in total five scope conditions on three levels are distinguished to limit the population and thereby achieve comparability across cases:

1. Time: January 2003 until March 2014

This time frame is chosen as collaborative activities of business association supporting the protection of OHS in work with nanomaterials were publicly known about since 2003. Arguably, it shall need to be acknowledged that there may have been other activities prior to this time, which have just not become public. March 2014 is chosen as a reasonable cut-off point due to the inherent time limitation of the research project.

2. *Territory:* US and EU

This scope condition is chosen because both within the EU and the US business associations have been most active in supporting OHS regulation for work with nanomaterials. On a global level there are, of course, other business associations that have been somewhat active but US and EU associations have taken a clear forefront position. It is interesting to investigate association activities within these legal jurisdictions because the protection of OHS is grounded in similar legal provisions for employers in view to conducting risk assessment to ensure safe workplaces. But at the same time their fundamental regulatory approaches differ (Hood et al. 2002).

3. Substance
(a) Policy field: OHS

It is a conscious choice to limit the research and its findings to the field of OHS. In the context of nanomaterials regulation, OHS is specifically relevant because there is limited knowledge around how to best protect workers who handle nanomaterials at workplaces. This area was identified early (i.e. in 2004) in the literature as an area of (potential) concern (RS-RAE 2004) (see section 2.3). At the same time there is a pressing need to find answers to these questions because such workers are among the first to come into contact with nanomaterials (NIOSH 2012). The exposure time and dose for workers is particularly high and thereby puts a vast group of actors at high risk of developing adverse health effects should certain types of nanomaterials be hazardous to human health. Also, the research is restricted to only one policy field so as to be able to conduct an in-depth analysis of a subject matter characterized by a relatively high level of technical intricacy. In addition, from a regulatory point of view, the restriction to one policy field is useful because the regulatory structures in different policy fields are very different thereby calling for the selection of a specific one.

3(b) Legislation: Employer duty to ensure the safety and health of workers through conducting risk assessment

The thesis focuses on the employer legal obligation to provide for safe workplaces through having risk assessment in place for chemicals handled in occupational settings. The research is restricted to this specific provision for two reasons. Firstly, it entails one of the most challenging aspects in the area of nanomaterials OHS regulation. Secondly, this provision has legal bases both in the US and EU and is therefore in line with the territorial scope condition.[64]

3(c) Actor group: Business associations

This scope condition is selected because the literature suggests that the role of business associations in the regulation of nanomaterials is important (Coglianese 2010; Bartis & Landree 2006). Associations can collect, negotiate and generate knowledge and (risk) data

[64] It should be noted that this legal obligation exists, next to the US and EU, in many other legal jurisdictions worldwide. Nonetheless, it is acknowledged that the territorial scope condition 'EU and US' does not allow for generalizing the findings of this thesis to the global level.

from their member companies (Bailey & Rupp 2006; Lane & Bachmann 1997), which is currently lacking for nanomaterials, but which is assumed to be crucial for the improvement of traditional risk assessment frameworks and hence effective OHS regulation (see chapter 1 and 4). While business associations supposedly play an essential role in nanomaterials OHS regulation, at the same time, their concrete contribution to the effective regulation is uncertain.

5.2 Case selection and research strategy

Having set the scope conditions, the population of cases and the case selection strategy can be explicated. Overall the population of cases in the context of this study is limited due to the definition of many concrete scope conditions; especially the territorial scope condition (US/EU) limits the population of cases. However, this does not constitute a problem since following such a strategy allows for choosing cases from a population as a whole as opposed to case selection that is merely sample-based. Following the latter strategy would imply that an element of uncertainty is added to the research because findings are made about a known subset of a population rather than a population as a whole (Rohlfing 2012).

The number of cases in the population is restricted to a total of nine business associations of which eight are situated within the EU (see section 3.3). These are the German Chemical Industry Association (VCI) with 21 collaborative activities directed at nanomaterials OHS, the European Chemical Industry Council (Cefic) with 16 activities, the Italian Federchimica with eight activities, the Dutch Vereniging van de Nederlandse Chemische Industrie (VNCI) with three activities, the French Union des Industries Chimiques (UIC) with three activities, the British Chemical Industries Association (CIA) with two activities, the Swiss Scienceindustries with one activity, and the Danish Procesindustries Brancheforening (PIBF) with one activity. In the US only one case is available as only one chemical business association exists unlike in Europe where associations exist by member country as well as on EU level. As such, the American Chemistry Council (ACC) has initiated 19 activities directed at nanomaterials OHS.

In addition to the US case, from the EU associations the case with the highest number of collaborative activities was chosen so as to conduct an analysis of an organization that appears highly committed to the subject matter of nanomaterials OHS. As such, the VCI in Germany and the ACC in the US were selected. It shall need to be acknowledged that even though the US and Germany have comparable administrative set-ups, they also differ as Germany is a (federal) nation state while the US is a federation of states. Consequently clear statements can be made about Germany, but this might not be possible for "the US" as a federation of states. Though OHS is regulated at the federal level, the eleven circuit courts may differ in their opinion on adequacy of OHS measures and instruments

After the two business associations have been selected for investigation of their collaborative activities in view to the contribution to effective nanomaterials OHS regulation, these activities are pre-selected in view to a specific strategy. Only collaborative business association activities that suffice three selection criteria were subject to in-depth study:

1. Association activities must be of the type *knowledge exchange* (see section 3.1 for the overview business association types of activities)[65] since these activities supposedly contribute to effective nanomaterials OHS regulation through inducing change in existing knowledge on nanotechnological risks and the assessment and management of these risks (see section 4.1),
2. Activities must be *verifiable*, i.e. are accompanied by publicly available documents (e.g. reports or commentaries), and
3. Activities must be *initiated* by the business association since we are interested in the contribution of these bodies to the effective regulation of nanomaterials OHS.

Following the application of the three selection criteria, the remaining collaborative business association activities are analyzed based on the previously developed analytical categories and conditions for effective regulation (see section 4.3). This approach ensures comparability among the two business associations. In this respect, association activities are expected to contribute to effective nanomaterials OHS regulation when aimed at extending the knowledge base that is needed to conduct risk assessment for nanomaterials. For instance, collaborative activities such as workshops or seminars aimed at collecting and deliberating on scientific data in a joint effort, but also the development of comments on (policy) documents may be important. Based on such activities soft regulation may be developed.

The aim is to provide a rich, or 'thick', analysis of business association collaborative activities. Therefore this thesis applies a triangulation of research methods. Triangulation refers to using various methods thereby relying on different sources of data in order to provide a rich description to instances of the phenomena under investigation due to different settings and investigations at different points in time (Denzin 1978). In other words, various sources of data provide a comprehensive description of how collaborative business association activities can contribute to effective nanomaterials OHS regulation under specific circumstances, i.e. under conditions of scientific uncertainty and within the broader context of US and EU.

In section 5.3 the methods will be specified and it will be explained how they are triangulated. Eventually, the results will be generalized as far as the scope conditions that have been set prior to the empirical research, allow.

5.3 Data generation and analysis

Qualitative interviewing and coding

In this thesis, interviews were the main method of data collection. Qualitative interviewing are an especially useful method to gain insights into the behavior of actors and to describe how and why change in social and political processes comes about (Rubin & Rubin 2005). The assumption is that a phenomenon under study does not merely have causes, but likewise a history that follows a certain rationality (Becker 1998). Against this background, qualitative interviews are described as 'conversations with a purpose' in order to encourage people to talk at length about a particular topic (Byrne 2004: 181). It is therefore assumed that "(…) interview contexts are situated in social worlds and researcher can capture elements of these

[65] As mentioned in sections 1.2 (p. 18) and 4.1 (p. 58) the focus on knowledge exchange does not preclude association activities that are labeled soft regulation; rather, soft regulation is considered to a potential results of knowledge exchange and generation.

worlds" (Miller & Glassner 1997: 105). As such a constructivist view on interviewing is taken, which enables to explore collaborative processes, directed at contribution to effective nanomaterials OHS regulation, in their socio-cultural contexts and under specific circumstances.

The interviews were done between 2012 and 2014, either in person or by phone. In total 38 interviews have been conducted, of which 22 were done over the phone and 16 in person, i.e. face-to-face. Interviews lasted on average approximately 45 minutes. The interviewees, depending on their affiliations, are classified into one of nine different categories in order to contextualize interview data in the empirical analysis. As such, the categories are: *association*, *industry*, *regulator*, *research institute*, *federal research institute*, *academia*, *NGO*, *consultancy*, *labor union*. Table 5.1 provides an overview of the interview numbers, types, and respective categories for the two case studies; in addition interviews on the transnational level, meaning with relevance for both case studies, are distinguished (in the appendix a more detailed overview including the dates of interviews is provided). Figure 5.1 provides an overview of the distribution of the total number of interviews across the nine categories.

Table 5.1. Overview interviews.

Interviewee	Category the interviewee represents	Type of interview
Interviews on transnational level (relevant for both case studies		
1	Industry (France)	Phone
2	Association (UK)	Phone
	Interviews case study ACC	
3	Research institute (US)	Face-to-face
4	Industry (US)	Phone
5	Federal research institute (US)	Phone
6	NGO (US)	Phone
7	Consultancy (US)	Phone
8	Consultancy (US)	Phone
9	Regulator (US)	Phone
10	Academia (US)	Face-to-face
11	NGO (US)	Face-to-face
12	Academia (US)	Face-to-face
13	(Former) Regulator (US)	Phone
14	Industry (US)	Phone
15	Industry (US)	Phone
16	Association (US)	Face-to-face
17	Academia (US)	Face-to-face
	Interviews case study VCI	
18	Regulator (Brussels)	Phone
19	Regulator (Finland)	Phone
20	Industry (Germany)	Phone
21	Association (Germany)	Phone
22	Labor union (Germany)	Phone
23	Labor union (Germany)	Phone
24	Association (Germany)	Phone
25	Association (Germany)	Face-to-face
26	Academia (Germany)	Face-to-face
27	Academia (Germany)	Face-to-face
28	Federal research institute (Germany)	Phone
29	Association (Germany)	Phone
30	Industry (Germany)	Phone
31	Industry (Germany)	Face-to-face
32	Industry (Germany)	Face-to-face
33	Association (Germany)	Face-to-face
34	Association (Germany)	Face-to-face
35	Federal research institute (Germany)	Face-to-face
36	Industry (Netherlands)	Face-to-face
37	Consultancy (Netherlands)	Face-to-face
38	Industry (Germany)	Phone

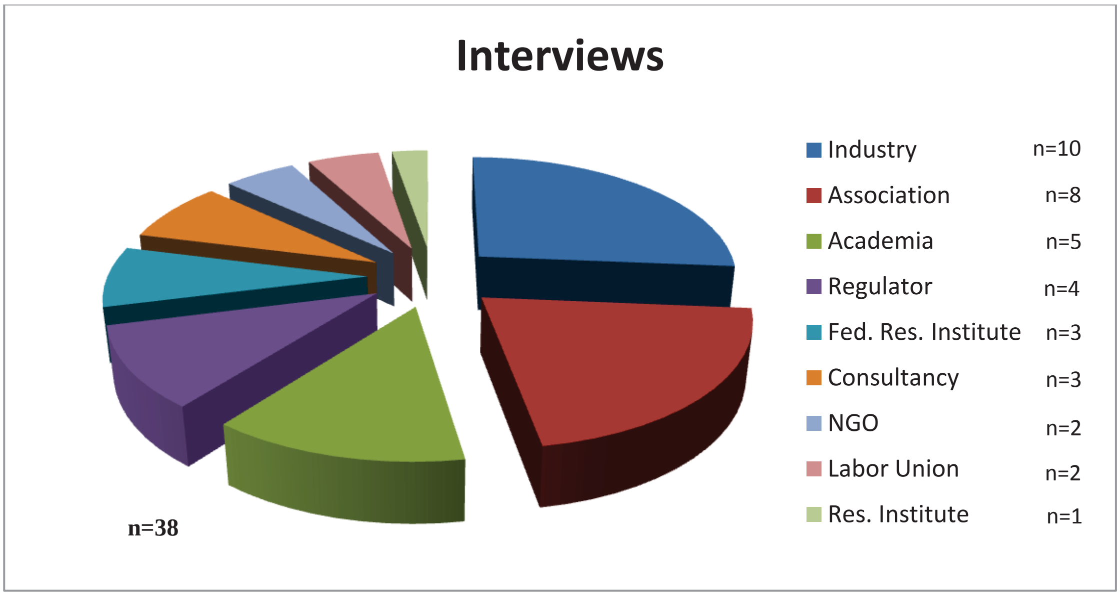

Figure 5.1. Distribution of interviews across 9 categories.

Initially interviewees were identified from publicly available documents supporting collaborative business association activities. These interviewees were asked to point out other relevant actors in the connection to specific activities of business associations. The use of this 'snowball method' ensured that relevant actors were identified. When no new names were given it was followed that the key important actors had actually been identified, i.e. the potential pool of interviewees was saturated.

The interviews were semi-structured. Using this format means that certain parts of the interview were structured with a set of questions asked sequentially while other parts are unstructured and are designed to explore the views of the interviewee in detail (Bloch 2004). To that end, prior to conducting interviews, a general interview guide was developed in a non-standardized manner in order to ensure that key topics were covered. When there was sufficient interviewing time available, an additional set of specialized questions, which were taking into consideration the interviewee's professional backgrounds, was asked (see the appendix for the list of interview questions). This was actually the case is almost all interviews. The exact order in which questions were asked and the wording of these questions are conceived to be less important so as to allow for flexibility, greater depth and more sensitivity to contextual variations in meaning. This approach differs from classical survey research in which standardized interviews or questionnaires are utilized mostly.

The interviews for the US case study were held in English and in the German context interviews were done in German. The interviews were recorded whenever interviewees gave their permission (n=29). When the interview could not be recorded for reasons of interviewee objection or related to technical issues, extensive notes were taken throughout the interviews, which were then written out directly after the talk. In cases where interviews were recorded the interviews were transcribed literally. Wherever literal quotes from interviews are used in this thesis, the interviewees have reviewed and approved these prior to publication. German quotes, as referred to within this thesis, have been translated into English by the author.

It should be acknowledged that the activity of transcription may follow different approaches thereby enabling different interpretations and meanings of the same interview (Seale & Silverman 1997). Transcribing merely specific parts of interviews may lead to biased analyses. A naturalistic transcription can normalize meanings, but it should be noted that there remains always an element of ambiguity since general meanings voiced by interviewees can be related to specific implicit assumptions (Rapley 2004).

The detection of patterns in (interview) data requires the identification of aspects of similarity within data. Therefore coding schemes–as ways of categorizing–are employed as a crucial step in the first analysis of data. Especially when being confronted with a large amount of data, that is a series of interviews, codes assist to highlight emerging themes and concepts and moreover help in comparing them according to the same standards to eventually be able to derive at valid research outcomes. Coding is conducted with the idea of a constant process, formed by a mutual relationship between implicit and explicit ideas (Seale 2004). In this sense, codes are conceived as dynamic in that they may be subject to changes during the process of data generation. Specific software is available on the market to approach and assess interview data, for instance NVivo or Atlas.ti. In this thesis it was decided against the use of software and, instead, interviews have been coded manually (by the author of this thesis) since the number of interviews was not on a large scale. The codes by which interview data was analyzed follow the analytical categories as developed in section 4.3 (see, below, for an overview Table 5.2).

Table 5.2. Codes for the analysis of interview data.

Coding Scheme
1. Scientific expertise by actors in the context of risk assessment for nanomaterials • Relevant actors • Knowledge exchange • Understanding problems • New scientific facts
2. Trust during the process of collaboration • Meetings • Relationships • Reliance • Common/individual goals • Disagreement • Additional collaboration
3. Rules of behavior (process-, and problem-oriented) • Informal agreements • Soft rules • Hardened rules

Document analysis

In addition to interviews, the method of document analysis was used to collect data from publicly available (policy) documents supporting collaborative business association activities. One can distinguish here between documents for internal (e.g. memos among business association members) and/or external use (e.g. a report written for publication) (Gidley 2004). Internal documents were not available; therefore only documents for external use have been collected and analyzed. While most of these documents were available in English, some documents were only available in German.

Document analysis in combination with interviewing provides opportunities for triangulation since a multiplicity of methods, and hence materials, provides not merely one view of an issue under investigation but mirrors multiple perspectives. For this purpose sources such as policy transcriptions of speeches or talks (as far as available) were compared to official views of business associations. Examples of documents that have been collected and analyzed are: association comments on, or reactions to, policy and research issues, statements of principles, reports from meetings, strategy and position papers, survey results and guidance material in view to conducting risk assessment for nanomaterials (see, for a more detailed overview, section 3.3). In order to contextualize documents published by business associations, documents issued by other actor groups within the collaborative network, e.g. regulators or (federal) research institutes, have been analyzed where available.

Handling of data from various sources

In addition to data gathered through interviews and publicly available documents, literature from the field of regulation and governance has also been used for the analysis of collaborative business association activities. The use of multiple data sources guards against selectivity in the data analysis.

The data was handled as follows: In the analysis of business association collaborative activities and their contribution to effective nanomaterials OHS regulation primacy is given to interview data as far as available. This data is compared with data from documents when available. When data from interviews and documents yield information or aspects that require elaboration in order to be understandable, other specialized literatures were consulted (e.g. policy documents, legislative texts or research on the potential risks of nanomaterials).

While all interviewees were asked the same questions, these were not answered equally extensive by all interviewees due to personal preferences to (not) talk at length about a certain topic. This resulted in the situation that for some issues more, or less, data is available. This is a methodological disadvantage that should be accounted for; because this thesis is explorative it is considered acceptable. When little interview data was available, data from documents was used to confirm, refute, or contextualize issues that came up during the interviews. In this connection it should also be mentioned that, depending on individual or personal interviewee preferences to (not) talk about certain issues, interview data is not always comparable. Thus, frequently it cannot be stated how many interviewees support (or not support) a certain issue because they decided–explicitly or implicitly–to focus on certain topics and neglect others. Accordingly, statistical information could not be derived from the interviews. This was rendered acceptable because the aim of the research is to explore a certain subject matter, i.e. the contribution of business associations to the process of effective regulation in terms of supporting compliance.

Chapter 6

Case study – The American Chemistry Council (ACC)

In this chapter, the activities by one industry association in the US chemical industry–the ACC–are described and analyzed in order to answer the first part of subordinate research question 4: *How do collaborative activities of US business associations contribute to effective nanomaterials OHS regulation in practice?* In section 6.1, general characteristics of the association's structure, organization and membership are provided and activities in the context of nanomaterials OHS are identified for analysis. Subsequently, in section 6.2, specific activities are described and analyzed in relation to their contribution to effective nanomaterials OHS regulation. When network actors learn how to make traditional risk assessment frameworks applicable to nanomaterials they can contribute to effective regulation. This analysis is conducted by applying the theoretical framework with its analytical categories and conditions (see Table 4.6). In the conclusion, the potential for learning is evaluated and the association's contribution to the effective regulation of nanomaterials is identified.

6.1 ACC Nanotechnology Panel activities

Structure and membership

The ACC is the sole chemical industry association in the US and is most known and discussed by regulatory scholars in view to its Responsible Care Program (RCP) (Evangelinos et al. 2010; King & Lenox 2000; Prakash 2000). The RCP is a voluntary system of principles and management practices for companies in the chemical sector with the aim to demonstrate and improve health, safety and environmental performance (King & Lenox 2000; Howard et al. 1999). The Program contains more than 100 specific management practices to be followed voluntarily by the member companies of most chemical business associations worldwide (ICCA 2012). The principles of the RCP underlie ACC's work in the area of nanomaterials health and safety, which is bundled in the ACC Nanotechnology Panel; however, the Nano Panel operates independent from the RCP (ACC 2014c).

Established in 2005, the Nano Panel is a self-funded body that is formally separated from the ACC, meaning membership in the Panel does not require simultaneous membership, i.e. double payment of membership dues, in the ACC (ACC 2014b; Interviewee 16, association). Membership in the Nano Panel is confined to representatives of multinational chemical companies. While fragmented data on Panel membership is available, complete data sets from 2005 through to 2014 are not at hand (see Table 6.1 for an overview of Panel membership[66]). Nevertheless, it appears that overall the number of member companies has declined over time: the Panel had 17 members in 2006 and in 2014 the number of members is reduced to 9.

[66] The data is elicited from the publicly available documents that accompany the ACC Nano Panel's activities in the area of nanomaterials OHS (see, the list in the appendix) as well as from information from interviews with Panel member and ACC staff.

The aim of the ACC Nano Panel is to advocate for the responsible development of nanotechnology among manufacturers and users (ACC 2014b). The Panel is headed by a manager (being ACC staff) and a chair (being a representative of a member company). The chair is appointed by the Panel members and usually serves for a period of two years. The position of manager is determined internally by the ACC and is not restricted to a certain time frame (Interviewee 16, association).

Table 6.1. Overview ACC Panel membership 2006-2014.

ACC Panel members 2006 Manager: ACC staff I Chair: Representative PPG Industries	**ACC Panel members 2007** Manager: ACC staff I Chair: Representative PPG Industries	**ACC Panel members 2008** Manager: NDA Chair: Representative DuPont
Air Products and Chemicals, Inc.	Air Products and Chemicals, Inc.	NDA
Arkema, Inc.	Arch Chemicals, Inc.	
BASF	Arkema, Inc.	
Bayer MaterialScience	BASF	
Cytec Industries, Inc.	Bayer MaterialScience	
Dow Chemical Company	Cytec Industries, Inc.	
DuPont	Dow Chemical Company	
Degussa Corporation	DuPont	
Elementis Specialties	Degussa Corporation	
Oxonica, Ltd.	Elementis Specialties	
PPG Industries, Inc.	Honeywell	
Procter & Gamble	Oxonica, Ltd.	
Rohm & Haas Chemicals	PPG Industries, Inc.	
Sasol North America, Inc.	Procter & Gamble	
Ciba Specialty Chemicals Corporation	Rohm & Haas Chemicals	
Southern Clay Products, Inc.	Sasol North America, Inc.	
3M		
Total members: 17	**Total members: 16**	**Total members: 17**[67]

ACC Panel members 2011 Manager: ACC staff II Chair: Representative Evonik	**ACC Panel members 2012** Manager: ACC staff II Chair: Representative BASF	**ACC Panel members 2013** Manager: ACC staff II Chair: Representative BASF
Arch Chemicals, Inc.	Arch Chemicals, Inc.	
Arkema, Inc.	BASF Corporation	BASF Corporation
BASF	Bayer MaterialScience	
Bayer MaterialScience	Cabot Corporation	Cabot Corporation
Cabot Corporation	Cytec Industries	
Cytec Industries, Inc.	Dow Chemical Company	Dow Chemical Company
Dow Chemical Company	DuPont	DuPont
DuPont	Evonik Degussa	Evonik Corporation
Evonik Degussa Corporation	Ferro Corporation	Ferro Corporation
Ferro Corporation	Lockheed Martin	Lockheed Martin
Procter & Gamble	Procter & Gamble	Procter & Gamble
3M	3M	3M
Total members: 12	**Total members: 12**	**Total members: 9**

[67] Only the total number of member companies has been published for the year 2008.

ACC Panel members 2014 Manager: ACC staff II Chair: NDA
BASF Corporation
Cabot Corporation
Dow Chemical Company
DuPont
Evonik Corporation
Ferro Corporation
Lockheed Martin
Procter & Gamble
3M
Total members: 9

Activities directed at nanomaterials OHS

Between its foundation in 2005 and (March) 2014 the ACC Nano Panel has been involved in 19 activities that aim at contributing to nanomaterials OHS. All activities, as will be shown in this section, form collective association goods with a focus on lobbying[68] (see the complete overview of VCI activities in Table 6.2, after their description). The activities are grouped into two main periods, or 'rounds of decision-making'.

(1) **2005 – February 2009**
General agenda setting

(2) **March 2009 – March 2014**
Specifying the agenda

Period 1. In the time from 2005[69] through to February 2009 the ACC initiated seven activities aimed at supporting nanomaterials OHS. All these activities can be understood as reactions to activities by policy-makers and (semi-) governmental institutions, thereby aiming at 'setting a strong, general agenda' for nanomaterials OHS.

In 2005 the ACC Nanotechnology Panel was established with the aim to foster responsible development and application of nanotechnology through facilitating exchange of information and furthering research among member companies and other domestic and international organizations as well as regulators (ACC 2014b). This activity is thus characterized as collective association good directed at *knowledge exchange* in view to nanomaterials OHS.

In June 2005, the Panel published a Joint Statement of Principles to better understand potential risks of nanomaterials in which they call upon the US government to assess existing regulatory frameworks in the light of nanomaterials (EDF & ACC 2005) (association good *lobbying*). Next, in January 2006 the Panel developed Comments on the EPA Nanotechnology White Paper External Review Draft, which constitutes the collective good *lobbying* with policy-makers (ACC 2006). While the Panel supports EPA's key recommendations, it asks for a different prioritization of research suggested in the White Paper; according to the Panel research should prioritize first and foremost chemical identification, characterization and metrology. Subsequently, in January 2007, the Panel published a statement before the NNCO

[68] See section 3.1 (pp. 43-46), for an overview of types of business association activities.
[69] There is no information available in which month of 2005 the ACC Nano Panel was founded.

asking for greater involvement of government institutions (NNCO, NNI) in collecting and reviewing scientific data on nanomaterials in the context of a public database and the importance of human health-related research to understand the behavior of nanomaterials in the body and to develop methods for quantifying and characterizing exposure to nanomaterials (ACC 2007a) (*lobbying*).

In March 2007, the Panel commented on the Draft Environmental Defense/DuPont Nano Risk Framework for Responsible Nanotechnology (ACC 2007b). Here, the Panel supports the collection of appropriate hazard information for all nanoscale materials, regardless whether substances are considered new or existing materials. Since the ACC Panel uses the occasion to promote the chemical industry's viewpoints on nanomaterials risk assessment this activity constitutes the association good *representation and reputation*.

Next, in May 2007, the ACC Panel commented on the Scientific Opinion of the EC Scientific Committee on Emerging and Newly Identified Health Risks (SCENIHR) on the Technical Guidance Documents of the chemicals legislation, for the risk assessment of nanomaterials. They argued that traditional risk assessment methodologies are overall adequate to characterize health risks of nanomaterials (ACC 2007c) (*lobbying*).

The last Panel activity in the period from 2004 to February 2009 was a survey among its member companies to obtain information on work practices employed to manage potential risks from engineered nanomaterials in September 2007 (ACC 2007d) (*knowledge exchange*).

In sum, during the period from 2005 to February 2009, the ACC commenced seven activities directed at nanomaterials OHS. All activities constituted collective association goods with a focus on lobbying (four activities). To a limited extent activities were characterized as representation/reputation (two activities) and knowledge exchange (one activity). In the following period, the focus on lobbying becomes even more pronounced (see, below, Figure 6.2 for an overview of the Panel activities in the first and second period).

Period 2. Between March 2009 and March 2014, the ACC Panel initiated twelve activities directed at supporting nanomaterials OHS, which constitute *lobbying* efforts as well as three activities that were directed at *knowledge exchange*. While in the previous period the Panel established a general agenda for nanomaterials OHS, in the second period the Panel specifies this agenda by providing specific comments on the technicalities of risk assessment for nanomaterials.

Since March 2009[70] (until today, i.e. February 2015) the Nano Panel has been a member of the Business and Industry Advisory Committee's (BIAC) Nanotechnology Committee that advises the OECD Working Party on Manufactured Nanomaterials (WPMN) (OECD 2009). Through BIAC the Panel collaborates with industry and regulators on a transnational level in matters related to the exchange and extension of knowledge and information on the health and safety of nanomaterials (*knowledge exchange*) (BIAC 2014).

In January 2011 the Panel commented on the NNI's draft 2011 Environmental Health and Safety (EHS) Strategy (ACC 2011a)[71]. It *lobbied* for the promotion of one standardized definition of a nanomaterial in the context of a federal EHS strategy with relevance for exposure monitoring. Subsequently, in February 2011 the ACC Panel provided comments on the NIOSH draft Current Intelligence Bulletin (CIB) Occupational Exposure to Carbon Nanotubes and Nanofibres (ACC 2011b). The Panel *lobbied* for NIOSH's effort to develop a

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[70] The ACC Nano Panel has been a member of BIAC at least since March 2009 (OECD 2009); there is no data available from publicly available documents that points to an earlier engagement.

[71] The NNI was established in 2000 with funding under the 21th Century Nanotechnology Research and Development Act (see 15 U.S.C. §§ 7501-09 (Supp. 2007) and is the federal agency meant to coordinate and facilitate research, education and responsible development of nanotechnology. The NNI is not involved in regulatory activities of nanotechnologies (Mandel 2008: 1347) but rather is said to be the central point of communication and cooperation among all Federal agencies involved in nanotechnology-related activities bringing together representatives from 20 federal departments and agency units (NNI n.d.c).

recommended exposure limit (REL) for nanomaterials that is based on coherent occupational exposure levels (OELs). In April 2011, the ACC Panel published a document arguing that Federal agencies, and specifically the NNI, should have an essential role in supporting and coordinating nanomaterials safety research in the US (ACC 2011c) (*lobbying*). Also in April 2011, the Panel expressed its perspective on NIOSH's strategic plan for identifying and prioritizing nanotechnology research (ACC 2011d). The Panel argued that NIOSH should focus its research on issues of exposure measurement methods and assessment, risk characterization, and risk management while aspects of hazard identification and characterization should be left to federal and international agencies (*lobbying*).

In May 2011 the Nano Panel became a co-sponsor of the NanoRelease Consumer Products research project in which several regulators, namely EPA, OSHA and Health Canada, were involved (ILSI 2011). Members of the Panel participated in the research and are members of the steering committee (Bloomberg BNA 2012; ILSI 2011). The NanoRelease Consumer Products 'aims to develop scientific tools necessary to generate critical information for decision-making among NGO, business, and government stakeholders alike' (ILSI 2014) with the intention to 'fill-in a critical gap for nanomaterial risk assessment' (Roberts 2011) *(knowledge exchange*).

In January 2012, the Panel commenced two activities in the form of *lobbying*; the ACC Panel commented on the EPA Office of Inspector General's Report on Nanotechnology arguing that EPA should have an internally consistent and coordinated approach to sharing information about nanomaterials (ACC 2012a). The Panel commented also on EPA's proposed significant new use rules (SNURs)[72] for 17 chemical substances (ACC 2012b). The Panel supported a weight-based threshold over a particle number, or surface area threshold.

The next Panel activity was commenced in September 2012; the Panel organized a workshop on Strategies for Setting OELs for Engineered Nanomaterials to which they invited stakeholders from academia, regulating agencies and industry (ACC 2012c). The workshop was realized to facilitate discussion and exchange among public and private actors in the development of OELs for nanomaterials (*knowledge exchange*). Five representatives of ACC Panel member companies (BASF, Bayer, DuPont, Evonik Degussa, 3M) participated.

In March 2013, the Panel initiated two more activities in the form of *lobbying*. The Panel presented a Poster at the 52nd Annual Meeting of the Society of Toxicology where it expressed the need to develop a clear, consistent and technically practical definition of a nanomaterial suited for nanomaterial-specific regulation (ACC 2013e). In addition, in March 2013, the Panel commented on NIOSH's draft strategic plan for nanotechnology research, characterizing it as lacking prioritization of research efforts (ACC 2013f). NIOSH should support nanomaterials OHS by developing exposure measurement methods and male this topic their highest research priority (*lobbying*). Lastly, the ACC Panel provided comments on the draft NNI Strategic Plan 2014 in which they urged NNI to include information on regulatory obligations that would be useful for SMEs in its strategic plan (ACC 2013g) (*lobbying*) (see Figure 6.2 for an overview of activities by the ACC Nano Panel).

Thus, from March 2009 through to March 2014 the ACC commenced twelve activities directed at nanomaterials OHS. Nine activities were collective association goods constituting *lobbying*, whereas *knowledge exchange* was less prevalent as the focus of three activities. Looking at both periods, no selective goods directed at nanomaterials OHS were provided (see Table 6.2 for an overview of ACC Nano Panel activities related to nanomaterials OHS).

[72] Under the TSCA, SNURs require that manufacturers, importers and processors of certain substances notify EPA at least 90 days before beginning any activity that EPA has designated as a "significant new use." These new use designations are typically those activities prohibited by the section 5(e) Consent Order of the TSCA. The notification required by SNURs, known as a Significant New Use Notification (SNUN), allows EPA the opportunity to review and if necessary prevent or limit potentially adverse exposure to, or effects from, the new use of the substance.

Table 6.2. Overview of ACC Nano Panel activities relevant for nanomaterials OHS.

PERIOD	TIME	ACTIVITY	FORM ACTIVITY
1	2005	Establishment of the ACC Nanotechnology Panel (ACC n.d.)	Knowledge exchange
		Publication of a Joint Statement of Principles for nanomaterials (together with the Environmental Defense Fund, EDF) (EDF & ACC 2005)	Lobbying
	2006	Issuance of Comments on the EPA Nanotechnology White Paper External Review Draft' (ACC 2006)	Lobbying
	2007	Statement before the National Nanotechnology Coordination Office (NNCO) (ACC 2007a)	Lobbying
		Comments on the Draft Environmental Defense/DuPont Nano Risk Framework for Responsible Nanotechnology' (ACC 2007b)	Representation / reputation
		Comments on the Scientific Opinion of the EC Scientific Committee on Emerging and Newly Identified Health Risks (SCENIHR) on the Technical Guidance Documents of the chemicals legislation, for the risk assessment of nanomaterials (ACC 2007c)	Lobbying
		Conduction of a survey among ACC member companies (ACC 2007d)	Knowledge exchange
2	2009	Became a member of the Business and Industry Advisory Committee (BIAC) Nanotechnology Committee that advises the OECD Working Party on Manufactured Nanomaterials (WPMN) (OECD 2009)[73]	Knowledge exchange
	2011	Comments on the Environmental Health and Safety Strategy of the National Nanotechnology Initiative (NNI) (ACC 2011a)	Lobbying
		Comments on the NIOSH draft Current Intelligence Bulletin (CIB) Occupational Exposure to Carbon Nanotubes and Nanofibres (ACC 2011b)	Lobbying
		Comments on the relevance of the NNI on safe work and use of nanotechnology (ACC 2011c)	Lobbying
		Comments on NIOSH's updated strategic plan for identifying and prioritizing nanotechnology research (ACC 2011d)	Lobbying
		Co-sponsor of the the NanoRelease Consumer Products research project (ILSI 2011)	Knowledge exchange
	2012	Comments on the EPA Office of Inspector General's Report on Nanotechnology (ACC 2012a)	Lobbying
		Comments on EPA's proposed significant new use rules (SNURs) (ACC 2012b)	Lobbying
		Organization of a workshop on Strategies for Setting Occupational Exposure Limits for Engineered Nanomaterials' was initiated (ACC 2012c)	Knowledge exchange
	2013	Publication of a Comparative assessment of nanomaterial definitions and considerations (ACC 2013e)	Lobbying
		Comments on NIOSH's draft strategic plan for nanotechnology research (ACC 2013f)	Lobbying
		Comments on the draft NNI Strategic Plan 2014 (ACC 2013g)	Lobbying

Taking into account all 19 activities, the ACC Nano Panel contributed to OHS and risk assessment at workplaces where nanomaterials are handled exclusively by means of collective association goods (see Table 6.3). The Panel did not provide selective association goods related to nanomaterials OHS. But delivering selective goods that benefit only individual members are said to be vital incentives for association membership by companies which allows associations to obtain income through membership fees in order to fund collective activities (Bennett 2000).

[73] The ACC Nano Panel has been a member of BIAC at least since March 2009 (OECD 2009); there is no data available from publicly available documents that points to an earlier engagement.

Table 6.3. Overview ACC activities on nanomaterials OHS.

TIME	FORM ACTIVITY	TYPE
2005 – February 2009	Lobbying (4x)	Collective goods
	Representation/reputation (1x)	
	Knowledge exchange (2x)	
March 2009 – March 2014	Lobbying (9x)	Collective goods
	Knowledge exchange (3x)	

One explanation for the absence of selective goods in the context of the ACC Panel could be that the topic of nanomaterials OHS is merely one amongst a great variety of other topics in which the ACC is actively engaged (e.g. energy, environment, trade, security, tax and rail transportation) and for which it provides selective goods. For instance, in the area of security, ACC members are provided with certain liability protections in case of a terrorist action at their facilities through the Responsible Care Security Code. On a general level ACC members received weekly, monthly and biannual economic forecasting and industry trends data and can attend educational webinars as well as training workshop on various topics (ACC 2013a). Given that ACC provides a broad range of selective goods next to nanomaterials, it appears that the association is not dependent on income constituted by selective nanomaterials OHS-related activities. Furthermore, one could argue, since the members of the Nano Panel are all multinational companies with established health and safety practices and experiences in the handling of hazardous chemicals, the members do not require support at the individual level thereby making the necessity to provide selective goods related to nanomaterials OHS obsolete.

Based on the ACC Nano Panel's activities in the area of nanomaterials OHS, the Panel's position towards nanomaterials OHS may be summarized by two key-observations:

(1) In the first period (2005-2009) the Panel's goal appears to be the establishment of a strong industry position on use and development of nanomaterials; in this regard, activities were initially directed at lobbying at the level of regulating agencies that were demanding first actions–i.e. the EPA–so as to allow for safe development of nanomaterials in the light of scientific uncertainties. While ACC acknowledged data gaps that hinder the characterization of risks related with nanomaterials, the association lobbied for the usefulness of traditional risk assessment to ensure safe use and work with nanomaterials. Over time research, to which the Panel appears committed, would close existing data gaps.

(2) In the time from 2009 to 2014, activities directed at exchange of scientific knowledge and experiences gained importance. The ACC Nano Panel initiated and actively participated in research projects aimed at closing data gaps especially in the area of exposure assessment for nanomaterials, being one element of risk assessment. Based on the state-of-the-art on the potential health risks related to nanomaterials the Panel postulated in its activities that existing regulation is adequate for nanomaterials and that no nano-specific regulation is needed to protect the health and safety of employees handling nanomaterials at workplaces.

Since the ACC Nano Panel is actively involved in the debate on nanomaterials OHS the questions as to the value of these activities become relevant. Hence, are the Panel's collaborative activities contributing to effective nanomaterials OHS regulation through facilitating learning in the area of risk assessment for nanomaterials?

6.2 Opening a window of opportunity

To be considered for the effectiveness analysis, activities by the ACC Nano Panel must fulfill three criteria (as explained in section 5.2): Association activities must be of the type *knowledge exchange* (since these activities supposedly contribute to the regulation of nanomaterials OHS), they must be *verifiable* (i.e. are accompanied by publicly available documents), and they must be *initiated* by the association (since we are interested in the contribution of these bodies to the effective regulation of nanomaterials OHS). After application of the three selection criteria, the remaining collaborative business association activities were analyzed based on the theoretical framework with the analytical categories and conditions for processes of learning that can contribute to effective nanomaterials OHS regulation (see Table 6.4, below).

Table 6.4. Theoretical framework with analytical categories and conditions for the evaluation of effective nanomaterials OHS regulation.

LEVEL	ANALYTICAL CATEGORY	CONDITIONS
Actor level	**Substantive learning** Characteristic: *Scientific expertise*	1. Relevant actors collaborate 2. Exchange of knowledge and (risk) data 3. Increased understanding of how to deal with core problems related to nanomaterials risk assessment, and 4. Generation of novel scientific facts
Game level	**Strategic learning** Characteristic: *Trust*	1. Meetings over a longer period of time 2. Intensified actor relations 3. Reliance among collaborators 4. Realization of common goals 5. Disagreement among collaborators is addressed and solved, and 6. Development of additional collaborative activities
Network level	**Institutional learning** Characteristic: *Rules*	1. Development of informal agreements 2. Design of soft rules of behavior, and 3. Soft rules become 'hardened'

After application of the three selection criteria, two activities of the type 'knowledge exchange' are not relevant for analysis. These are the Panel's survey on nanomaterials OHS practices in ACC member firms (ACC 2007d) and its participation in the OECD work on nanomaterials (OECD 2009); these activities are not analyzed since the survey was not labeled *verifiable* through publicly available documents and the participation in OECD work was not *initiated* by the Panel. The three relevant activities are the foundation and meetings of the ACC Nano Panel (2005), the NanoRelease Consumer Products research project (2011) and the Workshop on Strategies for Setting Occupational Exposure Limits for Engineered Nanomaterials (2012).

The first activity that is investigated is the ACC Nano Panel's foundation and their internal meetings between 2005 and 2014. The Panel meets with the goal to support the responsible development of nanotechnology and the development of science- and risk-based regulations that foster safety and innovation. Further, the aim is to exchange knowledge and support research in order to assess and manage potential health risks associated with nanomaterials as well as to address health and safety issues (ACC 2014b). The members of the Nano Panel were (and still are today) all representatives from multinational chemical companies.

The second activity that is analyzed is the Panel's co-sponsoring and participation in the NanoRelease Consumer Products project since May 2011 (until today). The project involves over 80 collaborators, including US regulators (EPA, OSHA), scientists from academia as well as various representatives from NIOSH and a labor union (ILSI n.d.a). The aim of NanoRelease is to advance safe development of nanomaterials through developing methods to understand the exposure from nanomaterials used in products. In this context scientific tools shall be developed that are necessary to generate critical information for decision-making (ILSI 2014) and nanomaterial risk assessment (Roberts 2011).

The third Nano Panel activity that is analyzed is a workshop on Strategies for Setting Occupational Exposure Limits for Engineered Nanomaterials that was held in September 2012. The Panel co-sponsored the workshop and also participated in it. Many stakeholders from academia, regulating agencies (OSHA, EPA), industry and federal research institute (NIOSH) (ACC 2012c) were invited to discuss and exchange insights relevant for the development of OELs for nanomaterials. Various Panel members–representatives from BASF, 3MM, Evonik Degussa–participated.

These three activities are investigated on three levels of analysis (the actor, game, and network level; see section 4.2) with three types of learning that may contribute to make risk assessment more applicable to nanomaterials and thereby contribute to effective nanomaterials OHS regulation. The business association activities are investigated based on interview data, accompanied by data from documents as far as available. This approach is to guard against selectivity in the data analysis (see section 5.3).

6.2.1 Actor level – substantive learning

On the actor level, four conditions are investigated in order to understand whether a process of substantive learning has taken place in regard to the three Nano Panel activities (see section 4.3):

(1) Relevant actors collaborate
(2) Exchange of knowledge and (risk) data
(3) Increased understanding of how to deal with core problems related to nanomaterials risk assessment, and
(4) Generation of novel scientific facts.

Or, in other words, have collaborative activities by the ACC Nano Panel culminated in the generation of new facts relevant for nanomaterials OHS? To answer this question, first, we need to identify the relevant actors in the collaborative network around the ACC Nano Panel.

1. *Relevant actors collaborate*

Based on the publicly available documents supporting the three relevant activities initiated by the Panel we can identify the collaborators (see, below, Figure 6.1).[74] Individual actors are grouped in view to the organization they are affiliated with. Hence, groups of collaborators range from

[74] See http://nanotechnology.americanchemistry.com/ and http://www.ilsi.org/ResearchFoundation/RSIA/Pages/NanoRelease1.aspx.

- chemical companies (ACC Nano Panel members) to
- regulatory agencies (OSHA; EPA), and
- (federal) research institutes (NIOSH; International Life Science Institute, ILSI),
- academia (various US and international universities),
- consultancies (some US-based (legal) advisory firms) and,
- labor unions (some US-based workers unions).

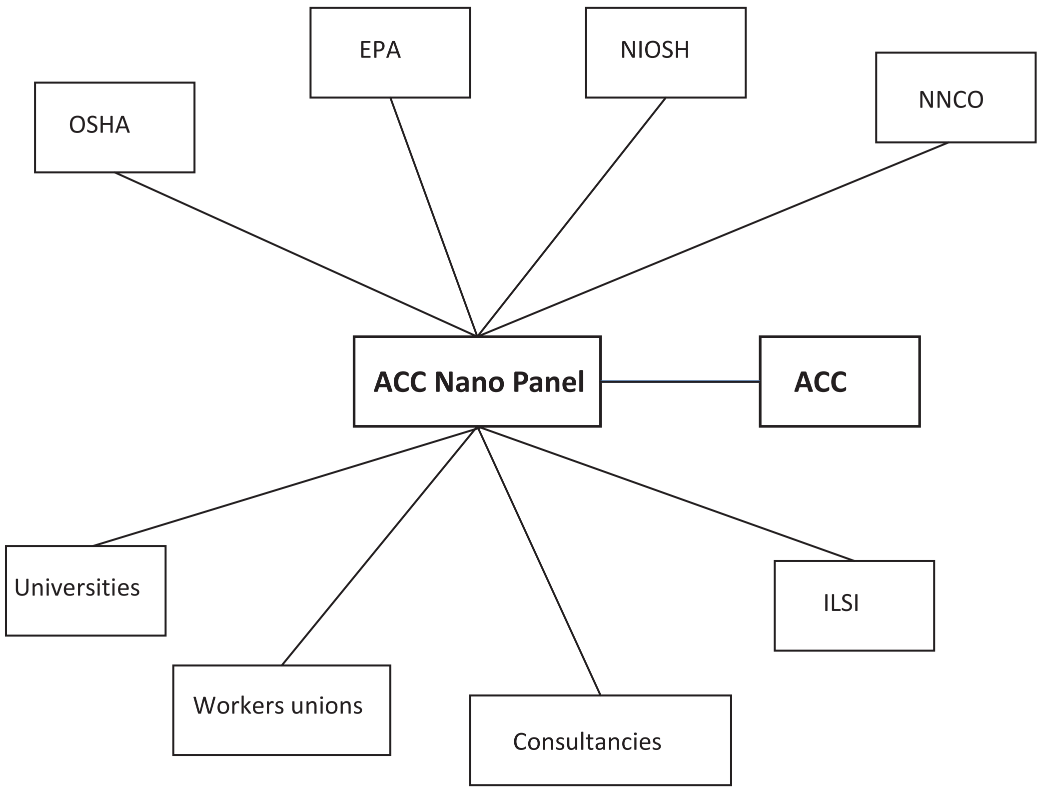

Figure 6.1. ACC network of collaborators.

Knowing who the collaborators of the ACC Nano Panel are, the question is who are *relevant* collaborators? To decide this, the principle of resource substitutability (Scharpf 1978) is applied.[75]

Since this thesis is concerned with OHS regulation for nanomaterials, and because of the challenge of current inapplicability of traditional risk assessment for nanomaterials, two most essential resources have been identified: scientific data and knowledge as fundamental asset to provide solutions to the challenge of nanomaterials risk assessment. In addition, decision-making authority is crucial to decide for the most adequate solution(s) to be implemented into policymaking. In this connection, relevant actors with the resource ‘knowledge/data’ are ACC staff and member companies, NIOSH and academia. Relevant actors with the resource ‘decision-making authority’ are regulators, namely OSHA as primarily responsible agency for workplace health and safety (see, for an overview, Figure 6.2). Since the EPA does not have a legislative mandate in matters of OHS it is not considered

[75] See section 4.2 (p. 63).

a relevant actor. Further, the Nanotechnology Coordination Office (NNCO), labor unions, and legal consultancies do not provide either one of the two essential resources and therefore are not relevant actors. This is not to say that these actors are not relevant per se in the discussion on nanomaterials OHS. Rather, they are not of key importance in the context of this research.

Relevant actors (principle of resource substitutability)

• ACC staff
• ACC Nano Panel member companies
• (Fed.) research institutes: NIOSH, ILSI
• Academia: various scientists
} **Knowledge/data**

• Regulators: OSHA } **Authority**

Figure 6.2. Relevant collaborators ACC Nano Panel.

Having identified the relevant actors in the network, we shall next examine whether these actors actually have generated novel facts that contribute to making risk assessment applicable for nanomaterials through exchanging their resources and joint deliberation. In other words, can we identify substantive learning among collaborators?

(2) Exchange of knowledge and (risk) data

As mentioned before, collaboration among industry and regulators can contribute to uncovering and avoiding the risks of nanomaterials when relevant knowledge is exchanged and extended (Coglianese 2010; Bartis & Landree 2006). With the exchange of knowledge and (risk) data a basis for meaningful deliberation and negotiation of (conflicting) scientific insights in view to conducting risk assessment for nanomaterials can be established. Based on the interview data, the relevant actors–i.e. ACC staff, Panel member companies, NIOSH, ILSI academia and OSHA–have indeed exchanged knowledge of various types. This has been confirmed by nine interviewees (see below).

But importantly knowledge in the form of raw, or primary, data is never exchanged, neither in internal Panel meetings nor among external collaborators and the Panel (Interviewee 14, industry; 9, regulator). Reasons are twofold: First, generating data is a costly process for organizations both in terms of invested money and manpower. To pass on such data to externals ‘for free’ would be against the profit-oriented nature of corporations. Second–and arguably more importantly–often raw data is protected as confidential business information (CBI), which relates to, or concerns, trade secrets, processes, apparatuses or other information of commercial value (Interviewee 11, NGO; 10, academia).[76] Information can be designated as CBI when their disclosure is likely to have the effect of either impairing the Commission’s ability to obtain such information to perform its statutory functions, or when disclosure causes substantial competitive harm to the corporation from which the information was obtained. Corporations must merely stamp information as “confidential” to an administrative protective order (APO) so that they are treated as CBI. Some raw data in the ACC Nano Panel network is treated as CBI (Interviewee 16, association). Under these circumstances company representatives do not share data with third-parties.

[76] 19 C.F.R. 201.6 – Confidential business information § 201.6 (a)(1).

However, exchanging such data in aggregate form is permissible. We see this type of knowledge exchange among members of the *Panel meetings*. Here, members regularly share and discuss such cumulative information to update themselves on new studies in the area of nanomaterials OHS (exchanging data in aggregate form) (Interviewee 16, association; 15, industry; 14, industry).

A different type of knowledge exchange prevails in the context of the *NanoRelease project* in which data was abstracted further. Collaborators worked together to build a broad knowledge base on nanomaterials release and exposure by developing novel approaches and methods. To reach this goal, already existing concepts, theories and methods were discussed and evaluated by exchange of scientist's experiences with particular approaches and tools. To this end, members of the Nano Panel shared their experiences on exposure-related issues relevant for nanomaterials with other participants in the project (exchanging general experiences) (Interviewee 15, industry). Even though exchange of general experience provided by Panel members is the primary mode of knowledge exchange in the NanoRelease project, exchanging data in aggregate form has certainly also played a role since probably types of knowledge exchange naturally overlap.

A participant in NanoRelease describes that in the project there has been 'an incredible level of participation of industry' in terms of sharing data and experiences on nanomaterials (Interviewee 7, consultancy). Not only the Panel, but also a research institute shared data in the context of the project. Representatives from NIOSH shared data in aggregate form that was generated through its Toxicology Testing Programme. The Programme was created in 2004 and aims at generating and assessing nanoparticle exposures for toxicological research and the development of sampling and analytical methods (NIOSH 2012). To this end, NIOSH has conducted over 40 field assessments in nanomaterial manufacturer and user facilities (ibid). Through the programme chemical companies can volunteer their materials to NIOSH who then tests what type of hazard this material might represent (Interviewee 5, federal research institute). When companies give NIOSH permission to use this data in anonymized form, the Institute shares the knowledge with others, as a representative from NIOSH emphasized:

> "NIOSH certainly shares any risk data that we generate. And we've been very aggressive about publishing risk data based on toxicology studies and risk assessment as well as understanding actually human exposure in the workplace and how that impacts our risk assessments as well" (Interviewee 5, federal research institute).

As the NIOSH representative further explains, companies do not share their risk data with NIOSH, unless it is data that is close to being published (ibid).

Sharing data that had been published in peer-reviewed scientific journals is another type of knowledge exchange (collecting published data) that we see in the context of the *OEL workshop*. While also the previous two types played a role, most importantly Panel members as well as scientists shared actual data on the potential risks of nanomaterials, which had previously been published in scientific journals (ibid). Deploying this strategy ensures that research results are validated by peers, hence are evidently representing 'correct science', namely science based on generally accepted standards and methods, that reflect the latest state-of-science on nanomaterials OHS (ibid). Additionally, deploying this strategy implies that the innovative potential of data under ownership of the publication's author and/or company that is represented are protected. During the OEL workshop published data was not merely collected but this data was also critically discussed and evaluated by the relevant actors, i.e. scientists from academia, multiple representatives from NIOSH and, one representative from OSHA. In this light, the scientific state-of-the-art was debated and expanded in a multi-disciplinary deliberation process (critical evaluation of state-of-the-art data) (Interviewee 9, regulator). Based on the different types of knowledge exchange related to the ACC Nano Panel's collaborative activities, next, we investigate whether an increased understanding of certain challenges in the risk assessment for nanomaterials was achieved (see Table 6.5 for an overview of types of knowledge exchange in the Panel's activities).

Table 6.5. Overview dominant types of knowledge exchange ACC Nano Panel collaborative activities.

Collaborative activity	**Dominant type knowledge exchange**
ACC Nano Panel meetings	Data in aggregate form
NanoRelease	Data in aggregate form/general experiences
OEL workshop	Collecting published data/evaluation of state-of-the-art data

(3) Increased understanding of how to deal with core problems related to nanomaterials risk assessment

Because members of the ACC Nano Panel have exchanged knowledge on the potential risks of nanomaterials in their *Panel meetings* and the relevant actors have deliberated on these in a joint effort, a better understanding of certain core problems in the context of risk assessment for nanomaterials could be gained. As three representatives of the Nano Panel emphasize, the focus of their work is on aspects of exposure assessment (Interviewee 16, association; 15, industry; 14, industry). Also representatives from academia and NIOSH have identified exposure assessment to be of high importance in order to make risk assessment applicable to nanomaterials (Interviewee 10, academia; 5, federal research institute).

Conducting exposure assessment for nanomaterials is currently problematic and is characterized by many uncertainties: for example, there is a lack of knowledge on exposure scenarios, measurement instrumentation and standardized methods. Linked to these key problems, the Panel stresses the need for understanding the potential and conditions for release of nanomaterials since this information is a pre-condition for exposure assessment, which is necessary to inform risk assessment. But to date studies that investigate release of nanomaterials are rare. There is little knowledge on how laboratory release scenarios relate to real-world conditions, and nanorelease data cannot be readily compared due to lack of harmonized methods and standards (Froggett et al. 2014).

The issue of release of nanomaterials from consumer products is the main area of concern in the *NanoRelease project*. The project members identified multi-walled carbon nanotubes (MWCNTs) embedded within polymer matrices as a nanomaterial of key importance; there is a need to describe standard release processes and standardization of the reporting of release and exposure processes. Accordingly participants described nine release scenarios more detailed (Nowack et al. 2013).

Lastly, the *OEL workshop* called for the development for OELs for nanomaterials to ensure health and safety at workplaces while recognizing that technical challenges about how best to measure exposures hinder the implementation of OELs (Gordon et al. 2014). Likewise, since toxicity data is limited as existing methods for toxicity assessment are slow and not cost-effective, possibilities for setting OELs for nanomaterials are limited. Therefore, strategies should be developed that allow setting nanomaterial OELs based on limited toxicity information and which can be adjusted as additional data becomes available (ibid). For the future development of OELs it has been suggested to gain a better understanding of toxicokinetics, dose metrics for extrapolating data from in vitro and short-term animal studies to humans, and associations between physiochemical properties and biological activity (ibid). At the same time workshop participants cautioned that there may be no one 'best approach' to setting OELs since adequate approaches depend on the properties of specific nanomaterials, the type of toxicity data available and whether the intended OEL is meant to be a non-regulatory provisional value or a regulatory limit (ibid).

(4) Generation of novel scientific facts

One possible way to determine whether new facts have been established by actors in a collaborative network is to examine whether publications in peer-reviewed scientific journals have resulted from collaborative activities. During the process of publication an extended group of scientists acts as expert peer group to validate whether results follow commonly accepted scientific standards and methods. In this connection it shall be acknowledged that typically representatives from industry (and government) do not publish in peer-reviewed scientific journals, but new findings are rather published in form of reports or white papers. However, in the case of the ACC Nano Panel, no such collective reports have been published and Panel members have, instead, published in peer-reviewed scientific journals. Individual Panel members have, in collaboration with actors from academia, regulators, and (federal) research institutes, published articles in the form of literature reviews and workshop reports in scientific journals between 2013 and 2014 (see Table 6.6).

With regard to the *Panel meetings* we have seen that members actively exchanged knowledge and data in aggregate form. However, based on the data from interviews and documents, there is no evidence that this exchange of knowledge enabled the generation of new scientific facts (as published in peer-reviewed journals and reports or white papers). Thus, merely considering internal meetings, the Panel has not evidently contributed to making risk assessment applicable to nanomaterials. However, the other two collaborative activities did actually contribute to the advancement of risk assessment for nanomaterials.

Primarily the *NanoRelease project* contributed to the generation of new facts in the area of nanomaterials OHS. The goal of the project was to develop a method for nanomaterial exposure measurement. In this connection, members of the Panel have indeed published articles in peer-reviewed journals, between 2013 and 2014, and in that way have generated novel facts for release and exposure measurement relevant in risk assessment for nanomaterials. Panel members were co-authors of three articles that have been published in journals, with an impact factor ranging from 2.31 to 9.18[77], as direct result of the collaboration in the NanoRelease project (Interviewee 16, association) (see, Table 6.6, paper number 1, 3 and 4).

[77] The impact factor of a scientific journal reflects the average number of citations to articles in that journal. Typically the impact factor of a journal gives an indication about the importance of this journal in a specific field of study.

Table 6.6. Overview ACC Nano Panel involved publications.

Collaborative activity	Authors	Title	Journal	Year	Impact factor
NanoRelease	1. Nowack et al.	Potential release scenarios for carbon nanotubes used in composites	Environment International	2013	6.248 (2012)
OEL workshop	2. Gordon et al.	Workshop report: Strategies for setting occupational exposure limits for engineered nanomaterials	Regulatory Toxicology and Pharmacology	2014	2.132 (2012)
NanoRelease	3. Froggett et al.	A review and perspective of existing research on the release of nanomaterials from solid composites	Particle & Fibre Toxicology	2014	9.18
NanoRelease	4. Kingston et al.	Release Characteristics of Selected Carbon Nanotube Polymer Composites	Carbon	2014	5.868 (2012)

ILSI was involved in one publication (see, Table 6.6, paper number 3) while NIOSH and OSHA were not involved. Instead, five representatives from EPA were co-authors in all three papers related to NanoRelease. Furthermore, ten members from academia have been involved in two articles related to NanoRelease (see, Table 6.6, paper number 1, and 4). Taking into account all published articles, new facts have been generated in areas related to understanding release and exposure potential of nanomaterials (see, Table 6.7, for a detailed overview).

The *OEL workshop* contributed to a lesser extent to the generation of new facts. Accordingly, one paper was published in 2014 (see, Table 6.6, paper number 2), which evaluates existing possibilities for setting OELs for nanomaterials and, on this basis, suggests most adequate approaches for particular circumstances (see Table 6.7). These novel facts were generated by a small group of workshop participants–including ACC Nano Panel members, a representative from OSHA and NIOSH (as well as EPA) and four scientists from academia. For a general overview of the ACC Nano Panel activities in relation to the generation of new scientific facts, see Table 6.8).

Table 6.7. New facts resulting from ACC Nano Panel's collaborative activities.

Category	New scientific facts
Release of nanomaterials	• Release of CNTs can occur during manufacturing and processing, especially during recycling operations • Manufacturing that involves high-energy machining processes (e.g. cutting, grinding or drilling) gives rise to significant release levels • Data on nanomaterial release dynamics and debris composition from commercially relevant nanocomposites are a useful starting point to consider fate and transport modeling, exposure and risk assessment for nanomaterials • The highest potential for release of MWCNT occurs during manufacturing and end-of-life phases; 4 activities are identified that have the highest release potential • In the production of composites fragments containing CNTs may be generated; standard industrial hygiene effectively ensures occupational safety.
Exposure of nanomaterials	• There is exposure of CNTs from high energy machining during manufacturing processing and especially recycling (e.g. when cutting, grinding, drilling, shredding, or sanding is involved)
OELs for nanomaterials	• Due to a lack of toxicity data for most nanomaterials bridging, based on intratracheal instillation studies in rats with suitable control material for which long-term inhalation data are available, appears to be an appropriate approach for setting OELs for certain nanomaterials • Qualitative categorical approaches, based on potency comparisons to benchmark materials from various mode of action classes, are promising for deriving OELs for poorly soluble, low-toxicity nanoparticles for which toxicity is related to lung overload

Table 6.8. Overview newly generated facts ACC Nano Panel collaborative activities.

Collaborative activity	Generation new scientific facts
ACC Nano Panel meetings	---
NanoRelease	Release & exposure measurement
OEL workshop	OELs for nanomaterials

Exchanging knowledge, data and experiences requires a minimum level of trust among collaborators that such information is not misused by other parties. For instance, regulators may misuse information for the purpose of company inspections and related fines. Or, research institutes may use such information to promote studies that could be against the interest of those actors who provided such information in good will. Trust among actors does not emerge by itself, collaborators must learn how to build and maintain trust. This is important because trust is assumed to be a pre-condition, and amplifier, for knowledge exchange and the generation of new scientific facts (see section 4.3). To investigate the process of collaboration we shall turn to the game level of analysis.

6.2.2 Game level – strategic learning

On the game level of analysis six conditions for the study of trust serve to understand whether strategic learning has emerged among actors in the process of collaboration (see section 4.3):

(1) Meetings over a longer period of time
(2) Intensified actor relations
(3) Reliance among collaborators
(4) Realization of common goals
(5) Disagreement among collaborators is addressed and solved, and
(6) Development of additional collaborative activities.

The literature on trust does not provide clear answers, based on empirical studies about how trust initially develops and how it progresses over time (see section 4.3). Therefore, while applying the conditions for trust to the case of the ACC Nano Panel, these conditions will be refined further by using the empirical material.

(1) Meetings over a longer period of time

Trust develops over time on the basis of personal interaction and experiences (Edelbos & Klijn 2007; Sako 1998; Lewicki & Bunker 1996). The meetings of the ACC Nano Panel have taken place twice a year since 2005 until today (i.e. March 2014). The Panel's manager has organized two yearly face-to-face meetings, in the headquarters of ACC in Washington, D.C.. Furthermore, small working groups exist on ad hoc basis, which may meet more often depending on their workload (Interviewee 16, association).

In contrast to the continuous *Panel meetings*, the *NanoRelease Consumer Products project* had initially a restricted time frame of three years (2011-2013). During this time face-to-face meetings in the US were realized where all relevant actors (and many more) participated. In total three workshops took place, each over a period of two days (Bloomberg BNA 2012; ILSI 2011; ILSI n.d.a). As a representative from ILSI explains, depending on the availability of funding, which derives from participants in the project, and interest by the participants of NanoRelease the project will continue in 2014 (and beyond) (Interviewee 3, research institute). Because the project exists only since 2011, participants have more limited possibilities for getting to know each other well as compared to the Panel internal meetings.

Even more limited is this potential in regard to the *OEL workshop* as it was merely a two-day event: members of the ACC Nano Panel gave presentations and participated in discussions and all other relevant actors were either present as participants or presenters. A participant from academia described the workshop as a first step in bringing together people with different backgrounds to exchange insights on nanomaterials health and safety. He expects, though, that a follow-up meeting in form of a second workshop would be necessary to familiarize people and thereby bring the discussion on nanomaterials OHS a step further (Interviewee 10, academia). Even though the Nano Panel plans to continue the discussion started during the OEL workshop (Interviewee 16, association), as of October 2014, a comparable second workshop has not been realized.

(2) Intensified actor relations

When collaborators have opportunities to meet over time, an important pre-condition for intensifying relations and getting to know each other better is provided. In this respect, when a limited number of actors collaborate, conditions for becoming familiar with each other are better compared to large groups. Based on (past) experiences in processes of interaction, trust can develop (Vangen & Huxham 2003; Gulati 1995). Since 2005 the ACC Nano Panel has, generally, organized at least two *Panel meetings* per year. While the number of Panel members declined over the years due to company mergers, acquisitions and shift of company focus, a small core group of persons (i.e. representatives of chemical companies)–BASF, Dow, DuPont, Evonik, Procter & Gamble and 3M–participated in the Panel meetings over time. These meetings have provided a good opportunity for company representatives to get to know each other (Interviewee 15, industry; 14, industry). As such actions of individual Panel members can become more predictable, thereby enabling people to enter meetings and discussions with realistic expectations. Since discussions in the Panel meetings are not public, members have a 'secured space' for the growth of their relationships. Additionally, through working closely together on specific projects and common travel to conferences and workshops, the Panel members actually deepened their relationships (Interviewee 15, industry). As one Panel member emphasizes, over the years he created partnerships and friendships that both have a personal and professional side, which enables open exchange of, and deliberation on, ideas (Interviewee 14, industry). Another representative of the Panel stresses that members know each other well and are familiar with each other's interests and viewpoints on matters of nanomaterials OHS (Interviewee 16, association).

In the period from 2008 to 2009, the tendency of intensifying relations is, however, disrupted. During this time internal structural changes and reorganizations within the ACC are one explanation for the absence of new Panel activities, thereby impeding opportunities for intensifying relations further (Interviewee 14, industry). The positions of Panel manager and chair are not deducible from the publicly available documents; concomitantly, the Panel did not initiate any activities directed at nanomaterials OHS during the period from October 2007 to February 2009. There is no data (either from interviews or from documents) available, which would show that ambiguity in regard to formal positions and structures in the Nano

Panel and the ACC influenced the Panel's ability for organizing new collaborative activities. Nevertheless, it is noticeable that since 2010 the positions of Panel manager and chair are evident while at the same time Panel activities are realized continually. Despite this temporary exception, the activities of the ACC Panel appear to provide ample opportunity for relationships among members to intensify.

In comparison, the *NanoRelease project* provides fewer opportunities, namely three face-to-face meeting over a period of 3 years in form of three workshops, each over a period of two days (ILSI n.d.). Possibilities for intensifying relations are also limited due to the relatively high number of participants, namely 50 to 60 people. All relevant actors participated, next to many representatives from EPA, labor unions, legal consultancies and regulating agencies from Canada (ILSI 2013; Bloomberg BNA 2012; ILSI 2011). Prior to collaboration through NanoRelease, NIOSH had already become familiar with, and had built an intensified relationship with, the Panel through other collaborative activities (Interviewee 14, industry). For instance, a representative from NIOSH was invited to one of the Panel's yearly meetings where major developments in the field of nanotechnologies were, and continue to be, summarized.

Hence in light of their earlier collaboration, the NanoRelease project needs to be understood as but another activity through which the Panel and NIOSH intensified their relationship. In contrast, for representatives from academia, the opportunities in NanoRelease to intensify relations with the Panel are restricted as this actor group typically does not look back at a history of common activities (Interviewee 10, academia).

The *OEL workshop*, as a two-day meeting, provided least opportunities for deepening relations. Actors, who did not know each other prior to the meeting, had very limited opportunities for getting to know each other. In addition, the number of participants (50 to 100) provided little space for intensifying relations. Participants included representatives from all relevant actors as well as EPA, consultancies, and labor unions (ACC 2012c; Interviewee 10, academia). It is noteworthy that during the OEL workshop a group of participants–consisting of the Panel manager, a Panel member, and each one representative of OSHA, EPA and NIOSH as well as scientists from universities–formed a work group in order to write a report of the workshop results (Gordon et al. 2014; Interviewee 9, regulator). This, in itself, does not necessarily mean that relations among these actors were actually intensified but it means that an additional platform was established by means of which actors could possibly deepen relations. Intensified actor relationships appear as a pre-condition for the development of reliance among collaborators as the following section will illustrate.

(3) Reliance among collaborators

When collaborators have developed intense relations over a longer period of time, and when during this period actors refrain from taking advantage of situations where others put themselves into a vulnerable position, collaborators may begin to rely on each other. Reliance refers to predictability and consistency of other actor's behavior and by 'trust beyond control' (Gabarro 1978). When actors perceive each other as trustworthy, less control is necessary (Nooteboom 2010) and actors can increasingly feel free to exchange personal ideas and knowledge.

Through their *Panel meetings* the members have developed relationships that are generally characterized by reliance among the individual company representatives and the Panel's Chair. Over many years the individual Panel members experienced the interaction and exchange of information in the meetings as very constructive. In this respect, a sign that Panel members actually rely on each other is that they put themselves into a vulnerable position by sharing knowledge on nanomaterials with the group. No contracts or non-disclosure agreements have been set up to protect sensitive information; members may talk about these issues with third parties (Interviewee 16, association). Based on the available data–arguably not surprisingly–no Panel member took advantage of this situation, for instance through using knowledge in order to gain a competitive advantage over another company. Overall, relationships among Panel members have developed in a way that allows open exchange of information based on which individuals, the companies they represent, and the industry as a whole has made progress (Interviewee 16, association; 15, industry; 14, industry).

Specifically in the relationship between Panel members and manager we also see reliance. This is, arguably, visible in the Panel's approach to dealing with requests from external actors for Panel-internal information: typically, when Panel members receive such requests they forward them to the manager, who then provides an evaluation of the situation, based on which the members decide to provide, or hold back, information (Interviewee 16, association). As such, Panel members rely on the manager to provide them with an adequate assessment based upon which they act; they do not seem to seem to control this.

In the *NanoRelease Project* and the *OEL workshop* reliance is visible particularly between Panel members and representatives from OSHA and NIOSH. As an OSHA representative explains, the collaboration with the Panel started after a certain Panel member, whom she knew well from her previous employment in industry where both used to collaborate frequently, invited her. When one left industry and started working for OSHA their good working-relationship prevailed, even though they were now working in different sectors (Interviewee 9, regulator). By working together both actors assume that the intentions for collaboration are based on goodwill. However, they cannot control that this is actually the case since no formal agreements for the partnership between OSHA and the Panel have been set up (ibid). By exchanging scientific data and knowledge with OSHA, the Panel puts itself in a vulnerable position as it has no guarantee that the agency will not use this data to its own advantage (for instance, by developing rules for nanomaterials that are disadvantageous for industry). However, any such situation did not apparently occur since this one OSHA representative has been a constant collaborator of the Panel ever since (Interviewee 15, industry; 9, regulator).

The relationship between the Panel and NIOSH is also characterized by reliance: the interviewed Panel representatives have emphasized that they have collaborated much over the course of many years. NIOSH relies on the input and opinion of the Panel in reviewing and calibrating its research program for nanomaterials; the Institute assumes that the thus provided information are 'correct' without controlling them (Interviewee 5, federal research institute).

In contrast, in the relationship between the Panel and certain representatives of academia we do not see reliance but rather mistrust due to the Panel's association with the American Chemistry Council. As a scientist in the area of toxicology explains, his experiences with the ACC are 'not good'; overall, the association appears not to be trustworthy in respect to exchanging information and facilitating productive cooperation (Interviewee 10, academia). Based on these experiences, the scientist was skeptical whether the Panel is trustworthy. However, based on the participation in the OEL workshop, the scientist had not experienced situations that would have justified mistrust towards the Nano Panel:

> "(…) you know they [ACC Nano Panel] were hosting it [OEL workshop], but they really took a back seat during the meeting. They weren't really trying to direct the agenda or the discussions. So I was very happy with them from that perspective, as compared to some of my other interactions with the ACC" (Interviewee 10, academia).

In this connection he appreciated that the ACC Nano Panel did not steer workshop discussions in a certain direction, but instead a representative from a university guided the debates. This provided more ‘neutral’ grounds for discussion (ibid).

While this divided view on the reliability of the Nano Panel compared to ACC might not account for all or most scientists in academia, another scientist in the field of administrative law, as well as member and past president of an NGO for the protection of health, safety and the environment, raises similar concerns as to the reliability of the ACC Nano Panel. In light of his past experiences regarding ACC-government interaction he expressed skepticism whether the Nano Panel is doing credible work that could be trusted without additional control by externals:

> “(…) [W]hat we’re skeptical about is just letting the industry do this in partnership with the government without allowing a lot of outside participation. There really need to be a lot of outside participation because otherwise the industry will rapidly co-opt the government” (Interviewee 6, NGO).

NGOs are critical about the reliability of ACC and its constructive involvement in the topic of nanomaterials. The EDF, an NGO which was actively involved in the topic of nanomaterials OHS and collaborated with the ACC Nano Panel in 2005, appears to distrust the ACC. It would appear from EDFs blog on chemicals and nanotechnology[78] since 2010, their beliefs and expectations regarding ACC’s goodwill for meaningful collaboration in regard to nanomaterials OHS were not met; based on these experiences the NGO started to distrust the association and its approach to chemicals generally.

(4) Realization of common goals

Another sign that trust has developed among collaborators is when actors hold back the realization of individual goals in favor of the network goal(s). The collaborators act in this way with the expectation that this situation will not result in opportunistic behavior by other network actors (Koppenjan & Klijn 2004). On the contrary, when certain network actors try to realize their individual goals at all cost and to the disadvantage of the common network goal(s), blockades and conflicts can emerge that hinder the collaborative process and may even lead to distrust (‘goal divergence’).

With regard to the internal *Panel meetings* there are no indications of blockades (based on the available data from interviews and documents). This might be the case because there are measures in place to forestall situations where members would have to choose between pursuing individual, or network, goals and which might induce conflict among collaborators. In internal Panel meetings conflicts, as a result of goal divergence, are circumvented through actively emphasizing common goals in the collaboration and by limiting possibilities to address topics related to individual interests (Interviewee 16, association). For instance, topics that relate to issues in which members companies are competing can never be addressed in meetings (ibid).

Instead, common interests and viewpoints are stressed by defining strategic goals of the Panel and by placing discussions on a level in which members have common objectives: the scientific realm (ibid). Based on the interview data it was not further specified whether this is something that members agree on implicitly or whether this is an explicit choice or

[78] See, EDF’s chemicals and nanotechnology blog, http://blogs.edf.org/health/category/nanotechnology/. The blog includes, between 2008 and 2011, a total of 13 in-depth analyses of nanomaterials including governance OHS aspects.

strategy adopted by the Panel manager. Therefore, it can only be speculated that, since the 'language of science' follows commonly accepted understandings and principles, individuals–each with individual goals in mind–can work together in view to solving a common (scientific) problem, which is to advance the scientific knowledge on nanomaterials and potential risks. Also, in order to emphasize common goals in cooperation, all meetings of the Panel are based on, and structured by, fully vetted agendas that require approval of the members (Interviewee 15, industry; 14, industry). Additionally, once a year the members re-align the Panel's strategic goals. Such deliberations, again, can further the focus of common rather than individual interests and the creation of constructive partnerships.

In this light, members realize they are inevitably competitors. But they cannot pursue individual goals since it is necessary to maintain professional relationships to uphold the collective power of the chemical industry as a whole (Interviewee 16, association; 14, industry). One Panel member put it, 'the Panel acts as an entity that speaks on behalf of its parts' (Interviewee 15, industry).

In the *OEL workshop* we see a similar approach to dealing with goal divergence through emphasizing commonalities. Discussions were led from the common interest to advance the science of nanomaterials and discuss which approaches to setting OELs would be must suitable by drawing on multiple stakeholder perspectives. A representative from OSHA pointed out that the workshop was excellent because all participants were on the 'same page' when it came to issues of scientific relevance, e.g. need for more consistent hazard information and methods to detect and measure worker exposure to nanomaterials (Interviewee 9, regulator). At the same time, participants could voice individual opinions and viewpoints on the appropriateness of these strategies (ibid). In this light, the Panel manager emphasized, "(…) we don't direct what happens, we let it happen" (Interviewee 16, association).

It thus appears that the strategy of placing discussions on nanomaterials OHS on the level of science is useful in the sense that diverging opinions are more readily accepted in the light of common or overall network goals. This approach has partly been adopted also in the context of the *NanoRelease project* where collaborators worked together with the goal to develop a knowledge base on nanomaterials exposure (Interviewee 16, association). But in contrast to the OEL workshop, here an extended period of time (nine month) was dedicated to explicitly encourage collaborators to voice their individual opinions and, on this basis, decide on the collective research focus of the project through voting (ILSI n.d.b). This approach provides an example how the issue of individual versus collective goals in collaboration can be addressed openly and solved to the overall satisfaction of actors. As we shall see, such an approach can pave the way for strengthened trust among collaborators.

(5) Disagreement among collaborators is addressed and solved

It is useful to have a strategy in place for handling situations of conflict among collaborators since actors may pursue individual and common interests, which can then lead to disagreement and conflict. Under these circumstances, previously established trust relations among actors can be destroyed or lead to the abolishment of collaborative ties. But when disagreements are addressed openly and can be overcome in a way so that collaborators are still willing to continue cooperative activities, trust among actors can be strengthened thereby improving collaboration (Edelbos & Klijn 2007; Koppenjan & Klijn 2004; Ostrom 1990).

All interviewed Panel representatives (n=3) described the interaction in the *Panel meetings* as typically not characterized by disagreement and no examples of conflict have been mentioned (Interviewee 16, association; 15, industry; 14, industry). Instead, the Panel representatives emphasized that building consent is valued at most by all members of the Panel. Therefore, given the data available, rather than investigating how disagreement among actors can be addressed and solved we will study how disagreement can be prevented.

One explanation for the apparent lack of clashes among Panel members may be that there is generally no space for disagreement during Panel meetings, i.e. conflict is actively prevented by the Panel chair by emphasizing common goals rather than individual goals. Since Panel meetings are structured by agendas (Interviewee 15, industry; 14, industry) this approach may also prevent disagreement among members. Another explanation may be that per se there is little ground for disagreement since membership is homogeneous, i.e. all members are representatives of multinational chemical companies that pursue strategic goals in regard to creating overall favorable conditions that allow leveraging the economic benefit from the development of nanomaterials. It could be reasoned that potential for disagreement could be created when SMEs were involved in the Panel given that such firms probably have interests that differ from those of multinational companies.

In contrast, the *NanoRelease Project* and the *OEL workshop* involved actors with diverse backgrounds and interests, thus, ground for disagreement was more likely. But also in this context disagreement or conflict was not visible from the available data. It appears therefore that rather than actively coping with solving disagreement, actors focused more on preventing disagreement in the first place. This seems to be visible in the conscious approach in NanoRelease to not have members of the ACC Nano Panel–which acts as co-sponsor of, as well as participant in, the research project–take an active stance in guiding or directing discussions. Doing so prevents disagreement among actors in view of the adequate choice of topics to be discussed and researched. If members of the Panel were to guide discussions this could limit the credibility of results (Interviewee 10, academia). To not deliver biased results, in the NanoRelease project an external institute (ILSI) managed the project.

Similarly, in the OEL workshop the relevant actors from academia and OSHA (as well as EPA) themselves guided discussions (ACC 2012c; interviewee 1, research institute). Adopting this approach allows people to come together and discuss such issues that they render important in the area of nanomaterials OHS; a Panel representative emphasized 'we don't try to come and tell people what to do' (Interviewee 16, association). To further increase the credibility of the OEL workshop results, people were invited to participate, who already have a well-known reputation in the field (Interviewee 16, association). Other stakeholders will recognize these names and thereby know that the Panel has invited reliable actors to the workshop and hence is contributing to trustworthy results.

The only occasion where disagreement among actors emerged (and was reported by one interviewee and within a document) was during the OEL workshop. Here a point of disagreement was the question whether the application of adjustment factors to existing OELs for larger particulate materials to derive OELs for corresponding engineered nanomaterials is an appropriate strategy. And, if so, how to make such adjustments (Gordon et al. 2014). During the workshop this point of disagreement was not solved by consensus (ibid; Interviewee 9, regulator). Instead, disagreement on certain issues was accepted in view to overall agreement among all actors that the development of OELs for nanomaterials is a desirable effort. In this example we also see that consensus is merely one answer to dealing with disagreement among actors. Another solution is to accept diverging actor opinions by reporting them transparently and, on this basis, draft conclusions to which actors, despite other points of disagreement, largely can associate with. However, as mentioned above, typically the collaborative activities of the ACC Nano Panel were not characterized by disagreement and conflict among actors. Thus, previously established trust relations seem to have not been affected neither in a negative nor positive way, i.e. trust relations have not been weakened or strengthened through (solving) disagreement.

(6) Development of additional collaborative activities

When trust among actors has developed over time, additional collaborative activities may be organized. Likewise it would appear that the organization of new partnership activities indicates that past and present relationships are based on overall trust, which is related to good experiences in working together. While new activities may strengthen trust among collaborators, at the same time future collaborative activities provide opportunities to damage existing trust relations (Edelbos & Klijn 2007).

In view to the internal *Panel meetings*, new collaborative activities are planned continuously by inviting external stakeholders to the Panel's end-of-the-year meetings. Here significant developments in the field of nanomaterials are reflected on (Interviewee 16, association). In this respect it is noteworthy that the continuous character of the end-of-the-year meetings strengthens the predictability of the participant's behavior (i.e. reliance among the participants can further stabilize). Past speakers have included representatives from NIOSH, EPA and a trade association (ibid). While this signals mutual trust among Panel members and externals, this could also serve to reaffirm interest in common network goals. External speakers with a well-known reputation in particular areas of nanomaterials are invited in order to bundle expertise, ensure that areas of research are covered in which the Panel members are not experts themselves, and to maintain credibility in the debate on nanomaterials OHS (ibid).

In connection to *NanoRelease* additional collaborative activities were realized. In 2013 the project NanoCharacter was founded by ILSI in which, again, all relevant actors, except OSHA, collaborated (ILSI n.d.c). While this points to trust among the relevant actors who continued working together, in turn, it does not say that OSHA did not collaborate in NanoCharacter due to weak trust or distrust; other explanatory factors, for instance, related to institutional decisions to focus the attention on projects related to the development of databases for (certain) nanomaterials might play a role (Interviewee 9, regulator).

As mentioned earlier, during the *OEL workshop* a mixed group, including representatives from the Panel, academia, OSHA and EPA, established a work group to write a report of the workshop results and to plan future activities related to the development of OELs for nanomaterials. This group met once more after the 2012 workshop, but no concrete plans to continue collaboration in terms of a second workshop have been made (Interviewee 16, association).

As the analysis shows, the relevant collaborators in the network around the ACC Nano Panel generally trust each other. In this respect, relations among ACC Nano Panel members internally, as well as among Panel members and various NIOSH representatives, are based on trust that has been build over many years. The relation between the Panel and one representative of OSHA can be characterized by trust, which, however, exists 'only' since 2011. However, we have also observed that certain representatives of academia (and NGOs) generally distrust the ACC and, to a certain extent they transfer this distrust to the Nano Panel (see Table 6.9 for an overview of the development of trust among the collaborators in the ACC Nano Panel network).

Table 6.9. Overview trust in the ACC Nano Panel collaborative activities.

Collaborative activity	Trust
ACC Nano Panel meetings	ACC Nano Panel members internally
NanoRelease	ACC Nano Panel/NIOSH ACC Nano Panel/OSHA
OEL workshop	Panel members/academia (distrust)

In the foregoing two sections we have seen that relevant actors mostly trust each other, albeit in varying nuances, and that new knowledge related to making risk assessment more applicable to nanomaterials has been generated. Next, we shall investigate whether, on this basis, collaborators have developed rules of behavior that would contribute to institutional learning.

6.2.3 Network level – institutional learning

As described in section 4.3, on the network level of analysis three conditions for the study of rules development serve to understand whether institutional learning has emerged in the process of collaboration:

(1) Development of informal agreements
(2) Design of soft rules of behavior, and
(3) Soft rules become 'hardened'.

Agreements and rules can be of two types[79]: they can refer to interaction among relevant actors in a network to structure, facilitate and stabilize processes of collaboration so that actors know acceptable ways how to act under certain circumstances (process-oriented agreements/rules). Agreements and rules can also refer to practices on how to handle nanomaterials at workplaces most safely based on the latest state of science and instrumentation (problem-oriented agreements/rules). The three conditions for the analysis of institutional learning are now applied to investigate the collaborative activities in the network around the ACC Nano Panel.

(1) Development of informal agreements

Informal, or ad hoc agreements are typically a precursor for the development of formal rules of behavior and these agreements may be process-, or problem-oriented. Informal agreements are unwritten and may be implicit in the sense that collaborators are not aware of them (Klijn 2001; Termeer 1993). Regarding the internal *Panel meetings* various informal agreements can be identified, which are process-oriented, while problem-oriented informal agreements are absent.

An example of an informal, process-oriented agreement is the Panel's approach to dealing with external requests related to Panel internal issues. Based on unwritten agreement,

[79] See section 4.2 (pp. 65-66).

Panel members give only certain information to third parties that they deem trustworthy; the decision who is trustworthy is made by the Panel manager and Panel members agree informally that the manager shall evaluate which parties to trust and which not (see, the game level analysis). Nevertheless, the Panel members can decide by themselves which information to give away because there are no formal non-disclosure agreements in place (Interviewee 15, industry). On a more generic level, independent from NanoRelease or the OEL workshop, a representative from NIOSH refers to an informal agreement between the Institute and the Panel to exchange information whenever a need to do so emerges:

> "If there's a topic that they would like to hear about from NIOSH, or NIOSH would like to communicate something to the Panel, we've been pretty open in both directions about either visiting with each other or having some time on the meeting agenda" (Interviewee 5, federal research institute).

In the context of the *OEL workshop* an academic scientist points out that the participants made an informal agreement that the discussion will be continued through the realization of a follow-up workshop (Interviewee 10, academia). Two years later (2014) another workshop has not come to fruition. With regard to the *NanoRelease Project* a representative of ILSI states that no informal agreements either process-, or problem-oriented have been made (Interviewee 3, research institute). Overall, based on the data from the interviews and documents, it appears that no informal, problem-oriented agreements have been made by the collaborators.

(2) Design of soft rules of behavior

Over time informal agreements among collaborators may be put in writing and, on this basis, agreements can develop into soft rules of behavior, which tell actors what ought to be done under certain circumstances (Black 2008, 2002). Soft rules, or regulation, refer to rules of conduct, which do not have legally binding force but they may be relevant in regulatory practice by, e.g. reflecting the latest state of science and technology (Senden 2004) (see section 4.2). Soft rules–either process-, or problem-oriented–may take the form of, for example, codes of conduct, guidance material and/or industry standards.

The *Panel meetings* are guided by various process-oriented soft rules as two interviewees point out (Interviewee 15, industry; 14, industry). While these soft rules are in place it is unknown whether they are based on previously informal agreements that developed into soft rules over time, or whether they have been put in place directly in the form of soft rules. One of these soft rules is that meetings should always be structured by means of an agenda, which mentions topics for discussion. The agenda is written by the Panel's chair and topics must be approved by an independent legal counsel from the ACC before a meeting takes place (Interviewee 15, industry). In case a topic is not mentioned on the agenda, it cannot be debated. As a member of the Panel explains, these rules are necessary since the companies that are represented in the Panel are actually competing companies in the same industrial sector. By having strict rules for meetings in place and having a legal counsel evaluate all points for discussion on the agenda, it is ensured that no antitrust discussions the place (Interviewee 15, industry; 14, industry).[80] Certain issues (such as marketing) can never be discussed in meetings (Interviewee 15, industry).

[80] The Sherman Antitrust Act 26 Stat. 209, 15 U.S.C. §§ 1-7 is a federal statute that was passed by Congress in 1890 according to which federal government regulators have authority to prohibits business practices that could potentially harm competition, e.g. cartels or monopolies.

In regard to problem-oriented soft rules three Panel representatives have stated that developing such rules of behavior is not a goal of the Panel. In its publication ACC Position on Nanotechnology (2014c), the Panel states that the principles of ACC's Responsible Care Management Systems® apply to nanotechnology-related activities. However, it is not specified how such principles shall be applied in workplace operations or be translated into rules of behavior that would provide support in dealing with the potential risks of nanomaterials. Panel representatives state that developing such practical tools is not necessary (Interviewee 16, association; 15, industry; 14, industry); many such guidelines have already been developed by NIOSH and are very helpful. Therefore the Panel does not see an urgent need to develop such materials itself (Interviewee 16, association). Rather, the Panel members actively support NIOSH's work by opening up their facilities and exchanging knowledge and data with the Institute on-site. In this way we can say that various Panel members have indirectly contributed to the development of soft rules by NIOSH (Interviewee 5, federal research institute).

A Panel member emphasized that in the area of risk assessment and management many instruments for chemical substances are already available. These instruments may be utilized by companies to practice good product stewardship; on this basis, companies ought to live up to their own responsibility for product stewardship and supplement existing practices in view to nanomaterials (Interviewee 15, industry). The company this Panel member represents has thus entered into a partnership with an NGO and on this basis developed its own instrument specifically for nanomaterials OHS. Another Panel member stressed that his company has been involved in the development of soft instruments that were generated by a non-US business association (the German VCI) (Interviewee 14, industry). Since all Panel member companies are global in nature, the soft rules that are occurring in one jurisdiction would also meet the needs of that global company in another jurisdiction, and hence there was no need to duplicate this effort (ibid). However, in comparison to multinational chemical companies the Panel member acknowledged that other types of rules of behavior might be beneficial for small and medium-sized companies (SMEs). While SMEs are not represented in the Panel, relevant issues would reach the ACC Nano Panel nevertheless because he participates in venues, such as the Society for Chemical Manufacturers and Affiliates where SMEs are represented (ibid).

In the collaborative network around the ACC Nano Panel, an actor that supports both the interests of SMEs and multinational companies in the nanomaterials manufacturing sector, is NIOSH. By developing problem-oriented soft rules on how to conduct risk assessment for nanomaterials based on the latest state of science the Institute provides guidance. Through NIOSH's toxicology testing program companies, including ACC Nano Panel member companies, can invite the Institute to their premises and volunteer to have their manufactured materials tested. The generated data is used by NIOSH in a generic way to develop soft rules, or best practices, to support workplace health and safety (Interviewee 5, federal research institute). A founder and chief technologist of an SME explains how NIOSH develops these soft rules:

> "[W]e've had the US NIOSH at [name of the company] twice; once in the very early stage of the company when we were only 10 people and we were doing nothing but R&D, we had them in and we, together, help write best practices around quantum dot R&D environmental health and safety in the workplace. Then (…) we had them back to look at our production processes and see what else we might do to design a safer facility (…) the best practices that they [NIOSH] wrote about R&D of nanoparticles, like ours, were largely generated from the back of the work they had done with us" (Interviewee 4, industry).

Thus, in exchange for helping companies to promote a safe work environment with nanomaterials, NIOSH receives scientific data; this may then be used by the Institute to develop problem-oriented soft rules of behavior. While collaborating with companies, including ACC Nano Panel members, NIOSH also collaborates intensively with academia to develop these best practices (Interviewee 10, academia). Overall NIOSH's role in the development of soft rules for dealing with the potential workplace risks of nanomaterials is valued highly and relied upon by all (relevant) actors in the network. As the owner of a law consultancy in the area of nanotechnology puts it:

> "I think that is exactly where NIOSH has kind of parachuted in and saved the day; it provided hands-on, very meaningful, extremely user-friendly guides (…) they are really, really good (…) [and] the feedback is universally positive and relentlessly enthusiastic (…) I don't know where the nano-community would be without those resources, it's infinitely valuable" (Interviewee 8, law consultancy).

Similarly, the founder of a consultancy that assists companies in the risk assessment and management of nanomaterials emphasizes the usefulness of NIOSH's problem-oriented soft rules:

> "I've advised them [her clients] to do some streaming-level testing and it does follow the protocol that NIOSH would also recommend for kind of an initial tier of assessment. I've recommended that they do this in order to really understand whether they should be designing control equipment for example in their manufacturing processes and where they should plan to put hose controls" (Interviewee 7, consultancy).

Besides the development of soft rules in the context of internal Panel meetings and the overall network, did the NanoRelease project and the OEL workshop also contributed in this respect?

In the *NanoRelease Project* the development of problem-oriented soft rules in form of best practice methods to induce, measure and characterize nanomaterials release from products was an explicit aim (Froggett 2014). However, in 2014, these best practice methods have not been developed yet as a representative of ILSI explains (Interviewee 3, research institute). More time to develop such methods is necessary as had been anticipated prior to the start of the project. Furthermore, NanoRelease does not (yet) make use of process-related soft rules of behavior such as codes of conducts or ethics; however, a representative of ILSI points out that in the near future such rules may be developed (Interviewee 3, research institute).

The *OEL workshop* was a onetime event, and did not result in the development of process-, or problem-oriented rules of behavior related to setting OELs for nanomaterials. A scientist and workshop participant found that the workshop was a good first step; but no consensus was reached about the approach to be taken for setting OELs for nanomaterials (Interviewee 10, academia). The workshop participant expressed further that a welcome goal, to be reached in a second workshop, could be to make agreements on whether soft rules in form of guidelines for appropriate exposure limits shall be put in place (ibid).

(3) Soft rules become 'hardened'

Soft rules of behavior may become 'hardened' by formalization, namely through written reference in 'texts of the law' (such as judicial decisions, commentaries or policy documents) and/or through oral reference by public authorities (i.e. 'law-in-books' and 'law-in-action') (see section 4.2). Regarding process-oriented rules, formalization means that actors have acknowledged what the proper *modus operandi* in collaborative processes is and thereby collaborative network structures are stabilized. Regarding problem-oriented rules, formalization means that regulatees–in this case companies that manufacture nanomaterials–have learned how to apply certain aspects of traditional risk assessment to nanomaterials; thereby an essential pre-condition for compliance with OHS legislation–i.e. the employer legal duty to ensure health and safety at workplaces through conducting risk assessment for (potentially) hazardous chemicals–is fulfilled. 'Hardened' rules provide certainty that those who follow the rules behave in the best possible way under specific circumstances. At the same time, hardened rules level down the playing field, i.e. the regulated parties have less flexibility in deciding how to behave under particular circumstances.

In regard to the above-mentioned process-oriented rules of behavior that were developed during the *Panel meetings* a 'hardening' of these rules did not take place over time. Rather, a Panel representative emphasizes that these rules are not backed by any form of legal binding documents (Interviewee 16, association).

But certain problem-oriented rules did become hardened. As mentioned above, the Panel itself did not develop problem-oriented soft rules. However, the Panel members contributed essentially to the development of such rules through NIOSH because they opened their facilities and invited NIOSH to do on-site testing of their materials. Based on the results of these tests, NIOSH developed problem-oriented rules of behavior. Therefore, the Panel is considered to have contributed indirectly to the development of these rules (Interviewee 5, federal research institute). Through reference by OSHA these rules actually became hardened. On its website OSHA refers to NIOSH's guidance material in the context of nanotechnology and health effects and workplace assessments/controls (OSHA n.d.). While use of the NIOSH guidance material is voluntary, OSHA recommends its use in order to ensure safe workplaces. While various other sources for information and best practices are mentioned, OSHA recommends first and foremost material by NIOSH (ibid). In this sense OSHA states, "NIOSH is the leading federal agency providing guidance and conducting research on the occupational safety and health implications and applications of nanotechnology" (ibid).

More specifically OSHA refers to NIOSH's Approaches to Safe Nanotechnology (2005), which includes guidelines for working with engineered nanomaterials. The final version of this document was published by NIOSH in 2009 (NIOSH 2009b), but OSHA does not refer to the updated document on its website, which provides much more specific guidance than the 2005 version. Rather the agency refers to guidance developed by NIOSH to provide practical support for nanomaterials OHS under its Current Intelligence Bulletins (CIBs), particularly the CIBs Occupational Exposure to Carbon Nanotubes and Nanofibres (2013b) and Occupational Exposure to Titanium Dioxide (2011).[81] NIOSH communicated both CIBs on nano-scaled titanium dioxide and carbon nanotubes and nanofibres–which both contain recommended exposure limits (RELs)–to OSHA before the documents were finalized (Interviewee 5, federal research institute). As a NIOSH representative remembers,

> "OSHA was an early recipient of that information even before we finalized it and we were sharing drafts of that information and communicating it to OSHA" (Interviewee 5, federal research institute).

[81] NIOSH's CIBs are issued to distribute new scientific information about occupational hazards that were either formerly unrecognized, provide new data on known hazards, or distribute information about the control of hazards. The CIBs are disseminated to various stakeholders including federal agencies, primarily OSHA as being responsible for ensuring worker's health and safety (Interviewee 5, federal research institute).

In 2013, OSHA recommended using both of NIOSH's RELs through its OSHA Fact Sheet for nanomaterials (OSHA 2013). The Fact Sheet "(…) reflects the current understanding of the health and safety issues relating to nanomaterials" (ibid: 1) and suggest to use NIOSH's RELs in a voluntary manner until there is more scientific certainty that existing occupational exposure limits provide adequate protection from nanoparticles. As such, OSHA has formalized these rules of behavior as developed by NIOSH. Thus, the members of the Nano Panel may have contributed nanomaterials data to particularly these two rules. But it may also be speculated that NIOSH did not receive its data from the Panel members, but from other companies.

With regard to the *OEL workshop* and the *NanoRelease Project* neither process-, nor problem-related soft rules have been developed and, thus, did not become 'hard' rules in any way. However, in this respect it should be mentioned that one goal of NanoRelease was to develop best practice methods to induce, measure and characterize nanomaterials release from products, which would then be used to develop international standards (Froggett 2014); in this way rules may become hardened in the future.

As the analysis in this section has indicated, the collaborative activities of the ACC Nano Panel generally did not lead to the development of process-, and problem-oriented rules. While the internal Panel meetings have resulted only in the development of process-oriented rules in neither of the collaborative activities problem-oriented rules have been developed to support making risk assessment more applicable for nanomaterials. Certain Panel members were only involved indirectly in the development of soft rules by NIOSH. For a general overview of the development of rules in the ACC Nano Panel collaborative network see Table 6.10.

Table 6.10. Overview rule development ACC Nano Panel collaborative activities.

Collaborative activity	**Rules** Problem-oriented	 Process-oriented
ACC Nano Panel meetings	--- (however, indirect contribution to soft rules developed by NIOSH)	Soft rules to structure meetings
NanoRelease	---	---
OEL workshop	---	---

Overall then, by considering the three levels of analysis has the ACC Nano Panel contributed to learning how to make risk assessment applicable for nanomaterials? And, on this basis, has the Panel contributed to effective nanomaterials OHS regulation?

6.3 Conclusions: Limited contribution to effective regulation

This chapter aimed at answering the question on how collaborative activities by business associations in practice contribute to effective nanomaterials OHS regulation in the US. In sections 1.2 and 4.1 it has been explained that this thesis conceives effective regulation (in the area of nanomaterials OHS) by the preparatory processes for rule compliance with the employer legal obligation to provide safe workplaces through conducting risk assessment for nanomaterials. Due to conditions of scientific uncertainty as to the potential health risks of certain nanomaterials and how to apply risk assessment to nanomaterials it is more useful to investigate the process how regulatees can prepare rule compliance rather than if regulatees comply, or not. This is also important because currently we do not know whether existing OHS rules that apply to nanomaterials are evidently, i.e. form a scientific point of view, protecting workers from the potential health risks of nanomaterials. Possible business association activities that can contribute to preparing rule compliance have been identified in section 4.1.[82]

In this context, collaborative business association activities can lead to three types of learning, i.e. substantive, strategic, and institutional learning, that are related to each other in an assumed order (see section 4.3). As such, we assume that strategic learning is a pre-condition for substantive learning: when collaborators trust each other, exchange of relevant knowledge among collaborators is facilitated and actors are open towards each other; this is assumed to enhance the potential for finding innovative solutions and generating new scientific facts necessary in order to deal with the problem of nanomaterials OHS. It is also assumed that strategic learning and substantive learning are pre-conditions for institutional learning. When collaborators trust each other and have generated new knowledge necessary to deal with the policy problem, the development of agreements and rules is facilitated because the collaborators have the necessary knowledge available to develop such rules and they believe that the rules will not be detrimental to them.

In the analysis of the three types of learning we differentiate between 'strong' and 'limited' learning (see section 4.3). We speak of strong learning when many, i.e. the majority, of the conditions of a certain type of learning are met in the process of collaboration. We speak of limited learning when only a few, i.e. half or less, of the conditions of a certain type of learning are met. Accordingly, when only one of the three learning types is defined as strong we speak overall of limited learning and hence limited contribution to effective nanomaterials OHS regulation.

Against this backdrop, overall the collaborative activities of the ACC Nano Panel have made a limited contribution to effective nanomaterials OHS regulation in the US. Strong learning has been identified in relation to substantive learning, i.e. the generation of new scientific facts relevant for making elements of risk assessment applicable to nanomaterials. Strategic learning, i.e. the development of trust among actors, and institutional learning, i.e. the development of rules, appears limited.

As such, between 2005 and 2014 the Panel has initiated 19 activities directed at nanomaterials OHS of which most are of the type lobbying (13 out of 19 activities). Three collaborative activities are of the type knowledge exchange with the possibility for substantive learning, i.e. dealing with essential uncertainties related to nanomaterials OHS. In regard to these activities, from the four conditions that lead to substantive learning (see section 4.3), all conditions have been met in the collaborative activities of the ACC Nano Panel.

In line with the first condition, relevant actors have collaborated and, second, these actors have exchanged knowledge. More precisely, knowledge has been exchanged among the Panel and the primary responsible agency in the area of OHS, namely OSHA, as well as other relevant network collaborators, i.e. (federal) research institutes (NIOSH, ILSI) and academia (various universities). The collaborators have exchanged knowledge in form of aggregate data, general experiences, and have collected published data of which they have provided a critical evaluation. Based on this knowledge exchange, third, an increased understanding of aspects related to conditions for release of nanomaterials and exposure measurement and assessment has been gained. As to the latter issue, an increased understanding of the possibilities for setting OELs for certain nanomaterials has been discussed. Fourth, new scientific facts relevant for making risk assessment applicable to nanomaterials have been

[82] See p. 58.

generated on the basis of specifically one collaborative activity: the NanoRelease research project (2011-2013). One representative of OSHA was involved in this activity based on which new facts related to release and exposure measurements have been generated. Overall, the collaborative activities of the ACC Nano Panel have contributed to strong substantive learning on aspects of risk assessment for nanomaterials.

Next, strategic learning was investigated. Accordingly, some conditions for the development of trust among collaborators have principally been met; however, other conditions appear to have not clearly been met in the collaborative activities (see section 4.3 for the six conditions for strategic learning). Generally, opportunities to meet over a longer period of time and to intensify relations were restricted in the OEL workshop and the NanoRelease project (first and second condition of strategic learning). Third, reliance particularly among representatives of the Panel, NIOSH, and OSHA was visible in all three collaborative activities in that sensitive information were exchanged without having contracts or non-disclosure agreements in place to protect sensitive information. In this respect, certain representatives of academia (and NGOs) have voiced distrust towards the ACC Nano Panel due to negative experiences related to handling of data in past collaborations with the ACC. When distrust among collaborators prevails, their collaboration may become fragile or even dissolve. However, no such indications were visible by the time of this research (2014). Fourth, while agreements on common goals have been made in the collaborative activities, only in the NanoRelease project common goals have also been realized. Next, or fifths, disagreement that was addressed and solved to the broad satisfaction of the collaborators was only visible in the OEL workshop. In the other collaborative activities disagreement was not visible and hence it is not possible to determine whether there was an influence on trust development among the collaborators. Lastly, additional collaborative activities have been realized in relation to the Panel internal meetings and the NanoRelease project. Considering these points, it appears that the collaborative activities of the Panel have contributed to strategic learning in a limited way.

Lastly, we have investigated whether the collaborative activities have contributed to institutional learning (see section 4.3 for the three conditions for institutional learning). Thus, based on the newly generated knowledge by the collaborators, have problem-oriented rules been developed to provide guidance on (aspects of) risk assessment for nanomaterials? And, have process-oriented rules been developed to structure and facilitate interaction in the network? As regards the first condition, during the collaborative activities of the ACC Nano Panel some informal, process-based agreements have been made (no problem-oriented agreements have been made). More specifically, in the internal Panel meetings, informal agreements to structure communication with externals have been developed. During the OEL workshop, the collaborators agreed informally to continue discussions through the realization of a second workshop. Based on the collaboration in NanoRelease informal agreements have not been made. Regarding the second condition, the development of problem-, or process-oriented soft rules, only in the internal Panel meetings written soft rules related to the structure and interaction in Panel meetings have been set up. No problem-oriented soft rules have emerged from any of the collaborative activities. Though it should be acknowledged that a future goal of NanoRelease is to develop problem-oriented soft rules to induce, measure and characterize nanomaterials release (a pre-condition for exposure). There are also plans to develop soft rules in form of codes of ethics to structure interaction in the project.

The Panel did not develop problem-oriented soft rules based on the reasoning that useful soft rules, e.g. in form of guidelines, have already been issued by NIOSH (and others) and can be used. Therefore the Panel saw no need to develop (more) guidelines itself to support companies in conducting risk assessment for nanomaterials. Existing guidance material is sufficient and can be used. This means the Panel does not focus on supporting

ACC member companies in conducting risk assessment for nanomaterials to thereby help them comply with existing OHS regulation under conditions of scientific uncertainty.

Instead, the Panel seems to focus on preempting potential future regulation: through collecting and generating nanomaterials (risk) data the Panel acknowledges that some data gaps exist, which however, can be closed through research. The Panel has contributed to closing (some) of these data gaps and has used these efforts to demonstrate that the traditional risk assessment framework can principally be made applicable to nanomaterials. Therefore the Panel argues that existing regulation is sufficient and no new, nano-specific regulation is required within the US.

However, indirectly Panel members have actually contributed to the development of such soft rules by NIOSH: Panel member's companies invited NIOSH into their premises where they provided data on nanomaterials for the institute's toxicity testing program. The member companies were aware that NIOSH used this data to develop guidelines that, under more, provide guidance on how to conduct risk assessment for (certain) nanomaterials. As such the Panel members have indirectly contributed to the development of the NIOSH guidelines. As regards the third condition for institutional learning, specifically two of these guidelines–the CIBs Occupational Exposure to Carbon Nanotubes and Nanofibres (2013b) and Occupational Exposure to Titanium Dioxide (2011)–became hardened through formal reference by OSHA: in its Fact Sheet for nanomaterials (OSHA 2013) the agency recommended using two RELs that were proposed in the context of the NIOSH guidelines. Whether these particular guidelines were based on nanomaterials data provided by Panel members, however, remains unclear. Therefore, overall we conclude that the collaborative activities by the Nano Panel have not directly, and only to a limited extent, contributed to institutional learning.

The collaborative activities of the US ACC Nano Panel have contributed to effective nanomaterials OHS regulation in a limited, but useful, way. As assumed above, trust among collaborators is a pre-condition for knowledge exchange and facilitates the generation of new scientific facts. Based on the analysis of the ACC Nano Panel collaborative activities we can specify this assumption: limited trust among collaborators appears sufficient for these actors to exchange nanomaterials knowledge and data among each other and also, on this basis, to generate new scientific facts. Furthermore we assumed that trust among collaborators, in combination with knowledge exchange and the development of new scientific facts, facilitates joint rule development. Based on the empirical analysis we can adapt this assumption: Limited trust among collaborators combined with strong scientific expertise appears not sufficient for these actors to engage in rule development.

Taken together the collaborative activities of the ACC Nano Panel have contributed to effective nanomaterials OHS regulation mainly by sharing and generating nanomaterials (risk) data. In doing so, the association has demonstrated that existing OHS regulation is adequate from a scientific point of view in protecting the health and safety of workers handling nanomaterials. Furthermore, though more limited, is the development of trust among Panel members and representatives from the responsible regulatory agency in OHS matters, (federal) research institutes, and academia. Institutional learning appears even more limited (see Table 6.11).

Table 6.11. Overview learning in the ACC Nano Panel collaborative activities.

Substantive learning	Strategic learning	Institutional learning
Strong	Limited	Limited

Chapter 7

Case study – The German Chemical Industry Association (VCI)

In this chapter, the activities of the VCI in view to the problem of nanomaterials OHS are described and analyzed to answer the second part of subordinate research question 4: *How do collaborative activities of German business associations contribute to effective nanomaterials OHS regulation in practice?* The structure of this chapter is identical to chapter 6. In section 7.1, general characteristics of the German association are provided and its activities in the context of nanomaterials OHS are identified. Next, in section 7.2, particular activities are analyzed regarding their contribution to learning among network collaborators on how to make risk assessment applicable to nanomaterials. Based on the analysis of learning, in section 7.3, the contribution of the VCI to effective nanomaterials OHS regulation is concluded.

7.1 Activities by the VCI

Structure and membership

The VCI was founded in 1877 under the name Verein zur Wahrung der Interessen der Chemischen Industrie Deutschlands and, today, is the fourth largest business association in Germany accounting for more than 90% (n=1,750) of all German chemical firms (VCI 2014a; VCI 2014b). The VCI is part of a hierarchically organized system of German associations, being one among 37 member associations, under the lead of the federation Bundesverband der Deutschen Industrie (BDI)[83] (BDI 2014). The VCI has approximately 1,600 member companies, including SMEs and multinational chemical firms, of which 400 are direct members and 1,200 are members through 21 sector associations[84] (VCI 2014a). The members are represented through the VCI headquarters in Frankfurt on Main (a./M.), and two branch offices in Berlin and Brussels. Offices also exist in eight regional branches (‘Landesverbands-Geschäftsstellen’) (see Figure 7.1 for an overview).

In 2003 the VCI became actively engaged in the topic of nanotechnology through the co-foundation of the working group Responsible Production and Use of Nanomaterials (RPaUoN) together with the Society for Chemical Engineering and Biotechnology (DECHEMA). The DECHEMA is an association of the type ‘Mixed’[85] with over 5,800 members that describes itself as “(…) the hub of an interdisciplinary network of topic-oriented committees, organizing events and professional development courses for all who are interested in a specialized subject area” (DECHEMA n.d.a). DECHEMA administers the working group and organizes its meetings that take place in the premises of DECHEMA in Frankfurt (a./M.) (Interviewee 33, association; 25, association). Representatives of VCI participate in the RPaUoN meetings and provide expertise in the area of OHS and regulatory

[83] According to Bennett’s differentiation of association types (see, section 3.1, p. 42) the BDI is a ‘Federation’.
[84] See, for a complete list of all 21 sector associations, https://www.vci.de/Downloads/VCI-Structures-2014-05.pdf.
[85] See section 3.1 (pp. 42-43).

aspects. Through the RPaUoN work the topic ‘nanotechnology’ was introduced into the VCI and its various committees and groups (Interviewee 34, association).

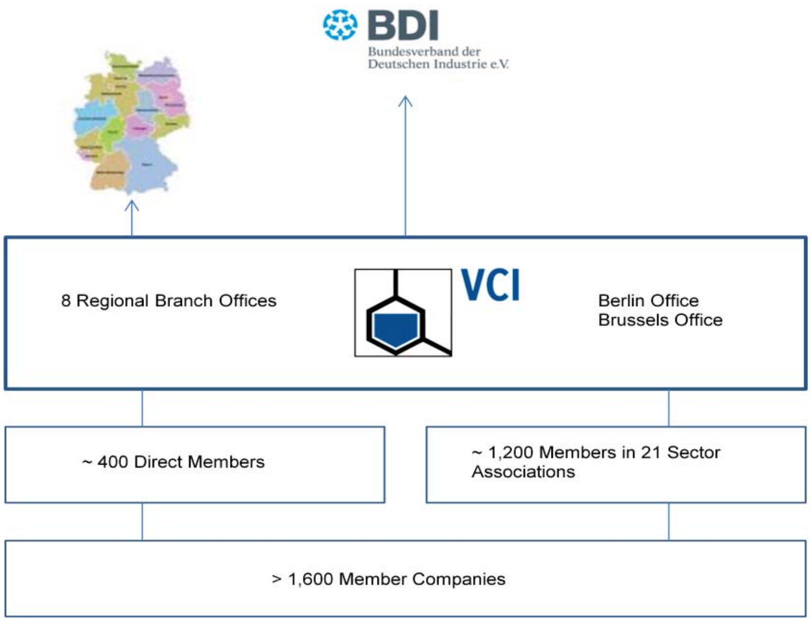

Figure 7.1. Overview VCI structure (retrieved in adapted form from VCI 2014e).

Usually, membership in the RPaUoN is linked to DECHEMA membership: interested organisations can either become a personal or sponsorship member of DECHEMA; the latter type of membership is directed at large companies, which can send a certain number of company representatives for participation in DECHEMA (DECHEMA n.d.b). Upon entry in DECHEMA members can chose to join one, or several, of 56 professional groups (‘Fachgruppen’) that are open to anybody willing to be affiliated with a particular topic; one of these 56 groups is the ‘Fachgruppe’ Nanotechnology with approximately 615 members (Steinbach 2014). The group is steered by an advisory body (Beirat) that consists of member experts in the field of nanotechnology, who form together the RPaUoN (Interviewee 25, association) (see Figure 7.2 for an overview of RPaUoN membership).

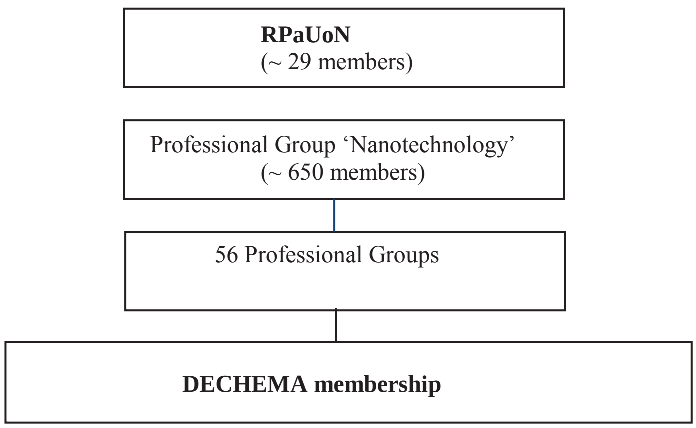

Figure 7.2 Overview membership RPaUoN.

The RPaUoN is a ‘closed group’, which means that individuals representing a certain group (e.g. industry or regulatory agencies), who are interested in participating, must apply either personally or are invited by other members. They are asked to give a presentation related to their particular field of expertise on nanomaterials, based on which membership is granted or rejected, for a period of five years (Interviewee 25, association). Complete membership lists of the RPaUoN are not available but, as two interviewees explain, the number of participants has been relatively stable over the years with 20 to 40 members and today (2014) approximately 29 members (Interviewee 27, academia; 25, association). RPaUoN members are representatives of industry–including representatives both from multinational chemical companies and SMEs–academia, regulatory agencies, (federal) research institutes, other associations, and a measurement instrumentation firm (Interviewee 25, association) (see Table 7.1 for an overview of the 2014 members).

Table 7.1. Approximate RPaUoN members in 2014 (based on information from interviewee 25, association).

RPaUoN members
Administration: DECHEMA Chair: Representative Bayer Vice-Chair: Representative EMPA
BASF
Bayer
Federal Institute for Occupational Safety and Health (BAuA)
Federal Institute for Risk Assessment (BfR)
Bremen University
Clariant
Society for Chemical Engineering and Biotechnology (DECHEMA)
DSM
Swiss Federal Laboratories for Materials Science and Technology (EMPA)
Evonik
Fraunhofer Institute
Grimm Aerosol Technik
Hohenstein Institute
ItN Nanovation
Institute of Energy and Environmental Technology e.V. (IUTA)
Kaisering Water GmbH
Karlsruhe Institute of Technology (KIT)
Linde
Merck
Nanotechnology Industries Association (NIA)
Institute for Applied Ecology (Öko-Institut)
Technical University Delft
Technical University Clausthal
Federal Environment Agency (UBA)
German Chemical Industry Association (VCI)
Verband der Mineralfarbenindustrie (VdMi)
Association of German Engineers (VDI)
Vienna University
Wacker

The RPaUoN is headed by a chair and vice-chair, being members of the group, who serve until further notice. Representatives of VCI provide, besides overall support, particular expertise in the area of regulation to the RPaUoN. The aim of the RPaUoN is bringing together experts

> "(…) to identify both the advantages and the potential risks of chemical nanotechnology and to promote its commercial and technologically successful implementation by initiating appropriate measures with consideration given to ethical, ecological, social and economic aspects" (ProcessNet n.d.).

In this context the topic of risk assessment for nanomaterials has been addressed.

Activities directed at nanomaterials OHS

The VCI started to actively participate in the discussion on nanomaterials OHS through the RPaUoN in 2003, but not much later the association also initiated own activities independent of the RPaUoN. Accordingly, as will be shown in the course of this section, the VCI delivers a broad range of business association collective goods related to nanomaterials OHS with a focus on soft regulation and knowledge exchange.[86] In the period from 2003 through to (March) 2014 the VCI has been involved in 21 activities directed at supporting nanomaterials OHS (see, below, the complete overview of VCI activities in Table 7.2). The activities are grouped into three main periods, which follow certain characteristics:

(1) **2003 – July 2007**
Setting the scene for an informed discussion

(2) **August 2007 – September 2011**
Provision of concrete advice

(3) **October 2011 – March 2014**
Participation in political discussions

Period 1. In the time from 2003[87] to July 2007, the VCI initiated six activities directed at supporting nanomaterials OHS all of which represent collective association goods. The activities in this period can be understood as 'setting the scene for an informed discussion' on nanomaterials OHS in which business associations, companies, policy-makers, scientists, trade unions as well as NGOs participated.

In 2003, by forming the RPaUoN together with DECHEMA, the VCI stressed the need to obtain scientific data on the potential risks of nanomaterials and to initiate measures to make risk assessment applicable to nanomaterials (DECHEMA & VCI 2007). This activity thus constitutes the collective association good *knowledge exchange* on nanomaterials OHS. The next activity took place in September 2005 when the VCI organized a first workshop on uses of nanomaterials in the workplace. Here members of the RPaUoN participated (VCI 2005). With the realization of the workshop the association emphasized the need for safety

[86] See section 3.1 (pp. 43-46) for types of business association activities.
[87] It is unknown in which month the RPaUoN was established.

research and initiated a broad stakeholder discussion on future steps to be taken in this respect (association good *knowledge exchange*).

Based on the results of the 2005 workshop, in February 2006 the VCI conducted a survey, in collaboration with BAuA, to learn about existing nanomaterials OHS practices among association member companies and to collect and exchange information on OHS methods applied in the chemical industry (*knowledge exchange*) (Plitzko et al. 2007; Plitzko & Gierke 2007).

Subsequently, in March 2007 the VCI provided comments on the Draft Environmental Defense/DuPont Nano Risk Framework for Responsible Nanotechnology (VCI 2007a). The association described the Risk Framework as a comprehensive instrument for responsible production and use of nanomaterials that reflects VCI's position in fundamental aspects, as illustrated by the association (ibid). Since the VCI used the occasion to represent its viewpoints on nanomaterials OHS, including risk assessment, this activity constitutes the good *representation and reputation*. Next, in April 2007, another workshop (as an extension to the one held in 2005) was organized to exchange information on nanomaterials OHS (*knowledge exchange*). The results of this workshop were intended to facilitate the development of soft regulation for nanomaterials OHS, which shall need to pay special attention to exposure measuring techniques, protection methods and issues of communication across involved actors (VCI 2007b).

In July 2007, the RPaUoN issued a Roadmap for Safety Research on Nanomaterials, in which knowledge on existing exposure measurement techniques and toxicological testing strategies for potential risks of nanomaterials was collected (association good *knowledge exchange*). On this basis the RPaUoN stressed that it would be useful to develop internationally harmonized standards on analytical measuring methods to be updated regularly (DECHEMA & VCI 2007).

Thus, in the period from 2003 to July 2007 the VCI participated in six activities directed at nanomaterials OHS. All activities constitute collective association goods with a focus on information exchange (five activities) and, to a lesser extent, representation and reputation (one activity). In the following period, from August 2007 to September 2011 a different focus in the activities emerges (see, below, Table 7.2 for an overview of the all VCI activities in the three periods).

Period 2. Between August 2007 and September 2011, the VCI initiated ten activities directed at supporting nanomaterials OHS. Overall activities in this period mark the beginning of the 'provision of concrete advice' on how to handle (certain) nanomaterials at workplaces safely. Concomitantly, legislators started to engage in the debate. Against this backdrop, based on the results of the 2006 survey, the VCI developed in collaboration with BAuA a guideline for handling and use of nanomaterials at workplaces (association good *soft regulation*).

In August 2007, this guide was issued being in line with the principles of the global Responsible Care Program[88] of the chemical industry (VCI & BAuA 2007). The VCI stressed the need to develop more such soft instruments to provide orientation for companies on specific matters of nanomaterials OHS, based on the latest state of science and technology. The association voiced concerns that exposure to nanoparticles might have effects different from those of larger particles and that the chemical industry shall need to initiate research accordingly. In October 2007 the VCI strengthened this position with the publication of a strategy paper on possibilities for the standardization of nanomaterials in the context of the International Organization for Standardization (ISO) and its Technical Committee 229

[88] See, section 3.1 (p. 45) for an elaboration on the Responsible Care Program.

‘Nanotechnologies’[89] (VCI 2007c). The VCI used this occasion primarily to emphasize its responsibility in providing expertise on matters of chemical risk assessment (*representation and reputation*). Independent from the ISO work, this call was put into practice by VCI with the development of five soft guidance documents that were issued throughout 2008 (VCI 2008a, b, c, d, e) (*soft regulation*).

Without going into the details of each one instrument, it suffices here to note that the VCI paid most attention to the appropriateness of existing risk assessment frameworks for nanomaterials in the context of the REACH Regulation[90] and Responsible Care Program. Essentially, the VCI postulated that existing risk assessment methods may require adaptation for nanomaterials and the chemical industry would be suited, and willing, to take a leading position therein. Against this background, the association acknowledged that there was much uncertainty on potential hazardous effects of nanomaterials, which should be resolved through exchange of knowledge among key stakeholders. To this end, the VCI organized, in collaboration with the trade union IG Bergbau, Chemie, Energie (IG BCE), a workshop in September 2008 in which actors from academia, regulatory agencies, worker unions and NGOs participated to exchange knowledge related to nanomaterials safety (VCI & IG BCE 2008) (*knowledge exchange*).

Building on one of the guidance instruments issued in 2008, the VCI developed another guidance document in August 2011 to support nanomaterials exposure measurement and assessment (IUTA et al. 2011) (*soft regulation*). Importantly this guide would be useful to SMEs and large chemical companies alike through improving existing exposure monitoring techniques for nanomaterials and making them applicable in routine workplace operations. Lastly, in September 2011 the VCI was involved in a survey–in collaboration with BAuA as a follow-up initiative of the VCI and BAuA survey from 2006–to learn more about particular aspects and OHS practices related to work with nanomaterials in German Firms (*knowledge exchange*) (Plitzko et al. 2013).

Between August 2007 and September 2011, the VCI was involved in ten activities directed at nanomaterials OHS, which all constitute collective association goods with a clear focus on soft regulation (seven activities). Other activities are of the type information exchange (two activities) and representation/reputation (one activity). This focus does not appear as a surprise against the background of European political activity. On 17 June 2008, for example, the European Commission published its first regulatory review of nanomaterials in a Communication on regulatory Aspects of Nanomaterials (EC 2008). The review was conducted to support the previous EC Communication Nanosciences and Nanotechnologies: an Action Plan for Europe 2005-2009 (EC 2005). The Commission stressed that Framework Directive 89/391/EEC on safety and health at work, which places obligations on employers to take measures for the protection of safety and health of their employees, fully applies to nanomaterials. Thus, employers must carry out risk assessments for nanomaterials handled at workplaces. Against this backdrop, the VCI appeared most active in supporting companies in their day-to-day work with nanomaterials and by helping to comply with their legal duty to conduct risk assessment for nanomaterials through providing extensive soft regulation instruments.

Period 3. From October 2011 to March 2014, the VCI activities show a focus on ‘participation in political discussions’. A hallmark event of this period was the development of the European Commission Recommendation for a definition of a nanomaterial from 18 October 2011.[91] Even though the EC definition is not in itself legally binding, it may be

[89] The ISO TC/229 consists of three working groups –‘Nomenclature and definitions’, ‘Measurement and characterization’, ‘Health, Safety and Environment’– of which the latter is specifically interesting to the VCI due to strong expertise by the German chemical industry in this area (VCI 2007c).

[90] See section 2.2 (pp. 35-36) for an elaboration on REACH.

[91] Commission Recommendation No 2011/696 on the definition of nanomaterials [2011] OJ L275/38.

enforced by recourse to legally binding policy instruments such as Directives. Immediately, after its publication, the content of the EC nanomaterial definition[92] was criticized widely including by the VCI. The association published a reaction in which the proposed definition was criticized as too broad with the result that the definition would apply to many chemicals that are on the market for decades already thereby posing an unnecessary burden to companies (VCI 2011a) (*lobbying*). The VCI criticized, in order for the definition to be applicable in practice, it shall need to be linked to specific exposure measuring methods. In its 2011 version it was argued that the EC would hinder worldwide harmonization of nanomaterials regulation because it would be the only political body that demanded a definition of a nanomaterial to be incorporated into legislation (ibid).

In November 2011, the VCI reacted to a report on nanomaterials risks by the German Advisory Council of the Environment (SRU) (VCI 2011b). The SRU argued that a precautionary approach to nanomaterials should be taken and that the improvement of risk assessment for nanomaterials would play an important role accordingly (SRU 2011). The VCI criticized various elements of the report and used this opportunity to lobby for safety research on nanomaterials, a harmonized definition of nanomaterials, the rejection of nano-specific legislation, and for the development of appropriate risk assessment and management for nanomaterials in the context of REACH (*lobbying*). The latter issue was taken up, in May 2012, with the revision and update of the 2007 VCI and BAuA guidance document (VCI & BAuA 2012) (*soft regulation*). The VCI stressed that nanomaterials have new characteristics compared to conventional chemicals, which require additional research, specific safety measures and conducting risk assessment. Specifically the association emphasized the complexity of existing exposure measurement techniques that oftentimes cannot be applied by SMEs but that can merely be applied by experienced research institutes with extensive resources.

In October 2012, the association published its reaction to the EC Communication on the 2nd Regulatory Review of Nanomaterials[93]. They argued for the overall adequacy of the traditional risk assessment approach for nanomaterials, which however require adaptation on particular aspects (VCI 2012a) (*lobbying*). Lastly, in February 2013 the VCI issued, together with another association (Verband Chemiehandel), a position paper on the EC REACH report of the same month (VCI & VCH 2013) (*lobbying*). The association agreed with the essential viewpoint of the EC as to the appropriateness of REACH for nanomaterials, but at the same time it lobbied for provision of additional, nano-specific guidance for companies in the conduction of risk assessment for nanomaterials.

Between October 2011 and March 2014, the VCI was involved in five activities that are predominantly of the type lobbying (four activities). While the development of soft regulation in support of their member companies in conducting risk assessment for nanomaterials was still relevant (one activity), VCI participation in political discussions on nanomaterials OHS regulation was the focus of association activities.

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[92] According to the EC Recommendation for a definition of a nanomaterial from 18 October 2011, a nanomaterial is "[a] natural, incidental or manufactured material containing particles, in an unbound state or as an aggregate or as an agglomerate and where, for 50% or more of the particles in the number size distribution, one or more external dimensions is in the size range 1 nm - 100 nm. In specific cases and where warranted by concerns for the environment, health, safety or competitiveness the number size distribution threshold of 50% may be replaced by a threshold between 1% and 50 %. By derogation from the above, fullerenes, graphene flakes and single wall carbon nanotubes with one or more external dimensions below 1 nm should be considered as nanomaterials".

[93] Communication from the Commission to the European Parliament, the Council and the European Economic and Social Committee *Second Regulatory Review on Nanomaterials* COM (2012) 572 final.

Table 7.2. Overview of VCI activities relevant for nanomaterials OHS.

PERIOD	TIME	ACTIVITY	FORM ACTIVITY
1	2003	Founding joint working group (with DECHEMA) Responsible Production and Use of Nanomaterials (DECHEMA & VCI 2007)	Knowledge exchange
	2005	Workshop Nanomaterials at the workplace l (VCI 2005)	Knowledge exchange
	2006	Survey I on OHS aspects in the production and handling of nanomaterials (collaboration with BAuA) (Plitzko et al. 2007)	Knowledge exchange
	2007	Feedback on the EDF/DuPont Nano Risk Framework (VCI 2007a)	Representation / reputation
		Workshop Nanomaterials at the workplace ll (VCI 2007b)	Knowledge exchange
		Roadmap for Safety Research on Nanomaterials (DECHEMA & VCI 2007)	Knowledge exchange
2	2007	Guidance for Handling and Use of Nanomaterials at the Workplace (collaboration with BAuA) (VCI & BAuA 2007)	Soft regulation
		Strategy Paper of the German Chemical Industry on the Standardization of Nanomaterials (in the context of ISO/TC 229) (VCI 2007c)	Representation / reputation
	2008	Guidance ‘Anforderungen der REACH-Verordnung an Stoffe, welche auch als Nanomaterialien herge-stellt oder eingeführt werden‘ (VCI 2008a)	Soft regulation
		Guidance for a Tiered Gathering of Hazard Information for the Risk Assessment of Nanomaterials (VCI 2008b)	Soft regulation
		Guidance for the Passing on of Information along the Supply Chain in the Handling of Nanomaterials via Safety Data Sheets (VCI 2008c)	Soft regulation
		Guidance Responsible Use and Production of Nanomaterials (VCI 2008d)	Soft regulation
		Guidance ‘Umsetzung von Responsible Care® für eine verantwortliche Herstellung und Verwendung von Nanomaterialien’ (VCI 2008e)	Soft regulation
		Workshop ‘Verantwortlicher Umgang mit Nanomaterialien‘ (collaboration with IG BCE) (VCI & IG BCE 2008)	Knowledge exchange
	2011	Guidance ‘Tiered approach to an Exposure Measurement and Assessment of Nanoscale Aerosols Released from Engineered Nanomaterials in Workplace Operations’ (IUTA et al. 2011)	Soft regulation
		Survey II on occupational health and safety aspects in the production and handling of nanomaterials in Germany (in collaboration with BAuA) (Plitzko et al. 2011)	Knowledge exchange
3	2011	Reaction to EC definition of a nanomaterial (VCI 2011a)	Lobbying
		Reaction to a report on nanomaterials risks by the German Advisory Council on the Environment (VCI 2011b)	Lobbying
	2012	Revised Guidance ‘Empfehlung für die Gefährdungsbeurteilung bei Tätigkeiten mit Nanomaterialien am Arbeitsplatz‘ (2007/2012) (VCI & BAuA 2012)	Soft regulation
		Reaction to EC Communication on the 2nd Regulatory Review on Nanomaterials (VCI 2012a)	Lobbying
	2013	VCI/VCH-Position zum Gesamtbericht der Europäischen Kommission zu REACH vom 5. Februar 2013 (VCI & VCH 2013)	Lobbying

Considering all 21 VCI activities, in the period from 2003 to March 2014, it is noticeable that only collective association goods have been provided (see, Table 7.3., below). Various selective association goods are only offered in form of non nano-specific services, for instance support for companies in the implementation of REACH, a service platform on Technical Rules for Hazardous Substances (TRGS)[94] including those relevant for OHS matters, or special offers for member companies in the purchase of certain services (VCI 2014c). One possible explanation as to why the VCI did not provide nano-specific selective goods could be the technology’s stage of development: nanomaterials were (still) characterized by various scientific and technical uncertainties that likely limited the

[94] TRGS “(…) reflect the state of technology, occupational safety and health and occupational hygiene as well as other definite knowledge relating to activities involving hazardous substances including their classification and labeling. The Committee on Hazardous Substances (AGS) establishes the rules and adapts them to the current state of development accordingly” (BAuA 2014a). Later in this chapter the issue of TRGS will be discussed more detailed.

association's ability to provide goods that are actually of lasting, or sustainable, to their members.

Table 7.3. Characteristics of VCI activities between 2003-2013.

TIME	ACTIVITY	TYPE
2003 – July 2007	Knowledge exchange (5x) Representation/reputation (1x)	Collective goods
August 2007 – September 2011	Soft regulation (7x) Knowledge exchange (2x) Representation/reputation (1x)	Collective goods
October 2011 – March 2014	Lobbying (4x) Soft regulation (1x)	Collective goods

On the basis of the above described VCI's activities the association's position towards nanomaterials OHS can be summarized as follows:

(1) Between 2003 and 2007 the VCI appears to have focused its attention on identifying the most pressing research needs in relation to the potential risks of nanomaterials in workplaces. Through collaborative activities with (member) companies, regulators and others, existing OHS knowledge was collected and assessed in view to the specific case of nanomaterials to determine future strategies.
(2) From 2007 to 2011, as a result of persistent uncertainty in the applicability of specific aspects of traditional risk assessment for nanomaterials, the VCI developed various soft regulatory instruments. These supported member companies that manufacture nanomaterials in the practice of risk assessment. These instruments seemed also to support the association's influence on the regulatory process of nanomaterials early in the policy and regulatory debates on the technology.
(3) Building on developed soft regulation, between 2011 and 2014, the VCI started to emphasize that some knowledge on nanomaterials was available, which does not suggest that there are recognized health effects specific to nanomaterials; rather, nanomaterials were viewed like any other chemical in the sense that some are dangerous, some are not. Based on the emerging knowledge base on nanomaterials OHS, the VCI then postulated that general, non-nano specific, regulation would be adequate to protect the health and safety of workers who handle nanomaterials.

The VCI, thus, actively participated in discussions on nanomaterials OHS. The question whether these activities contributed to effective nanomaterials OHS regulation is analyzed below.

7.2 Spinning a web of collaboration

As mentioned in section 5.2, association activities that fulfill three criteria are considered for in-depth analysis. Thus, activities must be of the type *knowledge exchange*, they must be *verifiable*, and they must be *initiated* by the association. After applying these criteria, all seven VCI activities of the type ‘knowledge exchange’ can indeed be considered verifiable, i.e. the activities were accompanied by publicly available documents and were initiated by the VCI. These seven activities are analyzed on the basis of the theoretical framework with its analytical categories and conditions for learning processes by means of which associations can contribute to effective nanomaterials OHS regulation (see chapter 4, recapture Table 7.4)

Table 7.4. Theoretical framework with analytical categories and conditions for the evaluation of effective nanomaterials OHS regulation.

LEVEL	ANALYTICAL CATEGORY	CONDITIONS
Actor level	**Substantive learning** Characteristic: *Scientific expertise*	1. Relevant actors collaborate 2. Exchange of knowledge and (risk) data 3. Increased understanding of how to deal with core problems related to nanomaterials risk assessment, and 4. Generation of novel scientific facts
Game level	**Strategic learning** Characteristic: *Trust*	1. Meetings over a longer period of time 2. Intensified actor relations 3. Reliance among collaborators 4. Realization of common goals 5. Disagreement among collaborators is addressed and solved, and 6. Development of additional collaborative activities
Network level	**Institutional learning** Characteristic: *Rules*	1. Development of informal agreements 2. Design of soft rules of behavior, and 3. Soft rules become ‘hardened’

As such, the seven activities for analysis are:

(1) the foundation and meetings of the VCI/DECHEMA RPaUoN (2003),
(2) the RPaUoN’s development of their Roadmap for Safety Research on Nanomaterials (2007) in which the group collected information on the potential risks of certain nanomaterials and identified research needs
(3) the VCI workshop I (2005),
(4) the BAuA/VCI survey in (2006),
(5) the VCI workshop II (2007), and
(6) the BAuA/VCI survey II (2011). Activities three to six built on each other, more specifically the workshops were meant to collect information from a broad range of stakeholders which was then fed into the development of the surveys on health and safety practices in companies were nanomaterials are handled (BAuA 2008; VCI 2007b; VCI 2005). And,
(7) lastly, the VCI/IG BCE workshop (2008) on the responsible use of nanomaterials. This workshop was part of a series of workshops organized by the VCI and IG BCE in order to engage a broad spectrum of actors in debates on chemicals, human and the environment (VCI & IG BCE 2008).

The seven activities are investigated on three levels of analysis (the actor, game and network level, see section 4.3 or Table 7.4), with three types of learning (substantive-, strategic-, and institutional learning) that may contribute to making risk assessment (more) applicable to nanomaterials. Thereby association activities may contribute to effective nanomaterials OHS regulation. The analysis builds on a triangulation of methods, i.e. interviewing accompanied by document analysis to avoid selectivity in the data analysis (see section 5.3).

7.2.1 Actor level – substantive learning

To answer the question as to whether substantive learning on nanomaterials OHS has developed between 2003 and 2014, based on the collaborative activities of the VCI, we investigate four conditions (see section 4.3):

(1) Relevant actors collaborate
(2) Exchange of knowledge and (risk) data
(3) Increased understanding of how to deal with core problems related to nanomaterials risk assessment, and
(4) Generation of novel scientific facts.

(1) Relevant actors collaborate

Based on the publicly available documents that support the seven VCI collaborative activities we can identify the collaborators (see, below, Figure 7.3).[95] Individual actors are grouped in view to the organization they are affiliated with. As such, the collaborators range from

- chemical companies (VCI/DECHEMA members) to
- regulatory agencies (Federal Environment Agency, UBA; Federal Ministry of Labour and Social Affairs, BMAS; Federal Ministry of Education and Research, BMBF; Federal Ministry of the Environment, BMU; EC DG Enterprise and Industry),
- federal research institutes (BAuA; Federal Institute for Risk Assessment, BfR),
- academia and research institutes (many German/international universities and research institutes),
- labor unions (Confederation of German Trade Unions, DGB; Hamburg Advice Centre on work and Health; IG BCE),
- associations (DECHEMA with RPaUoN members; Nanotechnology Industries Association, NIA; Association of German Engineers, VDI; Verband der Mineralfarbenindustrie[96], VdMi),
- social accident insurance (Institute for Occupational Safety and Health of the German Social Accident Insurance, IFA),
- measurement instrumentation firms (Grimm Aerosol Technik),
- NGOs (Friends of the Earth Germany, BUND), and
- consumer organizations (Verbraucherzentrale Bundesverband, VZBV).

[95] See Plitzko et al. 2011; VCI & IG BCE 2008; DECHEMA & VCI 2007; Plitzko et al. 2007; VCI 2007b; VCI 2005.
[96] There is no official translation of the VdMi; it may be translated as 'association of the mineral dyestuff industry'.

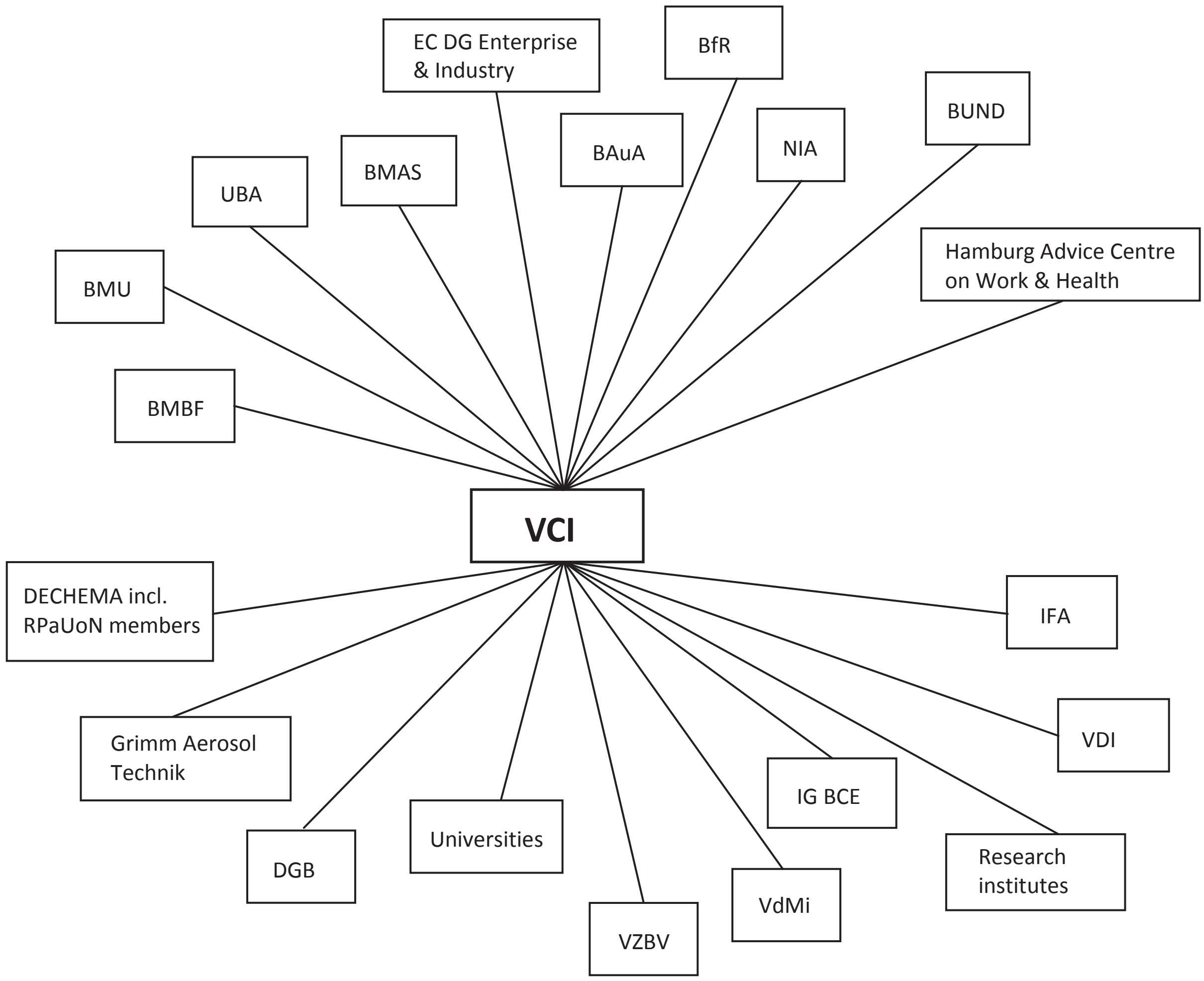

Figure 7.3. VCI network of collaborators.

Of these collaborators in the network around the VCI we can decide who the *relevant* collaborators are by applying Scharpf's principle of resource substitutability (1978).[97] Thus, in this thesis, two resources are most essential:

(1) knowledge/scientific data (to provide solutions to the challenge of nanomaterials risk assessment), and
(2) decision-making authority (to decide for adequate solutions to be implemented into policymaking).

Actors possessing knowledge and those possessing decision-making authority, depend on each other in the joint effort to deal with the problem of nanomaterials OHS: regulators typically have a lack of knowledge and scientific data which is, however, necessary to ensure that (existing) rules are evidence-based, i.e. are evidently protecting the health and safety of employees who handle nanomaterials.[98] Non-state actors, collectively, have more knowledge

[97] See, section 4.2 (p. 63).
[98] While regulators have a lack of knowledge, at the same time it needs to be acknowledged that regulators certainly have *some* knowledge available, e.g. as delivered by federal research institutes such as BAuA, which advises the BMAS.

and scientific data available than regulators and therefore regulators depend on non-state actors (Abbott 2012; Coglianese 2007). In turn, non-state actors depend on regulators because they can enforce rules of which compliance imposes unnecessarily high costs on these actors.

Accordingly, relevant actors with the resource ‘knowledge/data’ are VCI as well as DECHEMA staff and member companies, RPaUoN members, BAuA, BfR, and various German and international universities, as well as research institutes. Labor unions, social accident insurances, NGOs, consumer organizations, measurement instrumentation firms and associations are not considered relevant in this thesis since they do not provide knowledge that cannot be substituted by other network actors.[99] Relevant actors with the resource ‘decision-making authority’ in the field of OHS are BMAS, BMBF and EC DG Enterprise and Industry (see, Figure 7.4 below). While the primary responsible body in the area of OHS is BMAS, the BMBF holds also decision-making authority on health and safety matters of nanomaterials. The BMBF decides in which areas of nanomaterials (more) research is required and accordingly which research projects are to be supported by public funds. In making available funds for certain research projects, the BMBF also decides where data gaps on the risks of nanomaterials have been closed (BMBF 2011). Furthermore, on the European level, a relevant actor with decision-making authority is the EC DG Enterprise and Industry, which can make decisions related to REACH, and the chemicals industry more generally.

‘Relevant actors’ (principle of resource substitutability)

- VCI/DECHEMA staff
- VCI/DECHEMA member companies
- RPaUoN members
- Fed. research institutes: BAuA, BfR
- Academia: various scientists

} **Knowledge/data**

- Regulators: BMAS, BMBF, EC DG Enterprise & Industry

} **Authority**

Figure 7.4. Relevant collaborators VCI.

An overview of the relevant actors and in which of the seven VCI collaborative activities these actors participate, is provided below (see, Table 7.5).[100]

[99] These actors are not considered relevant in this thesis in order to decrease analytical complexity. It is not claimed that these actors are not important in the overall debate on nanomaterials. Rather, they are not of key significance in the context of the analysis of effective nanomaterials OHS regulation.

[100] Next to the here identified ‘relevant actors’, various other actor groups participated in the collaborative activities, e.g. NGOs, social accident insurers, and labor unions.

Table 7.5. Overview relevant actors in VCI collaborative activities.

COLLABORATIVE ACTIVITY	PARTICIPANTS
VCI & DECHEMA RPaUoN / Roadmap Nanomaterials (2007)	VCI/DECHEMA staff VCI/DECHEMA member companies BAuA, BfR Various academic scientists BMBF
VCI workshops (2005/2007) / BAuA & VCI surveys (2006/2011)	VCI staff VCI member companies BAuA Various academic scientists RPaUoN members (from academia, industry) BMAS
VCI & IG BCE workshop (2008)	VCI staff VCI member companies BfR RPaUoN members (from industry) EC DG Enterprise & Industry

As we have identified the relevant actors in the network, we shall now investigate whether these actors have, through knowledge exchange and their joint deliberation in the seven collaborative activities, generated new scientific facts that contribute to making risk assessment applicable for nanomaterials. Thus, can we speak of a process of substantive learning?

(2) Exchange of knowledge and (risk) data

As we have assumed throughout this thesis, collaboration of relevant actors can contribute to make traditional risk assessment applicable to nanomaterials when knowledge and scientific data is exchanged and deliberated in a joint effort. Overall, the relevant actors–i.e. VCI and DECHEMA staff and members, BAuA, BfR, academia, BMAS and BMBF–have actually exchanged knowledge. Accordingly, knowledge of various types has been exchanged as nine interviewees reported.

Most importantly, knowledge in form of raw data is exchanged only in the context of the DECHEMA/VCI working group *RPaUoN meetings* and usually when related to publicly funded research projects (Interviewee 27, academia; 25, association). Between 2003 and 2005 the RPaUoN developed a list with research needs related to nanomaterials and identified data gaps on nanomaterial risks, which had been made available to the BMBF. Later this list was developed further into the DECHEMA/VCI Roadmap (2007), based on which the BMBF initiated the research project NanoCare I (2005-2009)[101] (Interviewee 27, academia; 25 association; 20, industry). At that time NanoCare I was, within Germany, the largest research project on (human) toxicological aspects of nanomaterials and exposure measurement and control with the goal to develop new data for the characterization of nanomaterials and their risks (BMBF 2009a). Various members of the RPaUoN participated in specific projects within NanoCare I and in this relation raw data that resulted from the research project has been exchanged in meetings of the RPaUoN (Interviewee 27, academia; 25, association). In

[101] Based on the results of Nano Care I, and to continue its research, the BMBF initiated NanoCare II (2013-2016) (BMBF 2012).

difference, raw data generated by industry-funded research is typically not exchanged among members of the RPaUoN as a member explains:

> "Industry is not willing to report on internal research projects […] What they do in their own laboratories, without public funds [and] with their own resources, we will never come to see, never. They need this for their REACH submissions […] for the registration of their things. But they will never reveal the competitive advantage that they gained through their research, principally that is ready money" (Interviewee 27, academia).[102]

A VCI representative confirmed that data developed by companies is typically used for their registrations under the REACH Regulation and since the development of this data is costly companies will not exchange raw data with third-parties (Interviewee 21, association). In contrast, representatives of academia had infrequently shared knowledge in the form of raw data in the meetings of the RPaUoN (Interviewee 27, academia).

Though generally, in the *RPaUoN meetings*, all members including representatives from academia and companies most often shared and deliberated on cumulative data in the form of results from publicly and privately funded research projects (exchanging data in aggregate form). Overall, this abstracted form of knowledge exchange was most prevalent in the meetings of the RPaUoN (Interviewee 33, association; 27, academia; 26, academia; 20, industry). Exchanging and debating data in aggregate form was of primary interest to the RPaUoN members against the backdrop of research that started years ago and of which the results can be yielded now (Interviewee 27, academia; 20, industry). This data was exchanged and deliberated on in the meetings of the RPaUoN (critical evaluation of state-of-the-art data) (Interviewee 25, association; 20, industry). The results of these deliberation processes were applied to update of the group's Roadmap for Safety Research on Nanomaterials regularly (Interviewee 21, association). In this context, the BMBF stands in direct contact with certain members of the group and receives updates on the scientific state-of-the-art on nanomaterials OHS as debated in the RPaUoN's meetings (Interviewee 25, association; 20, industry).

In connection to the *VCI 2005/2007 workshops* and the *BAuA/VCI 2006/2011 surveys* two types of knowledge exchange appear dominant (based on the publicly available documentation of the workshops and surveys rather than interviews):

(1) exchange of general know-how (exchanging general experiences), and
(2) cumulative information (exchanging data in aggregate form).

In the two workshops, VCI staff and member companies, RPaUoN members (from academia and industry), various scientists from academia, and representatives of BAuA came together to deliberate on an overall strategy for the responsible development of nanomaterials; the topic of OHS and risk assessment was merely one issue amongst others (e.g. risk communication, public perception, information documentation, nano-product registry). Scientific data in aggregate form, related to toxicity and exposure of nanomaterials, was brought together and debated by the workshop participants (VCI 2007b, 2005). But also general experiences were exchanged in regard to available exposure measurement technology for nanomaterials and nano-specific reporting under REACH (ibid). Exchanging general experiences and data in aggregate form allowed people with highly diverse backgrounds and

[102] Original quote: "Die Industrie ist […] nicht bereit über die internen Untersuchungen zu berichten […] Was sie selbst in Ihren Labors machen, ohne öffentliche Förderung [und] mit eigenen Mitteln, das werden wir nie zu Gesicht kriegen, nie. Das brauchen die für Ihre REACH Zulassungen […] zur Registrierung ihrer Dinge. Aber sie werden den Wettbewerbsvorteil den sie mit ihren Forschungen gemacht haben niemals preisgeben, das ist im Prinzip bare Münze" (Interviewee 27, academia).

levels of expertise on nano-related topics to come to speak in a ‘common language’. On this basis they are able to arrive at general approaches for the responsible development of nanomaterials.

In contrast, the BAuA/VCI surveys were aimed at making an inventory of existing health and safety practices and methods applied to nanomaterials within multinational chemical companies and SMEs and sharing the results publicly through articles in scientific journals. To this end, in the 2007 survey data in aggregate form was collected and shared in relation to existing health and safety practices in companies working with nanomaterials (Plitzko et al. 2007). In addition, the 2011 survey made cumulative data on workplace exposure to nanomaterials, as well as measurement instrumentation, publicly available (Plitzko & Gierke 2013).

Lastly, in the *VCI/IG BCE workshop* the most prevalent type of knowledge exchange was that of general experiences (Interviewee 23, labor union). Next to the relevant actors, various stakeholders with highly diverse backgrounds coming from other labor unions, NGOs and consumer organizations participated in the workshop. Information and general experiences were discussed in regard to the definition of a nanomaterial, risk perception, information provision on potential risks and measuring techniques (VCI & IG BCE 2008). It must be acknowledged that these issues were discussed in the broader context of the so-called NanoDialog (Interviewee 23, labor union).

Based on a joint research strategy on the risks and benefits of nanotechnology by UBA, BfR and BAuA, the BMUB initiated the NanoDialog between 2006-2008 and 2009-2011. The NanoDialog provided a platform to enable, early in the policy and regulatory debates on nanotechnologies, a broad stakeholder debate on nanomaterials including health and safety aspects. The goal was to exchange experiences and knowledge among various stakeholder groups (Ökopol 2010a).[103]

In this light, the VCI/IG BCE workshop can be understood as an additional opportunity in an overall effort to exchange general experiences and information relevant for the responsible development of nanotechnology and thereby protect workers and workplaces and retain employees (Interviewee 23, labor union) (exchanging general experiences). Based on the different types of knowledge exchange among the collaborators in the VCI network (see Table 7.6 for an overview) we shall now investigate whether collaborators gained an increased understanding of certain challenges in the risk assessment for nanomaterials.

Table 7.6. Overview dominant types of knowledge exchange VCI collaborative activities.

Collaborative activity	Dominant type knowledge exchange
RPaUoN meetings / Roadmap Nanomaterials	Raw data/data in aggregate form/evaluation state-of-the-art data
VCI workshops/ BAuA & VCI surveys	Data in aggregate form/general experiences
VCI & IG BCE workshop	General experiences

[103] The follow-up initiative of the NanoDialog was the Nano FachDialoge between 2011-2012 and 2013-2015 (BMUB 2015). However, compared to the NanoDialog this initiative was less public, i.e. lists of participants and reports or minutes of meetings are not available.

(3) Increased understanding of how to deal with core problems related to nanomaterials risk assessment

In all VCI activities the collaborators have exchanged knowledge and (risk) data on nanomaterials. On this basis, overall a better understanding of key problems related to nanomaterials OHS has been gained by the parties. Specifically in regard to the *RPaUoN meetings* an increased understanding on aspects of human toxicology and exposure measurement/instrumentation has been achieved. As a representative of DECHEMA explained, in the time between 2004 and 2005, the group was not yet certain that there is no nano-specific toxicity. But over the years the group has gained more certainty accordingly:

> "Overall, I think we have made much progress in the area of human toxicology […] at the moment I would be relatively optimistic that, based on what we know, we do not have to expect to get an emergency notice tomorrow that any nanomaterial is so dangerous that we need to take it off the market" (Interviewee 25, association).[104]

In this respect, the RPaUoN updated their Roadmap for Nanomaterials in 2011. Here the group emphasizes confidence that "[t]he size label 'nano' does not also immediately mean 'toxic', so it does not represent an intrinsic hazard characteristic" (DECHEMA & VCI 2011: 3). While progress has thus been made in understanding the principles of human toxicology, a need to gain more knowledge necessary for transferring research results from model systems into real-life systems was identified. As a RPaUoN member explained, for instance, it shall be crucial to be able to estimate how many milligram of a nanomaterial injected into a rat would have the same toxicological effect within the human organism (Interviewee 25, association). In other words, doses associated with a specified response, meaning adverse health after a certain exposure time, need to be determined more accurately and must be made transferable from animal to human systems. Furthermore, the members of the RPaUoN identified a need to standardize available toxicological data through the harmonization of toxicological tests and methods to be able to arrive at consensus concerning risks of nanomaterials (Krug et al. 2012). While data sets on toxicological information on nanomaterials exist these are often not useful as they do not build on common toxicologically testing protocols as the vice-chair of the RPaUoN stressed,

> "[t]oxicologists must (…) work on ensuring that the basic principles and rules that apply to regulatory toxicology and epidemiology are also applied to nanotoxicological studies. If the various working groups (…) do not accept standard procedures, the regulatory bodies and authorities will not have a good foundation for decision-making" (Krug et al. in VCI 2012b: 6).

The other area where, over the years, knowledge has been gained by the RPaUoN members is exposure measurement. While exposure measurement instrumentation is a well-established field of study, it has been problematic to measure exposure on the nanoscale (Interviewee 25, association). But, to a certain extent related to the RPaUoN, new measurement instrumentation has been developed that allows for an increasingly better understanding of exposures in workplaces (Interviewee 26, academia).

[104] Original quote: "Ich glaube ganz pauschal kann man sagen humantoxisch sind wir relativ weit […] ich würde im Moment relativ guter Dinge sein und sagen naja, aus Sicht dessen, was ich hier überblicken kann, erwarte ich nicht, dass wir übermorgen die Katastrophenmeldung kriegen irgendein Nanomaterial ist so gefährlich, dass wir es vom Markt nehmen müssen" (Interviewee 25, association).

The two *VCI workshops (2005/2007)*, rather than engaging in concrete debate on (particular aspects of) risk assessment, appeared to focus on identifying overarching needs and approaches for dealing with the potential risks of nanomaterials. The two workshops pointed to the need for adequate exposure measuring technology (particularly being useful for SMEs) and intensification of toxicological research as well as data necessary for risk assessment of nanomaterials. In this respect the workshop participants identified a need to accompany such activities by a transparent risk communication strategy that includes all interested stakeholder groups to develop a 'joint risk assessment' (VCI 2005: 22). Here, "(…) much openness and strong criticism are desired" (ibid: 18).

The *BAuA/VCI surveys (2006/2011)* can be understood in the light of pursuing such an open strategy towards identifying the risks of nanomaterials. Accordingly, the surveys did contribute to a better understanding of exposure to nanomaterials: it was found that German firms, particularly SMEs, require support in conducting exposure measurement and assessment since existing measuring technology is work- as well as cost-intensive and no standard procedure for exposure measurement exists yet; in this respect, BAuA could provide practical support for companies (Plitzko & Gierke 2013; Plitzko et al. 2007). Furthermore, the survey results showed that companies demanded regulatory instruments for the handling of nanomaterials in the form of guidance material (Plitzko & Gierke 2013).

Lastly, the *VCI/IG BCE workshop (2008)* can be understood in a similar light as the other two workshops. Overarching needs and approaches to the potential risks of nanomaterials were identified. In this relation the participants stressed that 'filling the knowledge gaps' related to toxicological aspects of nanomaterials shall need to be accompanied by risk communication strategies (VCI & IG BCE 2008). Applying such strategies helps ensure the responsible development of nanotechnology in that the general public is informed openly about the state-of-the-art of the science and technology.

(4) Generation of novel scientific facts

One way to discern whether new scientific facts have been generated through collaborative activities is to investigate whether publications in peer-reviewed scientific journals have resulted from these activities. In regard to the *RPaUoN meetings*, some new findings have been validated through publication in peer-reviewed scientific journals. These publications emerged from the research project NanoCare in which the RPaUoN had a crucial role. As mentioned earlier, the BMBF funded NanoCare on the basis of the RPaUoN's priority list for health and safety research needs and their Roadmap for Nanomaterials (2007) (Interviewee 27, academia; 25, association; 21, association). Various RPaUoN members from industry (BASF, Bayer, Evonik, ItN Nanovation), academia (KIT, IUTA), and an association (DECHEMA) participated in NanoCare (BMBF 2009a, b; Interviewee 25, association). The VCI did not directly participate in NanoCare. But the RPaUoN vice-chair was the project leader of NanoCare (BMBF 2007) and another group member was concerned with the project coordination (DaNa 2.0 n.d.b). Thus, the RPaUoN was involved to an essential extent in knowledge generation in the context of NanoCare. Against this backdrop, RPaUoN/NanoCare participants from academia (IUTA, KIT) and industry (Bayer) were co-author of two articles, published in a journal with an impact factor of 2,278 (in 2011) (BMBF 2009a) (see, Table 7.7, for an overview).

Table 7.7. Overview NanoCare publications evidently involving members of RPaUoN.

Collaborative activity	Authors	Title	Journal	Year	Impact factor
RPaUoN meetings	1. Asbach et al.	Comparison of four mobility particle sizers with different time resolution for stationary exposure measurements	Journal of Nanoparticle Research	2009	2,278 (2013)
	2. Stahlmecke et al.	Investigation of airborne nanopowder agglomerate stability in an orifice under various differential pressure conditions	Journal of Nanoparticle Research	2009	2,278 (2013)
BAuA/VCI surveys	3. Plitzko & Gierke	Tätigkeiten mit Nanomaterialien in Deutschland. Gemeinsame Fragebogen-aktion der Bundesanstalt für Arbeitsschutz und Arbeitsmedizin (BAuA) und des Verbands der Chemischen Industrie (VCI)	Gefahrstoffe Reinhaltung der Luft	2007	---
	4. Plitzko et al.	Zweite Fragebogenaktion zu Aspekten des Arbeitsschutzes bei der Herstellung und bei Tätigkeiten mit Nanomaterialien in Deutschland	Gefahrstoffe Reinhaltung der Luft	2013	---

Furthermore, the results of NanoCare have been published by the BMBF in the project's final report Health Related Aspects of Nanomaterials (2009a). According to the report many new information relevant for making risk assessment applicable to certain nanomaterials had been generated. These new facts are in line with the RPaUoN priority list of research; the group listed the most urgent issues for research, namely 'decisive parameters for toxicity of nanoparticles', 'development of validated toxicological methods', 'studies on materials other than titanium dioxide and carbon black' and 'exposure assessment' (DECHEMA & VCI 2007). Accordingly, the NanoCare project has generated new scientific facts related to various different nanomaterials as we will see.

Overall, two results of NanoCare are stressed in the BMBF (2009a) report:

> "Firstly, none of the investigated nanomaterials exhibited a severe effect in the sense that cells or animals show signs of acute toxicity or a biological effect could be demonstrated by treatment with low concentrations. Secondly, the comparison of the in vitro and in vivo results showed a very good correlation, thus, in a first approximation the in vitro studies reflect relatively good the in vivo situation" (BMBF 2009a: 91).

More specifically, various new scientific facts have been generated for eleven different nanomaterials:

- Titanium dioxide (TiO_2)
- Carbon Black (CB)
- Cerium dioxide (CeO_2)
- Doped Cerium dioxide (CeO_2)
- Boehmite (AlOOH)
- Mixed Titanium–Zirconium oxide (Ti-Zr-Mixed oxide)
- Mixed Titanium-Aluminide-Zirconi-um Oxide (Ti-Al-Zr Mixed oxide)
- Zirconium dioxide (ZrO_2)
- Zinc oxide (ZnO)
- Barium sulphate ($BaSO_4$), and
- Strontium carbonate ($SrCO_3$).

New facts in regard to these eleven nanomaterials (in 19 variations) have been generated in the following categories:

1. toxicity of nanomaterials
2. dustiness testing and agglomerate stability
3. computer modeling of particle dispersion upon accidental release
4. development of exposure measurement techniques and methodologies, and
5. exposure measurement of nanoparticle concentrations at the workplace (BMBF 2009a, 2009b).

For an overview of the new scientific facts generated through NanoCare, see Table 7.8. Furthermore, new facts have been generated in respect to better understanding hazard, exposure (in vitro and in vivo), toxicology (uptake via the lung: in vitro and in vivo), and behavior (uptake in somatic cells: in vitro; blood-brain barrier: in vivo) of the eleven nanomaterials (see, for a detailed overview of new scientific facts regarding characteristics of eleven nanomaterials established through NanoCare, the appendix) (BMBF 2009a).

Table 7.8. New facts resulting from NanoCare.

Category	New scientific facts
Dustiness testing and agglomerate stability	• After testing 19 nanomaterial variations it was found that different materials show different intensities of dust generation; agglomerate disintegration also depends strongly on the nanomaterial used • A general propensity of a material and its variation to release particles smaller than 100nm cannot be given, but each material has to be investigated case by case because the increase of concentrations in the sub-100nm range are strongly dependent on the handling of the material; the increase of these particles indicates that deagglomeration may occur during the passage through an orifice and the increase of particles below 100nm is pressure- and material-dependent • Deagglomeration is not only dependent on the nanomaterial but also on the modification of the particles
Computer modeling of particle dispersion upon accidental release	• It is possible to predict and limit exposures at workplaces by use of a computer model, which was developed in NanoCare for the study of particle flows; it can supply data for any point in a room and has shown to be a very efficient tool for predicting the behavior and distribution of nanoparticles and the possible exposure at workplaces; it also helps to identify hot spots (e.g. areas with insufficient ventilation where particles may accumulate) in workplaces • The computer model has shown that temperature changes of aerosols released greatly influence the propagation of particles in a room, sometimes even favoring it and thereby increasing the exposure of workers
Development of exposure measurement techniques and methodologies	• Using different measurement tools to measure airborne nanoparticles it was found that the measuring gear showed agreement in particle size determination; however, when measuring the total concentrations agreement is not reached • More nanoparticle sensitive techniques are required to detect these particles in the workplace air • An exposure measurement strategy (Standard Operation Procedure, SOP) was developed, which–for the first time–allows for standardized assessments of nanoparticles at workplaces that differentiates nanoparticles in workplaces from background particles
Exposure measurement of nanoparticle concentrations at the workplace	• The SOPs were applied at 11 workplaces at 4 industrial locations manufacturing, packaging, and processing nanomaterials: none of these workplaces exhibited a significant increase in concentration of nanoparticles or smaller aggregates and agglomerates, respectively (below 400nm); thus, there was no significant exposure to nanoparticles • Standardization of measurement is needed and the NanoCare developed SOPs are a step in this direction
Toxicity	• SOPs for measuring biological effects of nanomaterials (were developed and) are available now • Most nanoparticles are taken up by alveolar macrophages and remain in the lung such as respirable particles; lung clearance mechanisms are efficient, thus, the qualitative aspects of deposition and clearance conform to the known defense mechanisms of the lung for respirable particles • Nanomaterials exert different toxicities ranking some samples as very low biological activity, others show moderate or more elevated biological activities • For all samples no effect levels (NELs) were detected (NELs form the precondition for defining OELs). Of the 11 different nanomaterials that were studied in detail all samples produced NELs, or lowest observed effect levels (LOELs), thus a possible risk assessment would be feasible • The experiments revealed for all investigated nanomaterials only slight effects or no effects • Agglomerates of nanoparticles show the tendency to deagglomerate when proteins are present in body fluids, subsequently the nanoparticles will be masked by the protein corona • The protocols for toxicological testing require standardization; NanoCare has developed several SOPs for analytical methods • Some nanomaterials exhibit different biological effects, therefore the 'nano' cannot be assessed in a generalized way but depends on the nanomaterial in question, e.g. the material's composition, size and structure

In regard to the two *BAuA/VCI surveys (2006/2011)* results were published in the journal Gefahrstoffe Reinhaltung der Luft[105] (see Table 7.7). It shall be noted that

[105] The journal is published by the Institute for Occupational Safety and Health of the German Social Accident Insurance (IFA) and the committee Reinhaltung der Luft in the Association of German Engineers (VDI) and the German Institute for Standardization (DIN) (see http://www.gefahrstoffe.de/gest/hinweise_fuer_autoren.php), which at the same time act as reviewer for articles submitted. We can assume that both bodies have a certain interest in the publication of validated scientific findings as they are acknowledged bodies in the German scientific landscape.

representatives of VCI and BAuA jointly worded the questions for the surveys, but only BAuA evaluated and published the results. This has been an explicit strategy that was decided upon in the 2005 VCI workshop in order to ensure that collected information and data is examined in a credible manner, i.e. by an independent body (VCI 2005: 22). Therefore the VCI is indirectly involved in the generation of new facts. These facts are relevant for making risk assessment applicable to nanomaterials in regard to the understanding of health hazards, exposure measurement and assessment, toxicology, and knowledge which types of nanomaterials are actually handled in workplaces (see Table 7.9).

Table 7.9. New facts resulting from the BAuA/VCI surveys.

Category	New scientific facts (survey 2006)	New scientific facts (survey 2011)
Health hazards	• Information on potential health hazards is passed on mainly in safety data sheets	
Exposure measurement and assessment	• It is not sufficient to determine the particle number in the work area (additionally, outside air concentrations need to be included, and further particle emitters (welding, separating, cutting, diesel vehicles etc.) in the direct surroundings of the workplace need to be quantified in order to obtain representative data • Exposure measurements in various workplaces were conducted but data was not comparable because a standardized measurement strategy was lacking; more exposure data was to be conducted to be able to generalize exposure to nanomaterials	• Exposure measurements in various workplaces are conducted but data is not comparable because a standardized measurement strategy was lacking; more exposure data shall need to be conducted to be able to generalize exposure to nanomaterials • A standardized measurement strategy is available –the SOP-Tiered Approach–since 2009[106] • In the application of the SOP-Tiered Approach SMEs shall require support
Toxicology		• Among the survey participants, many companies reported to not do toxicological tests for the nanomaterials they produce and some companies did not know whether toxicological tests had been conducted • More than half of the surveyed companies reported to have access to data from literature on toxicological effects
Nanomaterials handled in workplaces	• Most commonly handled nanoparticles[107] in companies are silicic acids and titanium dioxide, followed by iron oxide, other metal powders, silicates and pharmaceutical active substances	• Most commonly handled nanomaterials are silicon dioxide (amorphous), titanium dioxide, silicon dioxide (crystalline), polymer/-composites, and carbon black
Health and safety measures		• Big companies see problems in conducting nano-specific health and safety measures (28% of companies with more than 500 employees against 5% of companies with 1-10 employees) • Companies are interested to have more guidance material (soft regulation) available and state-issued nano-specific rules like Technical Rules for Hazardous Substances (TRGS) to support handling nanomaterials in workplaces

As to the two *VCI workshops (2005/2007)* and the *VCI/IG BCE workshop (2008)* no information from scientific publications or reports are available that would suggest the generation of new scientific facts related to these activities. Likewise, the interview data strengthens the view that new facts were not established as part of those activities. For a

[106] See BMBF (2009) in the context of BMBF-funded research project NanoCare in which members of the RPaUoN participated.
[107] In the context of the 2006 survey the term 'nanoparticle' was defined as: particles produced in powder form, which have at least two dimensions smaller than 0,1nm, including their aggregates and agglomerates (Plitzko & Gierke 2007: 419).

general overview of the VCI activities in relation to the generation of new scientific facts, see Table 7.10.

Table 7.10. Overview newly generated facts VCI collaborative activities.

Collaborative activity	Generation of new scientific facts
RPaUoN meetings / Roadmap Nanomaterials	New scientific facts on 11 nanomaterials (19 variations) related to: exposure measurement techniques & methodologies, exposure measurement (in vitro & in vivo), particle dispersion upon accidental release, hazard, toxicity (uptake via the lung: in vitro & in vivo), dustiness testing & agglomerate stability, behavior (uptake in somatic cells: in vitro; blood-brain barrier: in vivo)
BAuA & VCI surveys	Health hazards, exposure measurement & assessment, toxicology, nanomaterials handled in workplaces, health & safety measures
VCI workshops	---
VCI & IG BCE workshop	---

We have seen varying kinds of knowledge exchange in the VCI collaborative activities. It is assumed that exchanging knowledge, data and experiences requires a minimum level of trust among collaborators that such information is not misused by other parties. Collaborators must learn how to build, and maintain, trust (strategic learning) since trust is assumed to be pre-condition, and amplifier, for knowledge exchange and the generation of new scientific facts (see section 4.3). We shall now investigate this process of strategic learning in the VCI collaborative network.

7.2.2 Game level – strategic learning

On the game level of analysis six conditions for the development of trust are investigated in order to understand whether strategic learning has emerged from collaboration (see section 4.3):

(1) Meetings over a longer period of time
(2) Intensified actor relations
(3) Reliance among collaborators
(4) Realization of common goals
(5) Disagreement among collaborators is addressed and solved, and
(6) Development of additional collaborative activities.

(1) Meetings over a longer period of time

Based on face-to-face interactions and personal experiences, trust can develop over time (Edelbos & Klijn 2007; Sako 1998; Lewicki & Bunker 1996). As such, the *RPaUoN meetings* have taken place, three to four times per year from 2003 until 2014 (Interviewee 27, academia; 25, association). During these meetings the *Roadmap for Safety Research on Nanomaterials* has been discussed continuously since 2007. Compared to other professional groups in DECHEMA, which meet one to two times per year, the RPaUoN meets relatively often (Interviewee 25, association). The RPaUoN members thus have many opportunities for interaction, and thereby, gain experiences on what to expect from other members in the collaboration.

The *VCI workshops (2005/2007)* in connection with the *VCI/BAuA surveys (2006/2011)* build on less interaction over a limited time frame. The two workshops were both one-day events where RPaUoN members (representatives from academia and industry), VCI staff and member companies, representatives of BAuA and BMAS, as well as various scientists participated (VCI 2007b; 2005). The workshops started with lectures, followed by dialog groups in which all participants had opportunities for interaction and discussion, and ended with a panel discussion. In the second workshop, the results of the first VCI/BAuA survey (2006) were presented and discussed among the workshop participants (VCI 2007b). The results of these discussions were fed into the development of the second survey. However, in relation to the surveys, it is unclear how often representatives from BAuA and VCI met in order to develop the surveys; we know only that the two parties have met 'several times' (VCI & BAuA 2007). Though it should be acknowledged that BAuA and VCI representatives meet relatively often, for instance in the RPaUoN meetings and other venues (VCI & BAuA 2012; VCI & BAuA 2007).

The *VCI/IG BCE workshop (2008)* was as a one-time, nano-specific event in the context of an overall effort to engage in debates with a broad set of stakeholders on the topic of European chemicals regulation. Accordingly, representatives of the VCI, their member companies, RPaUoN members (representatives from industry) and representatives of the BfR and EC DG Enterprise and Industry interacted and engaged in discussions (VCI & IG BCE 2008). Overall, the workshop appears as a one-time event to demonstrate how the chemical industry's Responsible Care Program, and its principle of transparent communication and dialogue with stakeholders, can be applied to the example of nanomaterials (VCI n.d.).

(2) Intensified actor relations

When collaborators meet over a longer period of time relations can be intensified and actors become increasingly familiar with each other. On this basis trust among collaborators may develop (Vangen & Huxham 2003; Gulati 1995). As said earlier, the *RPaUoN meetings* have taken place three to four times per year between 2003 and today (2014). Because these meetings are not public, the 20 to 40 members interact in a so-called 'safe environment', which gives room for getting to know each other better. As such, the working group members have intensified their relations over the years, as a DECHEMA representative remembers:

> "[T]he first meetings were, well, we know each other and maybe somehow we have been in contact before, but we weren't very close (…) we all have, over time, gotten to know each other better, familiarity developed, and in a few cases something like friendships developed; and this grows the more you actually work together. Well, I actually got to know [name of person] through this circle (…) then we all addressed each other "Sie" [formal German announcement for a person] (…) and by now we visit each other in between those meetings and go for a beer or something like that. So one can clearly notice that personal relations become closer" (Interviewee 25, association).[108]

[108] Original quote: "[D]ie ersten Treffen waren noch eher so, naja man kennt sich, man hat vielleicht auch schon mal irgendwo Kontakt miteinander gehabt, war jetzt aber noch nicht so grässlich eng […] es hat sich bei allen […] über die Dauer dann natürlich irgendwo ein gewisser Bekanntheitsgrad, Vertrautheit, in einigen wenigen Fällen vielleicht auch so etwas wie eine Freundschaft entwickelt und das wird dann umso mehr je mehr man dann auch tatsächlich zusammen arbeitet. Also [Name der Person] habe ich tatsächlich in diesem Kreis kennen gelernt (…) da waren wir noch alle per Sie (…) und inzwischen besuchen wir uns auch mal so zwischendrin und gehen da auch mal zusammen ein Bier trinken oder irgendwie so etwas. Also das heißt, da merkt man ganz klar, dass die persönlichen Beziehungen enger werden" (Interviewee 25, association).

In addition to the RPaUoN group meetings various members met at other occasions, for instance, in the context of the research project NanoCare, and thereby had more opportunities to deepen relations. While various degrees of intensified relations exist, generally all members have continuously gotten to know each other better over the period of time (Interviewee 27, academia; 26, academia; 25, association). Based on the available data (from interviews and documents) there are no events reported that could have disrupted this continuous process of familiarization.

In comparison, opportunities to get to know each other well, in the context of the two *VCI workshops* and the *VCI/BAuA surveys*, were more limited. In the two workshops approximately 20 to 40 participants met on two occasions, each for one day (VCI 2007b, 2005). While this in itself provides a limited opportunity to intensify relations, it should be acknowledged that many workshop participants had additional meetings in another context; namely the NanoDialog, which was organized by the Federal Ministry for the Environment, Nature Conservation, Building and Nuclear Safety (BMUB) between 2006 and 2011. Based on a joint research strategy on the risks and benefits of nanotechnology by UBA, BfR and BAuA, the BMUB initiated the NanoDialog. The NanoDialog enabled a broad stakeholder debate on the responsible development of nanotechnology and explicitly covered the area of workplace health and safety in relation to the (potential) risks of nanomaterials.

The goal of the NanoDialog was to ensure the responsible development of nanotechnology through discussions, and interaction, by a broad range of stakeholders. Accordingly, at least six participants of the VCI workshops (2005/2007), i.e. VCI staff and member companies (Nanogate, Bayer), a regulator (BMAS) and a member of the RPaUoN (IUTA), were also participants in the NanoDialog (BMUB 2010; VCI 2007b, 2005). In this context the same workshop participants met approximately three times per year over a period of five years (Interviewee 29, association) (see, Table 7.11, below). While various representatives of BAuA participated in the NanoDialog, the available data does not provide information whether these representatives were also participants in the VCI workshops (2005/2007). There is also no evidence that the same representatives of BAuA and VCI, who were involved in the development of the VCI/BAuA surveys, were also participants in the NanoDialog. With regard to the RPaUoN, at least six members were also participants in the NanoDialog; namely two representatives of VCI staff, industry (BASF, Bayer), and academia (IUTA). Furthermore, a representative of a regulator (BMBF), who works together closely with the RPaUoN and was involved in the establishment of NanoCare, also participated in the NanoDialog.

Also various participants of the *VCI/IG BCE workshop (2008)* were participants in the NanoDialog: in total five representatives–two representatives of VCI staff and one representative of a VCI members, as well as a representative of a federal research institute (BfR) and a member of the RPaUoN (BASF). Thus, through the NanoDialog many collaborators in the VCI network had additional opportunities to intensify relationships.

Table 7.11. Overview VCI network actors active in the NanoDialog.[109]

Collaborative activity	Relevant actors VCI network &NanoDialog participants	
VCI workshop (2005)	VCI staff	(1 representative)
VCI workshop (2007)	VCI staff	(1 representative)
	VCI members	(2 representatives of Bayer, Nanogate)
	Academia	(1 representative of IUTA)
	Regulator	(1 representative of BMAS)
BAuA/VCI surveys (2006/11)	---	
VCI/IG BCE workshop (2008)	VCI staff	(2 representatives)
	VCI members	(2 representatives of Bayer, BASF)
	Federal research institute	(1 representative of BfR)
RPaUoN meetings	VCI staff	(2 representatives)
	VCI members	(2 representatives of Bayer, BASF)
	Academia	(1 representative of IUTA)
	Regulator	(1 representative of BMBF)

Another, industry-organized activity beyond the VCI-initiated activities, provided an additional opportunity for some VCI/IG BCE workshop participants to intensify relations. In the BASF Dialogforum Nano at least three participants of the VCI/IG BCE workshop (2008) met again (BASF 2013; Interviewee 23, labor union). The BASF Dialogforum was held between 2009/2010 (no exact data is available how many meetings took place) and between 2011/2012 in the form of six workshops (BASF 2012: 44). The goal of the Dialogforum was to debate among a broad range of stakeholders on the topic of information provision related to nanomaterials and risk-related information (ibid). This seems important in regard to the VCI/IG BCE workshop because the workshop was merely a one-time event with a relatively high number of participants (approximately 70) (VCI & IG BCE 2008). Therefore, by itself, the workshop provided little opportunities for actors get to know each other well.

(3) Reliance among collaborators

Collaborators who have intensified relations over a longer period of time may begin to rely on each other. Reliance is characterized by predictability and consistency of other's behavior and by 'trust beyond control' meaning where agreements among collaborators end, people trust each other and feel they can exchange personal knowledge, ideas or insights with others without these being used 'against' them (Nooteboom 2010; Gabarro 1978). The relations among *RPaUoN* members are characterized by reliance, as the interview data shows. This is visible in that the group's members have occasionally shared unpublished data and/or knowledge among each other (Interviewee 27, academia; 25, association). A representative from academia gives an example of this type of knowledge sharing:

> "(…) in the last meeting of the working group (…) I talked about an ongoing project, which is not yet finished (…) there I definitively presented preliminary results that are not finalized. And then I do not want these [data] to be circulated further" (Interviewee 27, academia).[110]

[109] The list of participants from the NanoDialog is retrieved from BMUB (2010) and compared with data from interviews with RPaUoN members and data from the publicly available documents supporting the collaborative activities.

[110] Original quote: "(…) beim letzten Arbeitskreis (…) da habe ich über ein laufendes Projekt gesprochen, das noch nicht abgeschlossen ist (…) da habe ich definitiv vorläufige Ergebnisse vorgestellt, die noch nicht endgültig sind. Und das möchte ich nicht, dass die im Umlauf sind" (Interviewee 27, academia).

The scientist shared unpublished data with the group based on trust that other RPaUoN members would adhere to the demand to not forward the results to non-members and, thereby breach the 'rules of the game' (Interviewee 25, association). Or, in other words, the scientist trusted that other RPaUoN members would not use his data for their own advantage even though there is no control in place. In this context, a representative of DECHEMA emphasizes that group members trust each other:

> "[T]he funny thing is it [reporting about data within the RPaUoN] is actually based on trust, it is not carved in stone through contracts of any kind. Well, if you have indeed a presentation where somebody in such a group talks about great, yet unpublished research results and then somebody else does not stick to the rules of the game (…) it is of course something that is not honorable" (Interviewee 25, association).[111]

The DECHEMA representative explained further that, to his knowledge, a situation where this trust among RPaUoN members had been betrayed never occurred (ibid).

While, thus, overall RPaUoN members appear to rely on each other, we also see reliance specifically in the relationship between group members and the chair. This is visible in the group's approach to dealing with requests by external parties for group-internal documents: members do not forward reports and lists of participants of the group's meetings without prior consultation with the chair (Interviewee 27, academia; 25, association). The chair then decides what kind of documents can be released. Thus, the RPaUoN members rely on the chair to act in all of their best interests. In difference, when merely general information rather than group-internal documents are requested, group members usually decide themselves, based on personal judgment, how to respond to such requests (Interviewee 26, academia; 25, association; 21, association; 20, industry). As such, the group members rely on each other to make decisions in the best interest of the group.

Furthermore, in the relation between the group and a regulator, the BMBF, reliance is visible. When the RPaUoN developed its Roadmap for Nanomaterials (2007) with its priority list for research on the potential risks of nanomaterials, the BMBF initiated and crafted the research project NanoCare accordingly (DECHEMA & VCI 2007; Interviewee 27, academia; 25, association; 20, industry). The BMBF relied on the group that the provided information and the group's judgment which nanomaterial data gaps needed to be addressed and closed most urgently is correct, without being able to control whether this is actually true (due to the scientific and technical intricacy of nanomaterials OHS as wicked policy problem). On the other hand, the RPaUoN members relied on the BMBF to not use the provided information to the group's disadvantage without being able to control this.

With regard to the *VCI workshops (2005/2007)* and the *VCI/BAuA surveys (2006/2011)* reliance developed between representatives of VCI and BAuA. These two bodies have cooperated since the early days of nanotechnology. In their partnership in the context of the surveys in 2006 and 2011 it is visible that they started to rely on each other: the VCI distributed the survey to its member companies and, by doing so, trusted that BAuA would not use the survey data in any way that would have negative consequences for companies in the chemical sector. At the same time the VCI could not control the effects the survey results may have, e.g. on regulators. While the VCI, thus, relied on BAuA, this reliance appears mutual because the Institute trusts that the association does everything they can to encourage

[111] Original quote: "Der Witz an der Geschichte ist eben tatsächlich, das ist so ein bisschen tatsächlich auf Vertrauensbasis irgendwo, es ist aber nicht durch irgendwelche Verträge festgehämmert. Also wenn Sie jetzt irgendwo tatsächlich einen Vortrag haben wo jemand in so einem Gremium über noch unveröffentliche Forschungsergebnisse redet und irgendjemand hält sich nicht an die Spielregeln (...) es ist natürlich dann schon so etwas, dass es dann halt eben im Zweifelsfall ehrenrührig ist" (Interviewee 25, association).

their member companies to participate in the survey, i.e. deliver data on nanomaterials. Whether this is actually the case BAuA cannot control.

Lastly, as to the *VCI/IG BCE workshop (2008)* there is no data (either from interviews or publicly available documents) that indicates whether, or not, the collaborators developed reliance. However, it would appear that a one-time-only workshop would, by itself, be insufficient to enable collaborators to start relying on each other.

(4) Realization of common goals

When collaborators hold back the realization of individual goals in favor of the common network goal(s) we see that trust characterizes the relationships. Or, when certain actors realize individual goals at all cost and to the disadvantage of the network goal(s) blockades and conflicts in the process of collaboration can emerge ('goal divergence') that further the development of distrust (Koppenjan & Klijn 2004). In regard to the *RPaUoN meetings* there are no signs that blockades occurred in the process of collaboration that resulted from a divergence between common network goals and individual actor goals. One explanation for the apparent absence of blockades is that the common goals of the working group appear largely compatible with the personal goals of the participants. The common goal of the RPaUoN was the identification of research and data gaps related to the manufacture and use of nanomaterials and accordingly to advise policy-makers which research projects should be funded most urgently (Interviewee 27, academia; 25, association; 21, association). This common goal formed the basis for the development of the group's Roadmap for Safety Research on Nanomaterials (DECHEMA & VCI 2007) and was further strengthened by RPaUoN's continuous efforts to discuss and update their Roadmap when new knowledge becomes available. This overall goal appears compatible with the individual goals of RPaUoN members, which ranged from information and knowledge exchange to establishing and maintaining contacts among industry, academia, and regulators (Interviewee 27, academia; 26, academia). As one RPaUoN member explained:

> "My personal goals were to (…) get a feeling of what makes industry tick, what makes regulators tick [and], what do they expect from academia (…). The VCI rather holds back; it gives an overview of what it does, what industry does, what their industry-partner do, but it's not propaganda. I wouldn't accept that! It's more knowledge exchange" (Interviewee 27, academia).[112]

DECHEMA furthers the development of these common goals actively and, at the same time, balances these with individual needs and demands of the working group's participants. For example, DECHEMA suggests, which topics could be discussed in the RPaUN meetings based on presentations by certain members (Interviewee 25, association; 20, industry). At the same time the association is willing to consider individual member interests if they accord with the overall goals of the RPaUoN. By employing this strategy of considering common and individual member interests through an independent body (the DECHEMA) goal divergence is overcome.

[112] Original quote: "Meine persönlichen Ziele waren (…) ein feeling dafür zu kriegen, wie ticken die bei der Industrie, wie ticken die bei den Bundesämtern [und], was erwarten sie von der Akademie (…). Der VCI hält sich eher zurück; er gibt zwar auch (…) einen Abriss über das was getan wird, was die Industrie tut, was die Industriepartner tun, aber es ist keine Meinungsmache. Das würde ich auch nicht mitmachen! Also es ist eigentlich mehr Wissensaustauch" (Interviewee 27, academia).

Similar measures to avoid goal divergence and blockades among collaborators were in place for the *VCI workshops (2005/07)* and the *BAuA/VCI surveys (2006/11)*. More specifically, VCI asked an independent third party–the Stiftung Risiko-Dialog, which has more than 20 years expertise in the observation, analysis, and moderation of risk debates (Stiftung Risiko-Dialog n.d.)–to develop a concept and moderate the workshops (VCI 2005). Prior to the workshop, the Stiftung conducted qualitative interviews on OHS aspects related to nanomaterials with a broad set of stakeholders to ensure that all viewpoints and important issues were covered in the workshop (VCI 2005). In this way an inventory of individual workshop participant's goals was created. The results were used to formulate common workshop goals; these were "(…) to build–jointly between stakeholders–more knowledge on toxicity, epidemiology and measuring technology (…) [and to] improve information, communication and networking" (ibid: 4). It would appear that pursuing this strategy ensured that workshop participants could communicate and debate on the same level of understanding, or in 'one voice'.

This is an important aspect because in the one-day workshops participants, who did not know each other beforehand had only limited possibilities to get to know each other's viewpoints and, on this basis, develop common goals 'naturally' over time. By asking a third party to make an inventory of participant's viewpoints on nanomaterials OHS and, on this basis, identify underlying common interests, the process of familiarization among actors was facilitated 'artificially'. The results of the inventory were used to develop a communication strategy that allowed collaborators to discuss particular questions, based on a common level of understanding, in order to contribute to nanomaterials OHS.

The results of discussions in the 2005 workshop were used to inform the design of the BAuA/VCI 2006 survey (VCI 2007b). After the survey had been conducted the results were discussed in the 2007 VCI workshop and were used in order to develop the Guidance for Handling and Use of Nanomaterials at the Workplace by BAuA/VCI (ibid). Hence starting with the 2005 workshop, the subsequent workshop and surveys were grounded on an explicit strategy to ensure that the debate on nanomaterial OHS is based on a common level of understanding.

The *VCI/IG BCE workshop (2008)* appears to not have been built on such a strategy. As mentioned earlier, the workshop was a broad effort to invite a diverse set of stakeholders to come together and talk about the transparent communication of nanomaterials including OHS aspects. While no explicit strategy seems to have been in place to deal with potentially emerging goal divergence against individual goals and against common workshop goals the VCI/IG BCE workshop implicitly build on a common goal among all participants: namely to support the competitive position of the German chemical industry and secure workplaces in the area of nanotechnology (Interviewee 23, labor union).

This underlying, implicit common goal emerged from experiences with the introduction of genetically modified organisms (GMOs) in Germany, and the EU more generally, starting in 1990[113]. The introduction of GMOs was met with a range of NGO activities that sought to highlight the perceived detrimental effects of this new technology on the environment and human health (Reichow & Bowman forthcoming 2015). These campaigns were underpinned by a strong and consistent media message, which significantly influenced the development of an overall negative perception, and eventually the rejection, of GMOs in their food by German citizens (Miller & Scrinis 2010; Bernauer & Meins 2003). NGOs were only, it would at least publically seem, brought into discussions with the government late, when the overall negative picture on GMOs was 'fixed' within public opinion and when NGOs were not willing to discuss proposed positive effects of this new

[113] See Richtlinie 90/220/EWG des Rats vom 23. April 1990 über die absichtliche Freisetzung genetisch veränderter Organismen in die Umwelt.

technology (Interviewee 28, federal research institute). Partly as a response to this rejection, the technology migrated to the US leading to loss of workplaces in Germany (Interviewee 29, association; 28, federal research institute; 23, labor union). In this context, a representative of the IG BCE explains,

> "We had some difficult experiences with genetic engineering in Germany (…) especially with green GM [agricultural genetic engineering] for industrial processing (…). You could say we lost this battle, [because] green GM is no longer existent in Germany, it migrated to the US because here it was no longer possible to develop anything (…) Principally this is why we said we want to do better with nanotechnology" (Interviewee 23, labor union).[114]

In this light, the participants of the VCI/IG BCE workshop pursued the common goal to prevent 'another GMO disaster' for nanotechnology. As concluded in the workshop report, the participants were interested in continuing this debate to ensure the transparent development, and the responsible use, of nanomaterials in the OHS environment. While individual view of workshop participants might differ on how to reach this common goal, they shared an interest in pursuing the same end-goal.

(5) Disagreement among actors is addressed and solved

Even though goal divergence may not be present in collaboration at a certain point in time, it is useful to have a strategy in place to deal with situations of blockades and conflict. For disagreement among collaborators can destroy previously established trust and may even lead to the termination of collaboration. But when disagreement is addressed and solved in a way that actors are still willing to collaborate, trust can even be strengthened (Edelbos & Klijn 2007; Koppenjan & Klijn 2004; Ostrom 1990). In view to the *RPaUoN meetings* disagreement among actors occurs frequently (Interviewee 27, academia; 25, association; 21, association). As a VCI representative explains, disagreement among group members occur 'naturally' since the RPaUoN consists of a heterogeneous set of actors:

> "There are certainly different opinions and that is fine, it is also important (…). Every research institute, every scientist has his own opinion, which nobody wants to take away from them, rather the opposite. And the representatives of industry must be distinguished in that they have yet another perspective on certain issues (…). And that certainly results in that they…hold on to their point of views (…) it is simply a lively discussion (…). The goal is not necessarily to reach a consensus, but to exchange with each other" (Interviewee 21, association).[115]

Usually such disagreements occurred in relation to specific professional debates, as a DECHEMA representative explains; for instance, the members of the RPaUoN have

[114] Original quote: " Wir haben da eine schwierige Erfahrung mit der Gentechnologie in Deutschland gemacht (…) insbesondere mit der Grünen Gentechnik für industrielle Prozesse (…). Da haben wir sozusagen den Kampf verloren wenn man so will, [weil] die Grüne Gentechnik ist nicht mehr in Deutschland, ist also in die USA abgewandert weil es hier gar nicht mehr möglich war irgendetwas zu machen (…). Das hat im Prinzip dazu geführt, dass wir gesagt habe wir wollen das bei der Nanotechnologie besser machen" (Interviewee 23, labor union).

[115] Original quote: "Natürlich gibt es da differenzierte Meinungen, das ist ja auch gut, das ist ja auch wichtig (…). Jedes Forschungsinstitut, jeder Forscher hat da so seine eigne Meinung, die will ihnen auch keiner nehmen, im Gegenteil. Und die Industrievertreter muss man dahingehend unterscheiden, die haben nochmal eine andere Brille auf (…) Und das hat natürlich da zur Folge, dass die natürlich schon irgendwo auch…auf ihrem Standpunkt irgendwo auch bleiben (…) das ist einfach eine lebendige Diskussion (…). Es ist ja nicht Ziel unbedingt einen Konsens zu erzielen, sondern sich entsprechend auszutauschen" (Interviewee 21, association).

disagreed which particular nanomaterials should be given priority over others in conducting OHS research. Another point of disagreement was whether companies should be communicating publicly that they are manufacturers of nanomaterials (Interviewee 25, association). As to the former aspect, RPaUoN members typically resolve such disagreements by finding a compromise everyone can 'live with', e.g. members agree on giving priority to one nanomaterial over another one even though not all members agree with this prioritization *per se*; as a tradeoff, at another time, the members, who did not agree with the prioritization, will get certain issues 'their way' (ibid). Disagreements on communication issues are more difficult to resolve and often the group members do not find a compromise; instead each one member deals with the issue as he or she desires (ibid). In such cases, as a DECHEMA representative states, it is important to accept disagreement and not force consensus so that group members are still willing to attend, and engage in, the RPaUoN meetings (ibid). While group members can generally dissolve disagreements, probably one member left the group due to insurmountable discrepancy (ibid).

Other members actively seek disagreements as a way to enable lively, in-depth discussions of particular subjects and, on this basis, are able to arrive at meaningful results on issues of nanomaterials OHS (Interviewee 27, academia; 21, association). Thus, rather than leading to blockades, disagreements appear to be an acknowledged aspect of collaboration in the RPaUoN. Overall, members trust that such disagreements can be handled adequately.

In relation to the *VCI workshops (2005/07)* and the *BAuA/VCI surveys (2006/11)* as well as the *VCI/IG BCE workshop* (2008) few concrete information on disagreement among collaborators is available (neither from interview data nor from documents). At the same time it is likely that disagreement emerged in regard to the two VCI workshops since a very heterogeneous group of stakeholders came together that probably held different viewpoints (i.e. representatives from industry, NGOs, regulatory agencies, academia, trade unions and business associations) (VCI 2007b, 2005). In this light, one aspect of disagreement among representatives from an NGO and industry is reported in the workshop's 2007 documentation: a representative of the BUND demanded that use of nanomaterials with unknown characteristics should be stopped until further notice (VCI 2007b: 11). However, it is unknown how this disagreement was dealt with in the workshop. Overall the participants appeared satisfied with the workshop outcomes (ibid). Also in regard to the VCI/IG BCE workshop the BUND made a similar demand and argued that, under REACH, nanomaterials of which insufficient data are available should not be allowed to enter the market (VCI & IG BCE 2008: 7). Also in this connection it is unknown how the disagreement was dealt with.

(6) Development of additional collaborative activities

When collaborators have learned to trust each other additional collaborative activities may be organized. Such activities provide opportunities for strengthening existing trust. But existing trust can also become more fragile when opportunistic behavior occurs (Edelbos & Klijn 2007).

In regard to the *RPaUoN meetings* additional collaborative activities have indeed been initiated. As mentioned afore, the RPaUoN developed a list with research needs on nanomaterials and identified data gaps on nanomaterial risks, which had been made available to the BMBF. Later this list was developed further into the DECHEMA/VCI Roadmap (2007), based on which the BMBF brought the research project NanoCare I (2005-09) into being (Interviewee 27, academia; 25 association; 20, industry). Various RPaUoN members participated in NanoCare I, and at the same time, have continued to be members of the RPaUoN until 2014. This indicates that, at least, additional collaboration in the research project has not led to distrust with trust continuing to characterize actor relations. By the end of NanoCare I the BMBF decided to launch two other research projects. One project was NanoCare II, which was devoted to health and safety aspects of nanomaterials including the issue of risk assessment for nanomaterials, and which ran between 2010 and 2013. The other project, NanoNature, was concerned with nanomaterials in the environment (BMBF 2009b).

In regard to the *VCI workshops (2005/07)* and the *BAuA/VCI surveys (2006/11)* it is unknown whether these particular activities have led to the organization of new collaborative activities. However, during the workshops various agreements were made to continue the debate on specific issues related to nanomaterials OHS (e.g. intensify exchange between toxicologists, public authorities, industry, and NGOs) (VCI 2007b, 2005). In this respect it is difficult to identify which activities emerged from others; rather, such activities appear to emerge and operate in connection to a wider web of collaborative activities on nanomaterials OHS that developed in the period from 2006 to 2011.

As mentioned before, the government-initiated NanoDialog (2006-2011) served as platform for a broad range of stakeholders, including members of the VCI network and RPaUoN members, to meet and realize new collaborative activities. An example of such activity was the BASF Dialogforum Nano that was initiated in 2009 (BASF 2012). The Dialogforum was also relevant in connection to the *VCI/IG BCE workshop (2008)*. As a representative of the IG BCE remembers, the Dialogforum provided new possibilities for collaboration:

> "[i]t is actually a continuous contact [with the VCI] and this develops further on various levels. For example, BASF had initiated a Nano Dialogforum where I participated as well (…) and we [participants of the Nano Dialogforum] developed a paper together" (Interviewee 23, labor union).[116]

In this respect it needs to be acknowledged that the collaborative activities of the VCI are connected to a broader web of activities in the area of nanomaterials OHS. Both industry and government have initiated such activities.

Thus, there are indications that the relations between the relevant actors–i.e. VCI and DECHEMA staff/members, RPaUoN members, federal research institutes, academia, and regulators–build on trust that has been developing since 2003. There are no examples of distrust. Overall the government-initiated NanoDialog played an important role as it provided additional opportunities for interaction and trust development among the collaborators (see Table 7.12 for an overview of the development of trust among the collaborators in the VCI network).

Table 7.12. Overview trust in the VCI collaborative activities.

Collaborative activity	Trust Relations
RPaUoN meetings / Roadmap Nanomaterials	RPaUoN members internally & relation with BMBF/BAuA/academia
VCI workshops / BAuA & VCI surveys	VCI/BAuA
VCI & IG BCE workshop	VCI/IG BCE

[116] Original quote: "[d]as ist eigentlich schon regelmäßiger Kontakt (…) [mit dem VCI] und der entwickelt sich einfach auf verschiedenen Fäden weiter (…) BASF hat zum Beispiel so einen Nano Dialogforum durchgeführt, an dem war ich auch beteiligt (…) und wir [Teilnehmer des Nano Dialogforums] haben ein Papier zusammen entwickelt" (Interviewee 23, labor union).

Having investigated strategic learning among actors in the VCI network and substantive learning in the foregoing sections, and having found that the relevant actors trust each other and have generated new knowledge that can facilitate making risk assessment more applicable to nanomaterials, we shall now turn to the aspect of institutional learning. Thus, have collaborators on the basis of trust and scientific expertise developed rules of behavior?

7.2.3 Network level – institutional learning

On the network level of analysis three conditions for the process of rule development enable to understand whether institutional learning has emerged in the collaboration (see section 4.3):

(1) Development of informal agreements
(2) Design of soft rules of behavior, and
(3) Soft rules become 'hardened'.

Agreements and rules can be of two types: they can refer to interaction among relevant actors in a network to structure, facilitate and stabilize processes of collaboration (process-oriented agreements/rules). Or, agreements and rules can refer to practices on how to handle nanomaterials at workplaces most safely based on the latest state of science and instrumentation (problem-oriented agreements/rules).[117] The three conditions for the network level analysis are now applied to investigate the collaborative activities in the network of VCI.

(1) Development of informal agreements

Typically, informal unwritten agreements are a precursor of formal rules of behavior. These agreements can be explicitly put in place, or they emerge implicitly during the process of collaboration (Klijn 2001; Termeer 1993). In the context of the *RPaUoN meetings*, both process-oriented, as well as problem-oriented agreements, were developed. An implicit process-oriented agreement is the group's approach in dealing with requests by externals to retrieve RPaUoN internal information: while no concrete agreements exist on how to deal with such requests, i.e. under which circumstances to provide what type of information to whom, implicitly members appear to agree that issues discussed in the group can principally be provided to externals (with the exception of group-internal documents) (Interviewee 27, academia; 25, association). An oral problem-oriented agreement that has been made and realized among certain group members and the BMBF was to develop a Roadmap for Safety Research on Nanomaterials (2007) to thereby collect information on the potential risks of certain nanomaterials. The BMBF was to use the Roadmap as basis for funding research projects (i.e. NanoCare I) that would contribute to close data gaps related to the health risks of nanomaterials (Interviewee 27, academia; 25, association).

In regard to the *VCI workshops (2005/07)* and the *BAuA/VCI surveys (2006/11)*, various problem-oriented agreements were made, and realized, in connection to nanomaterials OHS. During the VCI 2005 workshop participants from VCI and BAuA agreed to conduct a survey among VCI member companies to collect information on aspects of exposure and

[117] See section 4.2 (pp. 65-66).

industrial health and safety measures (VCI 2005). The questions were to be jointly formulated while the evaluation was agreed to be in the responsibility of BAuA alone (ibid). Furthermore, the workshop participants agreed that the results of this survey were to be used by VCI and BAuA in order to develop a guideline for handling nanomaterials at workplaces (ibid). In 2006, BAuA and the VCI conducted the survey and, based on the evaluation by BAuA, the two bodies developed a preliminary guidance (which will be described in more detail below) (VCI 2007b; VCI & BAuA 2007).

Lastly, in the *VCI/IG BCE workshop* (2008) an oral, process-oriented agreement was made among the participants; namely to continue discussions and joint deliberations how to realize the responsible use of nanotechnology in Germany (VCI & IG BCE 2008). It is unknown whether and how these agreements have been realized.

(2) Design of soft rules of behavior

Over time informal agreements among collaborators can develop into written soft rules of behavior that provide guidance of what ought to be done under certain circumstances (Black 2008; 2002). These soft rules, or regulation, do not have legally binding force but they may be relevant in regulatory practice by, e.g. reflecting the latest state of science and technology (Senden 2004). In the context of the *RPaUoN meetings*, based on the available data from interviews and documents, there is no evidence that the above-mentioned process-oriented informal agreements have been developed further into soft rules.

Independent from this discussion, a process-oriented soft rule that is in place refers to the minutes of the group's meetings. As a representative of DECHEMA explained, in the association's charter it is specified that meetings of the RPaUoN (and other working groups within the association) are not public and therefore the minutes of meetings cannot be forwarded to non-members (Interviewee 25, association).

Problem-oriented soft rules have been developed by the RPaUoN. In relation to the group's Roadmap for Safety Research on Nanomaterials (2007), the informal problem-oriented agreement has been made between the RPaUoN and BMBF to contribute to closing data gaps on the risks of nanomaterials. This informal agreement was developed into soft rules of behavior in the context of NanoCare. In the Roadmap it is stated that "(…) to assess potential risks of nanomaterials, DECHEMA and VCI jointly recommend focusing in the first step on the exposure assessment" (DECHEMA & VCI 2007: 4). The RPaUoN calls for the development of standardized exposure and toxicology test protocols or guidelines.

In the context of NanoCare I various RPaUoN members have actually been involved in the development of such guidelines; these are called Standard Operating Procedures (SOP's) (recapture Table 7.8). Accordingly, in 2009 a SOP for exposure measurement was developed that–for the first time–allows for standardized assessment of nanoparticles at workplaces and that differentiates nanoparticles in workplaces from background particles (BMBF 2009a, 2009b). Several other SOP's have been developed for analytical methods relevant for standardizing toxicological testing for nanomaterials and for measuring biological effects of nanomaterials (ibid). In 2011, members of the RPaUoN (and others) developed (parts of) the SOP for exposure measurement further into the guidance Tiered approach to an Exposure Measurement and Assessment of Nanoscale Aerosols Released from Engineered Nanomaterials in Workplace Operations (IUTA et al. 2011).

In connection to the *VCI workshops (2005/07)* and the *BAuA/VCI surveys (2006/11)* it was mentioned above that the VCI and BAuA used the results of the 2006 survey to jointly develop problem-oriented soft rules in a preliminary version of the Guidance for Handling and Use of Nanomaterials at the Workplace (VCI 2007b; VCI & BAuA 2007). This preliminary guidance was discussed and further developed in the VCI workshop in April 2007; in July 2007 the final version of the BAuA/VCI guidance was published (VCI & BAuA 2007). During the 2007 VCI workshop the participants agreed that the guidance was to be developed further when new knowledge on the potential risks of nanomaterials becomes available (VCI 2007b). Accordingly, the BAuA/VCI 2011 survey delivered some new insights, which were used to update the 2007 BAuA/VCI guidance in 2011 (VCI & BAuA 2011).

In the 2007 BAuA/VCI guidance recommendations for general worker's protection in the handling and use of nanomaterials are made, existing measuring methods for nanoparticles are identified and advice is provided on how to conduct a hazard assessment for nanoparticles at workplaces. It is important to note that the guidance makes a reference to NanoCare I and the RPaUoN in relation to their research on measuring methods; this demonstrates, again, the dense web of collaboration and interaction on the topic of nanomaterials OHS in Germany. In 2011 the VCI and BAuA provided an updated version of the 2007 guidance: the Empfehlung für die Gefährdungsbeurteilung bei Tätigkeiten mit Nanomaterialien am Arbeitsplatz[118] (VCI & BAuA 2011). The new guidance provides recommendations on worker protection in handling nanomaterials by employing a hierarchy of controls[119] and advises how to conduct risk assessment for nanomaterials, based on the latest state of science and technology on exposure measurement, and assessment following a tiered approach (ibid).

There is no evidence in the available data from interviews and documents that the *VCI/IG BCE workshop* (2008) has led to the development of either process-, or problem-oriented rules of behavior.

(3) Soft rules become 'hardened'

Soft rules can become 'hardened' over time through formalization, i.e. by written references in 'texts of the law' (e.g. judicial commentaries or policy documents) and/or through oral reference by public authorities (see section 4.2). In the context of the *RPaUoN meetings* at least one problem-oriented soft rule has become 'hardened'. As mentioned above, in the context of NanoCare I, members of the working group have developed an SOP for exposure measurement; in 2011 (parts of) this SOP had been developed further into the Tiered approach to an Exposure Measurement and Assessment of Nanoscale Aerosols Released from Engineered Nanomaterials in Workplace Operations (IUTA et al. 2011). Many actors were involved in the development of this guidance, under more representatives of BAuA and the German Social Accidence Insurance (DGUV). Even though these actors are not regulators they have a high authority in the German political landscape. Therefore these bodies are considered to have contributed to the hardening of the previous SOP on exposure measurement. In this light, a RPaUoN member (academia) emphasized that BAuA had been involved in order to formalize the guidance and thereby increase its acceptability among OHS experts (Interviewee 26, academia).

The soft rules that have been developed based on the *VCI workshops (2005/07)* and the *BAuA/VCI surveys (2006/11)* have also become 'hardened'. Overall the VCI/BAuA (2007) Guidance for Handling and Use of Nanomaterials at the Workplace has become formalized through the NanoDialog: participants from policy, i.e. UBA, BMUB, and the Ministry of the Environment, Forestry and Consumer Protection (as well as industry, trade

[118] The guidance is only available in German. The original title may be translated as 'Recommendation for the risk assessment of workplace activities involving nanomaterials'.

[119] See 2.2 (p. 38) for an elaboration on the 'hierarchy of controls'.

unions, NGOs and others) have mentioned, and discussed, the guidance extensively in the context of Issue Group 1 (Ökopol 2010a). Between 2009 and 2011 the group developed a guideline in order to implement five principles for the responsible development of nanotechnology[120] (ibid). In the process of developing this guideline the group members have used the BAuA/VCI guidance (2007) as an informative resource (ibid). In doing so the BAuA/VCI guidance became 'hardened' and communicated to a broad audience.

Furthermore the BAuA/VCI guidance (in its 2007 and 2012 version) became formalized through the Committee for Hazardous Substances (Ausschuss für Gefahrstoffe, AGS). The AGS consists of representatives from industry (including the VCI), trade unions, federal state authorities, statutory accident insurances and OHS experts and is established through the §20 Hazardous Substances Ordinance (BAuA 2012). The AGS is tasked to concretize the German Hazardous Substances Ordinance (GefStoffV), advice the Federal Ministry of Labour and Social Affairs (BMAS) and to develop supporting tools for companies in form of technical rules (TRGS) (BAuA 2011). TRGS reflect the state of the art of technology, science, and occupational health related to work with hazardous substances and are important insofar as their application leads to the assumption that the requirements of the hazardous substance ordinance are fulfilled (ibid).

In 2009 the AGS began to address the topic of nanomaterials OHS, in part, because the NanoDialog participants saw a need for action to protect workers (Interviewee 22, labor union). In 2010 the AGS developed a report in which OHS aspect of nanomaterials were discussed by reviewing the existing literatures; on this basis the AGS decided to develop an Announcement on Hazardous Substances 527 (Bekanntmachung) with advisory character to describe the state of knowledge (AGS 2011). The announcement provided support in ensuring health and safety at workplaces where nanomaterials are handled and gives concrete advice on how to conduct risk assessment for nanomaterials based on the latest state of science and technology (AGS 2013). In this context, both in the 2010 AGS report and the 2013 Announcement the AGS discussed, and made reference to, the BAuA/VCI guidance (2007/2012). As such, the AGS has contributed to the formalization of the BAuA/VCI soft instrument. It should be noted that the Announcement was meant to provide the foundation for a TRGS (with Vermutungswirkung[121]), which may be developed in the future, if necessary. As a representative of a trade union and member of the AGS stated, at the moment it is being discussed whether a TRGS for manufactured nanomaterials should indeed be developed (Interviewee 22, labor union).

In relation to the *VCI/IG BCE workshop* (2008) such a process of 'hardened' soft regulation could not take place since no soft rules of behavior have been developed in the first place.

Overall, the collaborative activities of the VCI have resulted in the development of rules. Process-oriented agreements and rules were made in the meetings of the RPaUoN and the VCI/IG BCE workshop (2008). Based on the RPaUoN meetings as well as the VCI workshops (2005/07) and the BAuA/VCI surveys (2006/11) various problem-oriented rules were developed that also became hardened. For a general overview of the development of rules in the VCI collaborative network see Table 7.13.

[120] The five principles for the responsible use of nanotechnology developed in the context of the NanoDialog, were: Definition and disclosure of responsibility and management (good governance); transparency regarding nanotechnology-related information, data, and processes; commitment to dialogue with stakeholders; establishment of risk management structures; and responsibility within the value chain (Ökopol 2010a).

[121] When employers follow a TRGS with 'Vermutungswirkung' it is assumed that this employer complies with OHS legislation. The employer may decide to apply another measure but must prove through the documentation of risk assessment that this measure is equally effective (BAuA 2014b).

Table 7.13. Overview rule development VCI collaborative activities.

Collaborative activity	**Rules** Problem-oriented	Process-oriented
RPaUoN meetings / Roadmap Nanomaterials	Soft rules in form of SOPs for toxicological testing of nanomaterials, measuring biological effects & exposure measurement (2009); the latter SOP was developed further into the soft regulation Tiered approach to an Exposure Measurement and Assessment of Nanoscale Aerosols Released from Engineered Nanomaterials in Workplace Operations (2011) (became hardened)	Soft rules regarding RPaUoN meeting's minutes
VCI workshops / BAuA & VCI surveys	Soft regulation Guidance for Handling and Use of Nanomaterials at the Workplace (2007) & its updated version Empfehlung für die Gefährdungsbeurteilung bei Tätigkeiten mit Nanomaterialien am Arbeitsplatz (2011) (both versions became hardened)	---
VCI & IG BCE workshop	---	---

7.3. Conclusions: Strong contribution to effective regulation

This chapter has been structured alongside the question how collaborative activities by a business association in Germany contribute to effective nanomaterials OHS regulation in practice (for the conception of effective regulation in the area of nanomaterials OHS, as well as for the definition of association activities that can contribute to effective regulation, see sections 1.2 and 4.1). Accordingly, the collaborative activities of the German VCI have been investigated in view of three types of learning, i.e. substantive, strategic, and institutional learning.

These types of learning are assumed to relate to each other in a certain order (see section 4.3). Thus, we assumed that strategic learning is a pre-condition for substantive learning. For when collaborators trust each other, exchange of relevant knowledge among collaborators is facilitated and actors are open towards each other; this is assumed to enhance the potential for finding innovative solutions and generating new scientific facts necessary in order to deal with the problem of nanomaterials OHS. It is also assumed that strategic learning and substantive learning are pre-conditions for institutional learning. When collaborators trust each other and have generated new knowledge necessary to deal with the policy problem, the development of agreements and rules is facilitated because the collaborators have the necessary knowledge available to develop such rules and they believe that the rules will not be detrimental to them.

With regard to each of the three learning types, as well as for learning overall, we have differentiated between 'strong' and 'limited' learning (see section 4.3). We speak of strong learning when many, i.e. the majority, of the conditions of a certain type of learning are met in the process of collaboration. We speak of limited learning when only a few, i.e. half or less, of the conditions of a certain type of learning are met.

Following this differentiation, overall the collaborative activities of the VCI have strongly contributed to effective nanomaterials OHS regulation. Strong learning has been identified in relation to all three types of learning.

Between 2003 and 2014 the VCI has initiated 21 activities directed at nanomaterials OHS in collaboration with many stakeholders and relevant actors. From these collaborative activities, seven were of the type knowledge exchange with opportunities for substantive learning. Regulators have been involved in all seven activities. From the four conditions that lead to substantive learning (see section 4.3) all conditions have been met in the collaborative activities of the VCI.

More specifically, according to the first condition, relevant actors have collaborated, i.e. those actors who hold either the resources knowledge or decision-making authority (related to nanomaterials OHS). As such, staff and members of the VCI and another association (DECHEMA), representatives of regulators (BMAS and BMBF), federal research institutes (BAuA, BfR) and academia (scientists from various universities) have collaborated. Second, these actors have exchanged knowledge in form of aggregate data, general experiences, and they have provided a critical evaluation of state-of-the-art data. Knowledge in the form of raw data has been exchanged as well. Through these activities, third, an increased understanding was gained of specific aspects related to (human) toxicological aspects of (certain) nanomaterials, exposure measurement (technology) and control, and overall the characterization of nanomaterials risks. On this basis, many new scientific facts relevant for making risk assessment applicable to nanomaterials have been generated.

Specifically the collaboration between the RPaUoN and BMBF resulted in many new facts that contributed to making risk assessment applicable to eleven different nanomaterials (in the context of the research project NanoCare, which was tailored jointly by the RPaUoN and BMBF). But also the collaboration between the RPaUoN and the federal research institute BAuA also led to the generation of new facts; namely in the area of health hazards, exposure measurement and assessment, and toxicology of 11 nanomaterials that are actually being handled at workplaces. These collaborative activities were taking place against the background of the government-organized NanoDialog, an effort to bring together all relevant stakeholders early in the development of nanotechnology to enable the responsible use of the technology. Overall the VCI collaborative activities have contributed to substantive learning on all aspects in the risk assessment of nanomaterials. Thus, the collaborative activities of the VCI have contributed to strong substantive learning on aspects of risk assessment for nanomaterials.

Next, strategic learning was investigated by means of the six conditions (see section 4.3). Generally, most conditions have been met in the collaborative activities by the VCI and no instances were apparent where trust among particular actors may have been weakened through opportunistic behavior. In regard to the first and second condition, ample opportunities to meet over a longer period of time and to intensify the relationships among collaborators were provided. In the context of the RPaUoN meetings, collaborators had most opportunities (as compared to the other collaborative activities) to get to know each other and to intensify their relationships in face-to-face meetings, three to four occasions per year since 2003 until today (2014). Other collaborative activities provided fewer opportunities for meetings. However, additionally actors could intensify their relations through the government-initiated NanoDialog, where approximately three meetings were realized over a period of five years (2006-2011). On the basis of intensified relations, specifically the collaborators within the RPaUoN started to rely on each other. This is most visible in that RPaUoN members have shared unpublished data/or knowledge in the group based on trust beyond control that others would not use such information for their own advantage.

Fourth, collaborators in the VCI network actually realized common network goals without this leading to clashes with particular actors, who would have given preference to realizing their own, individual goals. This was possible because an independent body balanced the realization of common network and individual goals (i.e. DECHEMA, Stiftung Risiko Dialog). As such, no instances of goal divergence and blockades in the collaboration have been observed that would have weakened trust relations among network collaborators. Fifth, especially in connection to the RPaUoN meetings, disagreement occurred frequently. But rather than leading to conflicts these disagreements were welcomed by the participants as a means of inducing lively discussions based on which actors could agree on a compromise or accept disagreement. Lastly, we have seen that trust has grown strong particularly among the

VCI, RPaUoN members, and representatives of BMBF and BAuA in that these actors have initiated additional collaborative activities. These activities emerged within, and were connected to, a wider web of government-, and industry-organized collaborative activities on nanomaterials OHS in the period from 2006 to 2011. Thus, the investigation of the six conditions for the development of trust indicates that the collaborative activities of the VCI have led to strong strategic learning.

Lastly, we have investigated the development of institutional learning based on the collaborative activities in the VCI network (see section 4.3 for the conditions of institutional learning). As to the first condition, various process-, and problem-oriented agreements have been made during the collaborative activities. Various problem-based agreements were developed further into soft rules (second condition) to guide behavior in the context of nanomaterials OHS including risk assessment for nanomaterials; some of these soft rules also became hardened (third condition).

More specifically, based on the RPaUoN meetings the Roadmap for Safety Research on Nanomaterials (2007) was developed. It was agreed with the BMBF that the ministry should use this document to initiate research projects that will contribute to closing data gaps on the potential health risks of nanomaterials. This agreement had been substantiated in the BMBF initiated research project NanoCare I where, under more RPaUoN members, developed various guidelines to support specific aspects of conducting risk assessment for nanomaterials (e.g. guidelines for exposure measurement and toxicological testing). At least one of these soft rules has become 'hardened' by having been developed further by actors with high authority in the German political OHS landscape, for example BAuA.

Similarly the collaboration between the VCI and BAuA in workshops (2005, 2007) and surveys (2006/2011) led to the development of informal agreements and soft rules of behavior. Thus, in the 2005 workshop, the collaborators agreed informally to conduct a survey on nanomaterials health and safety practices as well as needs among VCI member companies and to use the survey's results to develop a guidance for handling and use of nanomaterials at workplaces. This guidance was jointly developed by the VCI and BAuA in 2007 (it was updated in 2011). The rules underlying the guidance have become 'hardended' in two ways: first, between 2009 and 2011 the BAuA/VCI guidance (2007) has been mentioned and discussed extensively in the context of the government-initiated NanoDialog. Here the guidance serves as a resource for the development of another soft regulation instrument. Second, and arguably more importantly, the BAuA/VCI guidance (2007/2011) became 'hardened' through reference and discussion by the AGS that serves to advise the BMAS and concretize the Hazardous Substances Ordinance. The AGS mentioned the BAuA/VCI guidance (2007) in a report (AGS 2010). Likewise, the AGS also mentioned the BAuA/VCI 2011 guidance in its Announcement 527 (2011) where the AGS reviewed, and provided guidance on, nanomaterials OHS practices including risk assessment. Currently (2014) the AGS discusses whether the Announcement is to be elevated on to the level of a TRGS (with Vermutungswirkung).

Based on the analysis of substantive, strategic, and institutional learning we can conclude that the collaborative activities of the German VCI have strongly contributed to effective nanomaterials OHS regulation. Furthermore, the findings enable us to validate our assumptions as to the relationship between the three types of learning (see section 4.3). Thus, our assumption that trust among collaborators is a pre-condition for knowledge exchange and facilitates the generation of new scientific facts appears confirmed. More specifically, we may say that strong trust among collaborators appears to facilitate the exchange of valuable scientific knowledge and the generation of many scientific facts. Furthermore, we assumed that trust among collaborators, in combination with knowledge exchange and the development of new scientific facts, facilitates joint rule development. Based on the empirical results we can adapt this assumption: Strong trust among collaborators, combined with strong scientific expertise, appears to facilitate the process of joint rule development among collaborators.

The collaborative activities of the VCI have strongly contributed to effective nanomaterials OHS regulation. By sharing knowledge and generating nanomaterials (risk) data, it was shown that there were, and still are, scientific data gaps related to certain nanomaterials. In this context of scientific uncertainty, actors in the German OHS environment have learned to trust each other and, to jointly develop guidance material so as to support companies to conduct risk assessment for nanomaterials (see Table 7.14 for a summary).

Table 7.14. Overview learning in the VCI collaborative activities.

Substantive learning	**Strategic learning**	**Institutional learning**
Strong	Strong	Strong

Chapter 8

Comparing business association activities

This chapter compares the collaborative activities of the ACC Nano Panel with those of the VCI in view of their contribution to effective nanomaterials OHS regulation in the time period from 2003 to 2014. In doing so, it answers sub-ordinate research question 5: *What are the commonalities and differences between US and German collaborative business association activities with regard to effective nanomaterials OHS regulation?* In section 8.1, overall characteristics of association activities are compared. Findings from the analyses in chapter 6 and chapter 7 are described in section 8.2 and commonalities and differences among association activities are identified. This is done by following the structure of the analytical categories of the theoretical framework (developed in chapter 4). Doing so ensures comparability across the two cases. After the comparison a brief overview of the three learning types in the two cases is set out.

8.1 Overall characteristics of association activities

As the analyses presented in 6.2 and 7.2 have shown, both the ACC Nano Panel and the VCI have been involved in collaborative activities directed at contributing to nanomaterials OHS in their respective jurisdictions. Overall the number of association activities is similar: 19 for the ACC Nano Panel and 21 for the VCI.

All these activities may be considered as collective goods. This is important to note because selective goods cannot make a contribution to regulation since these activities are only accessible to members. However, as argued in section 3.2, association activities are said to necessarily center around the provision of both collective and individual (or selective) goods to their members.[122] When an association merely provides collective goods, non-member firms essentially free ride (Howard et al. 1999) on the benefits provided to others. In effect association membership and resources are limited, which may impact association sustainability.

However, this does not appear to be the case with the ACC and VCI. The associations have existed since 1872 and 1877 respectively and are the most predominant associations in the chemical sector within the US and Germany. Therefore the associations can be expected to continue to exist in the future. One explanation as to why it is apparently not necessary for the associations to provide selective goods related to nanomaterials OHS is that selective goods are provided in relation to other topics, e.g. environment, trade, security, energy (ACC 2013a), REACH as well as Technical Rules for Hazardous Substances (TRGS) (VCI 2014c). Thus, associations can attract members, and gain income, through membership rates by offering non nano-specific selective activities. Nanomaterials OHS is but one topic amongst many in which the associations engage.

Therefore, in the evaluation of business association activities in a particular area such as nanomaterials, we shall need to keep in mind that associations are organized around

[122] See section 3.1 (pp. 43-46) for an elaboration on the importance of collective and selective association goods.

multiple interests. The sum of these interests accounts for association durability, rather than engagement on a particular topic.

Association activities that are considered relevant in the context of this thesis (see 4.1), i.e. activities of the type knowledge exchange that may result in the development of rules, have been investigated in view to their contribution to effective nanomaterials OHS regulation. Both the ACC Nano Panel and the VCI have initiated activities of the type knowledge exchange. However, the number of relevant activities differs. Accordingly, three activities of the ACC Nano Panel have been investigated:

1. the foundation and meetings of the ACC Nano Panel (2005),
2. the NanoRelease Consumer Products research project (2011), and
3. the Workshop on Strategies for Setting Occupational Exposure Limits for Engineered Nanomaterials (2012).

In comparison, seven collaborative activities of the VCI were considered relevant:

1. the foundation and meetings of the VCI/DECHEMA RPaUoN (2003),
2. the RPaUoN's development of their Roadmap for Safety Research on Nanomaterials (2007),
3. the VCI workshop I (2005),
4. the BAuA/VCI survey in (2006),
5. the VCI workshop II (2007),
6. the BAuA/VCI survey II (2011), and
7. the VCI/IG BCE workshop (2008) on the responsible use of nanomaterials.

In the following section the relevant activities of the two associations are compared in order to determine their contribution to effective nanomaterials OHS regulation.

8.2 Commonalities and differences of association contribution to effective nanomaterials OHS regulation

Collaboration among business associations and regulators is considered as having made a contribution to effective nanomaterials OHS regulation when learning of three types has taken place (substantive, strategic, and institutional learning). These learning types can support the preparation of compliance with the employer legal obligation to conduct risk assessment for nanomaterials through making traditional risk assessment frameworks (more) applicable to nanomaterials. Thereby a contribution to effective regulation is made. Accordingly, we have analyzed the relevant collaborative activities of the ACC Nano Panel and the VCI based on a theoretical framework, and its conditions for learning processes (see chapter 4, and Table 4.6). In the empirical analysis of learning we have differentiated between strong and limited learning (see section 4.3). In this section, we compare these results relative to each other by following the structure of the analytical framework. Firstly the commonalities among association activities are identified and described and, secondly, differences are delineated. Thus, what are the commonalities and differences regarding the two associations' contribution to substantive learning (see Table 8.1)?

Table 8.1. Conditions for substantive learning.

Substantive learning *Scientific expertise*	1. Relevant actors collaborate 2. Exchange of knowledge and (risk) data 3. Increased understanding of how to deal with core problems related to nanomaterials risk assessment, and 4. Generation of novel scientific facts

Considering the first condition (‘relevant actors collaborate’), a commonality among both associations is that they have ongoing and sustained cooperation with relevant actors. Such actors either hold the resource ‘knowledge/data’ or ‘decision-making authority’ in the area of OHS. Collaborators that participated in the association activities come from regulatory agencies, (federal) research institutes, and academia. More specifically, the ACC Nano Panel cooperated with representatives from OSHA, NIOSH, ILSI, and with scientists from various universities. The VCI has collaborated with BMAS, BMBF, EC DG Employment and Industry, BAuA, BfR, and with various scientists from universities (see Table 8.2). In difference to the ACC Nano Panel, the VCI collaborated closely with another association of the type ‘Mixed’ and, in this relation, with the work group RPaUoN.

Comparing the results in the second condition (‘exchange of knowledge and (risk) data’) shows also commonalities but likewise important differences. As to the former, we see that knowledge exchange in three forms (sharing data in aggregate form, general experiences, evaluating state-of-the-art data) has taken place in the collaborative activities of both associations. In contrast, knowledge exchange in the form of collecting published data has only been observed in a collaborative activity by the Panel. And sharing raw data with collaborators has only been observed in VCI collaborative activities.

In the third analytical category (‘increased understanding of how to deal with core problems related to nanomaterials risk assessment’) a comparison of the results reveals important commonalities. All investigated collaborative activities by the two associations appear to have contributed to a better understanding of aspects and challenges related to exposure and release measurement of nanomaterials. In addition, the meetings of the RPaUoN and their work on the Roadmap for nanomaterials allowed for a better comprehension of the human toxicology of certain nanomaterials.

Lastly, when comparing the results of the fourth condition (‘generation of novel scientific facts’), we see that both associations have generated new facts in the area of exposure and release measurement. More specifically, the activities of both associations have led to joint image building[123] (Koppenjan & Kljn 2004). In other words, knowledge has been exchanged and negotiated among the collaborators and agreements about insights based on research findings, that are scientifically defensible, were reached. However, the VCI has, relative to the ACC Nano Panel, contributed to the generation of more facts, in more areas, relevant for making risk assessment applicable for nanomaterials (see, for an overview, Table 8.2). Thus, overall we can observe that the collaborative activities of the VCI have contributed to substantive learning slightly more strongly than those activities of the ACC Nano Panel.

[123] See the definition in section 4.3 (p. 67).

Table 8.2. Comparison ACC Nano Panel and VCI substantive learning.

Association	Commonalities	Differences
	1. Relevant actors collaborate	
ACC	**• Regulators** ACC: Panel meetings, NanoRelease, OEL workshop (OSHA) VCI: RPaUoN meetings, VCI workshops, VCI & IG BCE workshop (BMAS, BMBF, EC DG Enterprise & Industry) **• (Federal) research institutes** ACC: Panel meetings, NanoRelease, OEL workshop (NIOSH, ILSI) VCI: RPaUoN meetings, VCI workshops, BAuA & VCI surveys, VCI & IG BCE workshop (BAuA, BfR) **• Academia** ACC: NanoRelease, OEL workshop (universities) VCI: RPaUoN meetings, VCI workshops, VCI & IG BCE workshop (universities)	
VCI		**• Association** DECHEMA: RPaUoN meetings
	2. Exchange of knowledge and (risk) data	
ACC	**• Sharing data in aggregate form** ACC: Panel meetings, NanoRelease VCI: RPaUoN meetings, Roadmap nanomaterials, VCI workshops, BAuA & VCI surveys **• Sharing general experiences** ACC: NanoRelease VCI: VCI workshops, BAuA & VCI surveys, VCI & IG BCE workshop **• Evaluating state-of-the-art data** ACC: OEL workshop VCI: RPaUoN meetings, Roadmap nanomaterials	**• Collecting published data** OEL workshop
VCI		**• Sharing raw data** RPaUoN meetings, Roadmap nanomaterials
	3. Increased understanding of how to deal with core problems related to nanomaterials risk assessment	
ACC	**• Exposure & release measurement** ACC: Panel meetings, NanoRelease, OEL workshop VCI: RPaUoN meetings, Roadmap nanomaterials, VCI workshops, BAuA & VCI surveys, VCI &IG BCE workshop	
VCI		**• Human toxicology** RPaUoN meetings, Roadmap nanomaterials
	4. Generation of novel scientific facts	
ACC	**• Exposure measurement** ACC: NanoRelease VCI: RPaUoN meetings, BAuA & VCI surveys	**• OELs for nanomaterials** OEL workshop
VCI	**• Release measurement** ACC: NanoRelease VCI: RPaUoN meetings	**• Exposure measurement techniques & methodologies** RPaUoN meetings, BAuA & VCI surveys **• Exposure assessment** RPaUoN meetings, BAuA & VCI surveys **• (Health) hazards** RPaUoN meetings, BAuA & VCI surveys, **• Toxicity** RPaUoN meetings, BAuA & VCI surveys **• Dustiness & agglomerate stability** RPaUoN meetings **• Behavior (uptake in somatic cells: in vitro; blood-brain barrier: in vivo**) RPaUoN meetings **• Nanomaterials handled in workplaces** BAuA & VCI surveys **• Health & safety measures** BAuA & VCI surveys

Next, the process of building and maintaining trust among collaborators (strategic learning) was analyzed in respect to the ACC Nano Panel and VCI collaborative activities (see chapter 4, Table 8.3).

Table 8.3. Conditions for strategic learning.

Strategic learning *Trust*	1. Meetings over a longer period of time 2. Intensified actor relations 3. Reliance among collaborators 4. Realization of common goals 5. Disagreement among collaborators is addressed and solved, and 6. Development of additional collaborative activities

Comparing the results of the analysis regarding the first condition ('meetings over a longer period of time') shows that the activities of the two associations have various commonalities. No differences were observed. As such, all collaborative activities can be grouped into three kinds of meetings:

1. short-term meetings (i.e. one-time meetings),
2. long-term meetings (over, at least, a period of nine years), and
3. medium-term meetings (over, at least, a period of three years).

Both the ACC Nano Panel and the VCI activities provide at least one example for each form of meeting (see Table 8.4).

When collaborators have opportunities to meet over a period of many years, relationships may intensify and trust may develop. In this respect, the results of the analysis in the second condition ('intensified actor relations') show that the collaborators in both association networks had most opportunities for deepening relationships through non-public meetings. These meetings of the ACC Nano Panel included primarily association members (only to the end-of-the-year meetings selected externals were invited). In contrast, the non-public meetings in the VCI network included actors from all relevant stakeholder groups and therefore provided opportunities for intensifying relations among a larger set of actors.

Furthermore, the empirical results show that workshops, in themself, provide only limited possibilities for actors to strengthen relationships. However, in the case of the VCI, it would appear that the workshops were nevertheless useful for deepening relationships; this is why these workshops were taking place in concert with other, government-, and industry-organized, meetings in which the relevant actors participated (e.g. the NanoDialog, the BASF Dialogforum Nano).

The analysis of the Panel's collaboration through NanoRelease shows that research projects can provide some opportunities for actors to intensify relationships.

Regarding the third condition ('reliance among collaborators') we investigated whether collaborators have, on the basis of intensified relations, developed reliance in the sense of 'trust beyond control'. The results of the two case studies indicate that reliance among collaborators has developed generally. This was visible predominantly in that actors have exchanged knowledge and information that appeared not to be protected by private law instruments such as contracts and non-disclosure agreements. Collaborators shared knowledge with the assumption that others would not use such information 'against them'.

While knowledge sharing as sign of reliance is a commonality in ACC Nano Panel and VCI collaborative activities, there are differences in the strength of this reliance. This is visible in the kind of knowledge that was exchanged in relation to its risk of misuse by others: the more costly exchanged information is, the higher the risk for misuse is and therefore the more trust is required to exchange such information. Accordingly, in the Panel network data in aggregate form was exchanged (no examples of misuse). In comparison, in the VCI network, more costly, raw data has been shared (no examples of misuse either).

In the context of knowledge exchange and joint deliberation we observed what appeared to be distrust among certain actors in the ACC Nano Panel network, while distrust was not observed in the VCI network. More specifically, from the entire sample of 15 interviewees in the Panel case study, two interviewees (representatives from academia and an NGO) voiced distrust in the ACC due to past experiences in collaborations where the association had hindered knowledge exchange. In the VCI network no examples of distrust were observed; concomitantly there were various examples of trust among collaborators from all stakeholder groups. For instance, when the VCI distributed the BAuA/VCI surveys (2006/2011) among its members the association relied on the BAuA to not use the thus generated data in a way that would have negative consequences for the chemical industry. In turn, BAuA relied on the VCI to have encouraged their members to actively participate in the surveys.

In the fourth condition ('realization of common goals'), we analyzed whether trust among collaborators has developed, being visible in that actors give preference to the realization of common network goal(s) over their individual goals in the collaboration. In this respect, a commonality among the two associations' activities is that common goals have been defined on the basis of individual goals of the collaborators. Following this strategy helps to avoid goal divergence. Looking more closely, we see differences in the way these common goals were agreed upon: in the Panel network, collaborators decided on the common goals through voting. In the VCI network, this decision was reached most commonly by making an inventory of individual actor goals through an independent body. Based on the results of this inventory, common goals were identified and balanced with individual actor goals.

Rather than actively dealing with the issue of goal divergence, within the ACC Nano Panel network it appears that the focus was to prevent these situations to occur in the first place. In this context, a twofold strategy was observed:

1. situations where collaborators may consider pursuing individual goals were actively prevented (e.g. through having agendas in place that prescribe which topics are to be discussed in meetings), and
2. common goals have been continuously emphasized by placing discussions on the level of science, where collaborators have common objectives–i.e. to advance the science of nanomaterials–and are more readily accept diverging opinions.

An implicit agreement, rather than conscious decision, to pursue a specific common goal was observed in the VCI network. Due to past experiences of 'technological failure' related to the introduction of GMOs in Germany, collaborators implicitly pursued the common goal of preventing a similar 'disaster' in the context of nanomaterials.

With regard to the fifths condition ('disagreement among collaborators is addressed and solved'), we investigated how disagreement and conflict has been dealt with and whether this led to weakened or strengthened trust relations. In both the Panel and VCI networks, a common approach to dealing with disagreement among collaborators was to accept diverging opinions on certain issues and to report these openly. Thus, the goal was not to achieve consensus by all means.

Against this backdrop, important differences are visible: in the Panel network, collaborators appeared to focus on preventing disagreement while those in the VCI network appear to acknowledge disagreement as a ‘natural’ aspect of collaboration. Some actors even sought disagreement as a way to enable lively, in-depth discussions that further arriving at meaningful results. It is therefore not surprising that in the VCI network many examples of disagreement were observed. In comparison, in the ACC Nano Panel network only one example of disagreement was reported. As such, it would appear that members in the VCI network, relative to those in the Panel network, showed trust that disagreements is handled and solved to their satisfaction. However, it should be acknowledged that there was no evidence that the way how disagreement was handled in the two networks led to a decrease of trust among collaborators.

In the last condition for the analysis of strategic learning (‘development of additional collaborative activities’) we investigated whether new collaborative activities were organized in the two networks. This would indicate that past, and present, relationships among actors were based on overall trust and related to positive experiences in working together. The results show that both associations have realized two kinds of additional activities:

- the continuation of already existing activities (i.e. the Panel’s and RPaUoN’s regular meetings), and
- new research projects.

As to the latter, some collaborators within the Panel network have been involved in the research project NanoCharacter (2013). The VCI network collaborators have become involved in NanoCare I (2005) and NanoCare II (2013). We also see differences among the two associations: one of the Panel activities has led to the foundation of a new work group (which has, however, met only once) while various VCI activities have contributed to the development of new collaborative activities in a wider web of collaboration. This web of collaboration has been established by the German government (e.g. the NanoDialog between 2006 and 2011) and industry (e.g. the BASF Dialogforum between 2009 until today (2014)).

Based on this comparison it would appear that collaborators in the VCI network have developed relatively stronger trust in each other compared to collaborators in the ACC Nano Panel network. While the activities of both associations have contributed to strategic learning there are indications that trust among actors in the VCI network is relatively stronger when compared to those in the Panel network. This is supported in four aspects:

1. In the VCI network, the actors had more opportunities for interaction in face-to-face meetings and therefore for intensifying relationships that provide an essential foundation for the development of trust.
2. The actors in the VCI network showed stronger reliance, which is visible in that they have exchanged knowledge in form of raw data. This bears a bigger risk for opportunistic behavior by others, compared to exchanging data in aggregate form; the latter type of knowledge exchange was most common in the ACC Nano Panel network.
3. In the VCI network, disagreement was a 'natural' aspect of the collaboration and actors trust that disagreement can be resolved with some actors valuing disagreement as providing opportunities for lively, intense discussions that can yield innovative results to problems; in the ACC Panel network disagreement was prevented, and
4. In the VCI network no instances of distrust were observed; in the ACC Nano Panel network distrust was visible (i.e. certain representatives of academia and NGOs distrust the ACC).

It should be acknowledged that in the two networks additional collaborative activities occurred. This is usually a sign that collaborators trust each other. However, since both associations have initiated such additional activities, we have no indications that point towards stronger or less strong relationships in one or the other network.

Table 8.4. Comparison ACC Nano Panel and VCI strategic learning.

Association	Commonalities	Differences
	1. Meetings over a longer period of time	
ACC	**• Long-term meetings over a period of ≥ 9 years (2-4 meetings per year)** ACC: Panel meetings VCI: RPaUoN meetings, Roadmap nanomaterials **• Medium-term meetings over a period of ≥ 3 years (1 meeting per year)** ACC: NanoRelease VCI: VCI workshops, BAuA & VCI surveys **• Short-term meetings (one-time meeting)** ACC: OEL workshop VCI: VCI & IG BCE workshop	
VCI		
	2. Intensified actor relations	
ACC	**• Many opportunities through non-public meetings** ACC: Panel meetings VCI: RPaUoN meetings	**• Many opportunities through non-public meetings restricted to ACC members** Panel meetings **• Some opportunities through research project** NanoRelease **• Limited opportunities through non-public meetings to which few selected non-ACC members were invited** Panel end-of-the-year meetings **• Limited opportunities through workshop** OEL workshop
VCI		**• Many opportunities through non-public meetings involving VCI & non-VCI members** RPaUoN meetings, Roadmap nanomaterials **• Many opportunities through workshops in concert with government- & industry-organized meetings** VCI workshops, VCI & IG BCE workshop
	3. Reliance among collaborators	
ACC	**• Knowledge sharing without information being protected** ACC: Panel meetings, NanoRelease, OEL workshop VCI: RPaUoN meetings, Roadmap nanomaterials, VCI workshops, BAuA & VCI surveys, VCI & IG BCE workshop	**• Sharing data in aggregate form** Panel meetings, NanoRelease **• Indications of distrust** OEL workshop
VCI		**• Sharing raw data** RPaUoN meetings, Roadmap nanomaterials
	4. Realization of common goals	
ACC	**• Defining common goals on basis of individual goals** ACC: NanoRelease VCI: RPaUoN meetings, VCI workshops, BAuA & VCI surveys	**• Decision on common goals through voting** NanoRelease **• Forestalling situations where collaborators may chose to pursue individual goals** Panel meetings **• Placing discussions on the level of science** Panel meetings, NanoRelease, OEL Workshop
VCI		**• Decision on common goals by considering & balancing these with individual goals through an independent body** RPaUoN meetings, VCI workshops, BAuA & VCI surveys **• Implicit agreement on common goals** VCI & IG BCE workshop
	5. Disagreement among collaborators is addressed and solved	
ACC	**• Accepting & reporting diverging opinions** ACC: OEL workshop VCI: RPaUoN, VCI workshop (2007), VCI & IG BCE workshop	**• Preventing disagreement** Panel meetings, NanoRelease
VCI		**• Disagreement as 'natural' aspect in collaboration** RPaUoN meetings
	6. Development of additional collaborative activities	
ACC	**• Continuation of existing activities** ACC: Panel meetings VCI: RPaUoN meetings **• New research projects** ACC: NanoRelease: NanoCharacter VCI: RPaUoN meetings: NanoCare I, NanoCare II	**• Establishment of a new work group** OEL workshop
VCI		**• New activities in a wider web of collaboration** VCI workshops, BAuA & VCI surveys, VCI & IG BCE workshop

Lastly, we have investigated institutional learning by means of three conditions (see chapter 4, Table 8.5).

Table 8.5. Conditions for institutional learning.

Institutional learning *Rules*	1. Development of informal agreements 2. Design of soft rules of behavior, and 3. Soft rules become 'hardened'

In regard to the first condition ('development of informal agreements') we have studied the development of rules to facilitate, and stabilize, processes of collaboration (process-oriented rules), as well as rules to provide guidance on how to handle nanomaterials at workplaces most safely (problem-oriented rules). In respect to process-oriented rules, commonalities among the two collaborative networks were visible; both had an unwritten, implicit agreement in place for dealing with requests by externals for collaboration-internal information. However, how such requests are dealt with differs across the two networks. In the Panel meetings, association staff evaluates whether such requests come from trustworthy individuals and, on this basis, Panel members decide individually what kind of information they want to provide. In comparison, the RPaUoN members evaluate whether externals are trustworthy and, accordingly, they decide individually what information they want to provide. Another common, process-oriented agreement in the networks is the oral agreement among actors to organize follow-up activities. In this respect, an additional oral agreement that is visible only in the Panel network is the exchange of information on nanomaterials OHS matters with a federal research institute on ad hoc basis, regardless of whenever a need to do so, or not, emerges.

No problem-oriented agreements were identified in the Panel network. In contrast, such agreements have been made in the VCI network. Accordingly, in various collaborative activities representatives of the association, regulators, federal research institutes, academia, and industry have agreed to define the state-of-the-art of nanomaterials and to collect data relevant for the risk assessment of nanomaterials. This information was to be used for the development of soft rules to guide behavior on (specific aspects of) nanomaterials OHS including the conduction of risk assessment (see, below, Table 8.6).

With the next condition ('design of soft rules of behavior') we have analyzed whether oral agreements among collaborators had developed further–specifically into written soft rules. This was only observed in the VCI network. Here, the collaborators realized their agreement to collect (risk) data on nanomaterials and define the state-of-the-art on (certain) nanomaterials. On this basis, soft regulation in the form of guidelines for exposure measurement, standardizing toxicological testing and hazard assessment of nanomaterials were developed. These guidelines have since been updated by the collaborators after the development of new knowledge. In comparison, in the ACC Nano Panel network, a development from informal problem-oriented agreements into soft rules was not observed. Rather than contributing directly to the design of soft rules, the association appeared to have contributed indirectly to their development: by facilitating the generation of necessary scientific data, soft rules on exposure measurement and assessment were developed by a federal research institute (NIOSH).

Different process-oriented soft rules were developed in the two networks. The ACC Nano Panel developed rules to structure interaction among collaborators (e.g. meetings should be structured by agendas that determine possible points for discussion). In comparison, the RPaUoN had rules in place to restrict forwarding of collaboration-internal documents (e.g. minutes of meetings) to externals.

Lastly, as regards the third condition (‘soft rules become ‘hardened’’) we investigated whether soft rules had been formalized and, in doing so, became ‘hardened’. With respect to process-oriented rules, a hardening process was not observed in the two networks. Within the ACC Nano Panel network, problem-oriented rules had not been developed directly as a result of the investigated collaborative activities. Rather, a collaborator in the network (NIOSH) developed these rules, which became hardened through recommendation by the responsible regulatory agency in OHS matters (OSHA). In contrast, various problem-oriented soft rules had been developed directly in collaborative activities of the VCI became hardened.

In this respect, two forms of hardening were observed: first, the hardening of a guidance–i.e. the SOP for exposure measurement for nanomaterials (2009)–through its further development, by actors with high authority in the German political landscape (namely BAuA and the German Social Accidence Insurance), into the Tiered approach to an Exposure Measurement and Assessment of Nanoscale Aerosols Released from Engineered Nanomaterials in Workplace Operations (2011). Second, the hardening of two guidelines, by actors with decision-making authority on OHS matters–namely the German government and the Hazardous Substances Committee (AGS)–was observed. More precisely, the 2007 version of the BAuA/VCI guideline for handling of nanomaterials at workplaces was used as informative resource in the government-initiated NanoDialog in which many policy representatives participated. Furthermore, both the 2007 and the updated 2012 version of the guideline were used as informative resource by the AGS in order to develop a report on OHS aspects of nanomaterials (2010) as well as an Announcement (2013) that described the state of knowledge on nanomaterials.

Based on these results it would appear that collaborators in the VCI network have contributed much more strongly to the development of rules relative to the collaborators in the ACC Nano Panel network. While in both association networks process-oriented informal agreements were made, only in the VCI network, in addition, problem-oriented agreements were made. In the VCI activities we observed a move from informal agreements towards the development of rules and the hardening of these rules. This type of development was not visible in respect to the ACC Nano Panel activities (see Table 8.6).

Table 8.6. Comparison ACC Nano Panel and VCI institutional learning.

Association	Commonalities	Differences
	1. Development of informal agreements	
ACC	**• Dealing with external requests** ACC: Panel meetings VCI: RPaUoN meetings **• Follow-up collaboration** ACC: OEL workshop VCI**:** IG BCE workshop	**• Association staff evaluates which externals are trustworthy** Panel meetings **• Ad hoc information exchange** Panel meetings • No problem-oriented agreements
VCI		**• Collaborators evaluate which externals are trustworthy** RPaUoN meetings **• Definition of the state-of-the-art & data collection** RPaUoN meetings, VCI workshops, BAuA & VCI surveys
	2. Design of soft rules of behavior	
ACC		**• Indirect involvement in development of guidance material** Panel meetings **• Structuring interaction among collaborators** Panel meetings
VCI		**• Development of guidelines** RPaUoN meetings, VCI workshops, BAuA & VCI surveys **• Protecting internal documents** RPaUoN meetings
	3. Soft rules become 'hardened'	
ACC		
VCI		**• Continuous development of guidelines involving actors with political authority** RPaUoN meetings **• Reference to guidelines by actors with decision-making authority** RPaUoN meetings, VCI workshops, BAuA & VCI surveys

Having compared learning of three kinds in the collaborative activities of the ACC Nano Panel and the VCI we can derive that the latter activities have generally led to learning more strongly. In this context, least different among the two association activities appeared to be substantive learning. While both associations have developed a strong scientific expertise the VCI appears to take the forefront position. Most different among the association activities seems to be institutional learning. While this type of learning appeared strong in the VCI activities, the ACC Nano Panel facilitated this kind of learning only to a limited extent. Strategic learning was observed in both collaborative association activities. However, trust among collaborators in the VCI network appears to be stronger relative to the ACC Nano Panel network.

Chapter 9

Conclusion and recommendations

This chapter brings together the key findings from chapters 2–8 and answers the main research question of the thesis: *What can be learned from the activities by business associations, in the US and Germany, aimed at contributing to effective nanomaterials OHS regulation?* In answering this question, in section 9.1, the main findings are identified and the lessons learned are drawn. In section 9.2, concrete recommendations are set out on how to improve interaction in the investigated collaborative networks. In section 9.3, some methodological remarks are made, key findings are discussed and a proposal for future research in the area including hypotheses is provided.

9.1 Main findings

This research project has sought to understand, and evaluate, the contribution of business associations within the US and Germany, to the effective regulation of nanomaterials in OHS under conditions of scientific uncertainty. In addition to the legislative requirements set down by governments, business associations and regulators co-regulate nanomaterials through collaborative partnerships because it bears benefits for both parties: industry–by sharing their knowledge and health and safety data on nanomaterials–can possibly influence the development of (stricter) rules for nanomaterials. Regulators–by leveraging association data and knowledge–can deploy their decision-making authority to ensure that (existing) rules are evidence-based, i.e. are protecting the health and safety of employees adequately.

Business associations may contribute to the effective nanomaterials OHS regulation through preparing compliance for companies in which nanomaterials are manufactured and/or handled in workplaces with the employer's legal obligation to provide safe workplaces by conducting risk assessment for nanomaterials. Through knowledge exchange, and joint deliberation, the traditional risk assessment approach may be made (more) applicable for nanomaterials. Based on the generated knowledge, associations may develop soft regulation, which is based on the latest state of science and technology and that supports their member companies in conducting risk assessment for nanomaterials. In doing so, a crucial first step in the process towards effective regulation is realized.

By evaluating processes of collaboration among business associations and regulators, a process-oriented perspective to effective regulation is taken. When the collaborators learn how to improve traditional risk assessment frameworks for nanomaterials, based on newly developed scientific data or knowledge that may result in the development of soft regulation, the collaboration contributes to effective regulation. The soft regulation may increase the possibility for regulatee compliance if and when future hard regulation is implemented. When representatives of the regulated parties (i.e. industry) were involved fundamentally in the process of rule formulation, regulatees' willingness and capacity to comply with rules is likely to be higher.

Lessons from the theoretical framework and the case studies

In this part, the lessons learned related to the theoretical framework, developed in this thesis, and its application to the US and German situation, are spelled out.

When research question three ('how we can evaluate business association activities as a process towards effective nanomaterials OHS regulation') was answered, we developed an analytical framework that draws on the literature of networks governance. This literature points to the importance of learning among collaborators. Accordingly, three types of learning were distinguished:

1. substantive learning (with the key characteristic 'scientific expertise'),
2. strategic learning (with the key characteristic 'trust'), and
3. institutional learning (with the key characteristic 'rules').

These learning types were adopted and, based on the literature, we derived the conditions under which these three learning types emerge (in section 4.3, recapture Table 9.1).

Table 9.1. Theoretical framework with analytical categories and conditions for the evaluation of effective nanomaterials OHS regulation.

LEVEL	ANALYTICAL CATEGORY	CONDITIONS
Actor level	**Substantive learning** Characteristic: *Scientific expertise*	1. Relevant actors collaborate 2. Exchange of knowledge and (risk) data 3. Increased understanding of how to deal with core problems related to nanomaterials risk assessment, and 4. Generation of novel scientific facts
Game level	**Strategic learning** Characteristic: *Trust*	1. Meetings over a longer period of time 2. Intensified actor relations 3. Reliance among collaborators 4. Realization of common goals 5. Disagreement among collaborators is addressed and solved, and 6. Development of additional collaborative activities
Network level	**Institutional learning** Characteristic: *Rules*	1. Development of informal agreements 2. Design of soft rules of behavior, and 3. Soft rules become 'hardened'

We have also investigated whether these conditions 'work in practice' (see chapters 6 and 7). On this basis lessons are drawn on how to refine the conditions.

Before doing so, it should be noted that we differentiated between 'strong' and 'limited' learning, both on the level of the various types of learning and on the overall level. When many, i.e. the majority, of the conditions of a certain type of learning are met in the process of collaboration we speak of strong learning. When only a few, i.e. half or less, of the conditions of a certain type of learning are met we speak of limited learning. Additionally, when one learning type is defined as strong but the other two types are limited, we speak of overall limited learning.

Furthermore, based on the literature, throughout this thesis a certain order, or relationship, among the three types of learning has been assumed. We have assumed that trust among collaborators is a pre-condition, and amplifier, for knowledge exchange. And, that trust facilitates joint deliberations among collaborators, which may give rise to the generation of new scientific facts (see section 4.3). We have also assumed that trust among collaborators, in combination with knowledge exchange and the development of new scientific facts, facilitates joint rule development (see section 4.3). Considering the results of the empirical analysis (in chapters 6 and 7) we can now refine these assumptions.

Based on the analysis of the collaborative activities of the US ACC Nano Panel, the first assumption can be specified in the US context: *limited trust* among collaborators appears sufficient for these actors to exchange specified nanomaterials knowledge and data among each other. And, on this basis, to generate new scientific facts. As to the second assumption, *limited trust* among collaborators combined with *strong scientific expertise*, appears not to be sufficient for these actors to engage in rule development.

In this respect, based on the result of the VCI collaborative activities, we can refine the first assumption in the Germany context: *strong trust* among collaborators appears to facilitate the exchange of valuable knowledge and the generation of many new scientific facts. Regarding the second assumption we find that *strong trust* among collaborators, combined with *strong scientific expertise*, seems to facilitate the process of joint rule development among collaborators.

The proposed conditions for each of the three learning types were assumed to largely build upon each other. For instance, in the of category substantive learning, we assumed that, first, relevant actors have to collaborate so that, second, exchange of knowledge and (risk) data can take place. This would then, third, enable an increased understanding of how to deal with core problems related to nanomaterials risk assessment. On this basis, new scientific facts could be generated, which support making risk assessment (more) applicable to certain nanomaterials.

For *substantive learning*, the order of the conditions was met in both case studies. In addition, we can refine the second condition (knowledge exchange). Accordingly, we have learned that knowledge can be exchanged in five different forms (see Table 9.2).

Table 9.2. Refinement condition ‘knowledge exchange’

Forms of knowledge exchange
1. Sharing raw data
2. Sharing data in aggregate form
3. Collecting published data
4. Evaluating state-of-the-art data, and
5. Sharing general experiences

With regards to *strategic learning*, in both case studies, a clear order in the conditions was only visible in relation to conditions one to three. All six conditions for strategic learning were principally met in the two cases, albeit to varying levels. Thus, first, meetings over a longer period of time appeared to be required in order to be able to intensify actor relations (second). On this basis, third, collaborators would start to rely on each other. It could not be clarified whether reliance is required in order to be able to fulfill the fourth, fifth, and sixth condition (i.e. realization of common goals, disagreement among collaborators is addressed and solved, and development of additional collaborative activities). Thus, we need to better understand whether these conditions are antecedents, or consequences, of trust that has already developed among collaborators.

For strategic learning we can refine four conditions and, in addition, identify a relationship between conditions of two types of learning. As to the former, conditions one (‘meetings over a longer period of time’) can be specified. We have learned that a ‘longer period of time’ can be specified proportionately to one-time meetings (see Table 9.3).

Table 9.3. Refinement condition ‘meetings over a longer period of time’

Forms of meetings
1. Short-term meetings (one-time meetings)
2. Medium-term meetings (≥ three years), and
3. Long-term meetings (≥ nine years)

Furthermore, we can identify a relationship between condition three (‘reliance among collaborators’) and condition two of substantive learning (‘knowledge exchange’). A sign that reliance among collaborators is present is that actors exchange knowledge, which is not protected by private law instruments. In doing so, actors who share knowledge accept the potential risk that this information could be misued by others. In this respect, it has been found that specifically the exchange of costly knowledge (i.e. raw data) requires collaborators to rely on each other. This is why it can be expected that the more costly the exchanged information is, the higher the risk for misuse is, and therefore the more reliance as ‘trust beyond control’ is required for the exchange of such information.

We can also refine condition four (‘realization of common goals’) of strategic learning. The realization of common goals implies the broad agreement among actors on these goals. In this respect, we can differentiate between two forms of common goal agreement: explicit and implicit goal agreement with specific examples (see Table 9.4).

Table 9.4. Refinement condition ‘realization of common goals’

Forms of realizing common goals *Explicit goal agreement*	*Implicit goal agreement*
Deciding on common goals through voting	Pursuing a common goal due to past, broadly similarly conceived, experiences
Deciding on common goals by means of an inventory of individual actor goals through an independent body; based on the results, this body identifies underlying common goals	

In addition, condition five (‘disagreement among collaborators is addressed and solved’) may be refined. As such we can specify ways of addressing and solving disagreement (see Table 9.5).

Table 9.5. Refinement condition 'disagreement is addressed and solved'

Forms of addressing disagreement *Seeking disagreement as desirable aspect in collaborations*	 *Preventing disagreement as non-desirable aspect in collaborations*	**Forms of solving disagreement**
Reporting on diverging opinions by the collaborators openly and transparently		Accepting disagreement
	Structuring meetings by means of the topics that may be (not) discussed	
		Achieving consensus

The last condition for strategic learning ('developing additional collaborative activities') may also be refined. Accordingly, we can specify the forms of these activities (see Table 9.6).

Table 9.6. Refinement condition 'additional collaborative activities'

Forms of additional collaborative activities
1. Continuation of existing activities
2. Realizing new, individual projects, and
3. Realizing new activities in a wider web of collaborations

For *institutional learning* the order of the conditions were met in the VCI case only. The question as to why most of these conditions were not met in the ACC case is discussed in section 9.3. For now, we can refine condition one ('development of informal agreements'). As such, we find that five forms of informal agreements exist (see Table 9.7).

Table 9.7. Refinement condition 'development of informal agreements'

Forms of informal agreements *Process-oriented*[124]	 *Problem-oriented*
Dealing with requests by externals for collaboration-internal information	Collecting data and thereby defining the state-of-the-art
Organizing follow-up collaborative activities	Developing soft rules
Exchanging information	

Against the background of the three learning types and their conditions, more generally we have learned that it is important that relationships among collaborators are characterized by trust so as to facilitate knowledge exchange/generation and joint rule development. While trust appeared to be advantageous for learning processes in collaborative activities among business associations and regulators, it has also been said that trust among private actors and regulators can also have detrimental effects. Namely, under certain

[124] See section 4.2 (pp. 65-66).

conditions, trust can further capture[125]. Risk of capture was identified in the ACC Nano Panel network (see section 6.2.2).

The collaboration among OSHA, represented by one individual, and the Panel is based on trust, rooted in a personal relationship and a common background in industry. But since interaction among the two bodies does not entail elements of control, i.e. is merely based on informal agreements, it is possible that the particular OSHA representative might be captured by the interests of industry. Capture is fostered by the very same conditions that foster cooperation; through regular repetition of encounters with the same parties that nurtures reliance and trust. In this respect, we have learned that in order to prevent capture, formalized partnerships can be useful since personal interests and relationships among industry and regulators are kept 'in check' by the boundaries provided for by formal agreements. Furthermore, applying a form of tri-partism[126] can help securing the advantages of cooperation while avoiding capture.

Lessons from the comparison

In this part, we will derive the lessons learned from the comparison of the two business association collaborative activities. Chapters 6 and 7 have demonstrated that co-regulation among business associations and regulators is taking place within the US and Germany. In both jurisdictions associations have contributed to nanomaterials OHS regulation, though with different focal points.

The comparison of the two case studies (in chapter 8) indicated that, overall, the VCI appeared to have contributed more strongly to the effective nanomaterials OHS regulation through three learning types, relative to the ACC Nano Panel (see, below, Table 9.8). First, this would appear to be due to the generation of many new scientific facts in the VCI network that are relevant for all steps in the risk assessment for nanomaterials (substantive learning). In the ACC Nano Panel network, new facts were also generated, but they were restricted to release, exposure measurement, and possibilities for setting OELs for nanomaterials.

We consider the VCI to have, second, contributed more strongly to effective nanomaterials OHS regulation because the collaborators have developed relationships that are characterized by strong trust (strategic learning). In the Panel's network, limited trust among the collaborators was visible and distrust was observed in the relationship between the ACC and certain representatives from academia (and NGOs). The relationship between the ACC Nano Panel and the responsible agency in OHS matters, i.e. OSHA, appeared to be characterized by trust, which bears the risk of capture. In comparison, in the VCI network trust among the association and regulators appeared to be stronger. No risk of capture was identified due to the formalized nature of the collaboration, partly through the government-initiated NanoDialog, and also because third parties (e.g. NGOs and trade unions) were involved in the collaboration.

Third, the collaborative activities of the ACC Nano Panel have not directly contributed to the development of problem-oriented rules. Rather process-oriented rules were put in place to structure interaction among the collaborators (institutional learning). In the VCI network process-oriented soft rules were developed in order to guide interaction among actors in the network. But the focus of the VCI was more on developing problem-oriented soft rules. The latter were developed to provide guidance on how to conduct risk assessment for (certain) nanomaterials and thereby support compliance with the employer's legal obligations. The

[125] See section 3.2 (pp.48-49) for an elaboration on the concept 'capture'.
[126] See section 3.2 (pp. 48-49).

latter became hardened through reference and take-up by the AGS and the participants of the NanoDialog.

In this respect, the ACC Nano Panel did not seem to focus on supporting ACC member companies in conducting risk assessment for nanomaterials, in order to help them prepare compliance with existing OHS regulation. Instead, the Panel appeared to focus, instead, on preempting potential future regulation: through collecting and generating nanomaterials (risk) data the Panel acknowledged that some data gaps exist, which however, can be closed through research. The Panel contributed to closing (some) of these data gaps and used these efforts to demonstrate that the traditional risk assessment framework can, in principal, be made applicable for nanomaterials. Therefore the Panel argued that existing regulation is sufficient and that no new, nano-specific regulations are required. In this context it was not evident that OSHA has used, or will use the knowledge generated by the ACC Nano Panel to develop new, or concretize existing, legislation applicable to nanomaterials that are handled in workplaces.

In contrast to the Panel, the VCI developed various soft regulation instruments to support their member companies in conducting risk assessment for nanomaterials. As such, the association prepared compliance with existing OHS regulation. This is a crucial first step in the process towards effective nanomaterials OHS regulation.

German regulators have taken up the new knowledge. Specifically, the BMBF has used the knowledge generated in the collaborative activities to decide in which areas more research on the health risks of nanomaterials is desired and where data gaps have been closed. Additionally, the AGS, as an advisory body to BMAS, has taken up the newly generated knowledge to ensure that workers are evidently (i.e. based on the latest state of science and technology) protected from the potential health risks of nanomaterials.

Table 9.8. Comparison business association contribution to effective nanomaterials OHS regulation.

Business associations	**Learning** *Substantive learning*	*Strategic learning*	*Institutional learning*
ACC Nano Panel	Strong	Limited	Limited
VCI	Strong	Strong	Strong

9.2 Recommendations

Based on the empirical analysis of association activities (chapters 6 and 7) we have gained important insights on how private-public governance networks contribute (not) to effective nanomaterials OHS regulation. Based on these findings, and the results of the comparison of association activities (chapter 8), we can formulate concrete recommendations for the two collaborative networks, which may help advance collaboration. We thus make three recommendations, based on the empirical results as well as the literature, related to the three types of learning:

1. facilitating the generation of new scientific facts,
2. facilitating trust among the collaborators, and
3. facilitating rule development.

After an elaboration of these points in the context of the two case studies, we arrive at a series of recommendations.

The first recommendation for the ACC Nano Panel and the VCI networks, in order to advance collaboration, is to facilitate the generation of new scientific facts. In this respect, it is recommended that the generation of new scientific facts can be supported through ensuring that a heterogeneous set of relevant actors are involved in any collaborative activities. Nooteboom et al. (2007) have stressed, when actors with different backgrounds, experiences and viewpoints come together and are able to work together, there is an innovative advantage. As such, cognitive distance among the collaborators opens up new ways of thinking.

In other words, the composition of relevant collaborators can be important for creating opportunities to arrive at innovative solutions to the problem of effective nanomaterials OHS regulation. This reasoning seems to apply to our two case studies. For, as we have seen, membership in the ACC Nano Panel is homogenous (see section 6.1). The Panel is made up exclusively of representatives from multinational chemical companies.[127] In contrast, membership of the VCI/DECHEMA RPaUoN is heterogeneous.[128] While many innovative, new facts have been generated based on the collaboration in the RPaUoN (heterogeneous membership), in comparison, the ACC Nano Panel itself has not generated new facts (homogenous membership).

Against this background, in order to facilitate the generation of new scientific facts, it is recommended that the ACC Nano Panel may want to include members that are not representatives of multinational chemical companies but, for instance, representatives of SMEs.

The second recommendation, in order to advance collaboration in the two networks, is to help facilitate trust among the collaborators and/or ensure that existing trust prevails. Accordingly, Table 9.9 gives an overview of the recommendations.

Table 9.9. Recommendations to facilitate trust among collaborators.

How to facilitate trust among collaborators
• Overall, it is useful for associations to organize in-depth talks with the collaborators (e.g. through interviews) in order to understand their viewpoints and opinions in relation to the collaboration. Doing so makes implicit actor interests and assumptions explicit and issues that may hinder/support the process of trust building can be identified and considered.
• In order to facilitate trust building–as well as maintaining existing trust–it is useful to organize repetitive, non-public meetings in which collaborators can get to know each other in a ‘safe environment’ and intensify their relationships with each other.
• The ‘natural’ process of intensifying relationships may be supported ‘artificially’ by making an inventory of the individual goals of actors in the collaboration thorough an independent body. By communicating the results of this inventory to all participants, the ‘natural’ process of familiarization is facilitated and actors come to know ‘what makes other collaborators tick’.
• The same conditions that foster trust building among industry and regulators–i.e. repetition of encounters with the same parties–also foster capture. Formalized partnerships and application of a form of tri-partism can help to avoid capture through keeping ‘in check’ personal interests and relationships among industry and regulators by the boundaries of formal agreements/third parties while securing the advantages of trust among collaborators.

[127] See section 6.1 (pp. 86-87).
[128] See section 7.1 (pp. 118-119).

Lastly, a third recommendation can be made in respect to the facilitation of rule development. In this context, it is recommended to have a suited 'network manager'[129] in place in order to facilitate the development of rules to make collaborative structures sustainable and/or to provide support on how to conduct risk assessment for nanomaterials. Doing so may help facilitate ongoing learning and thereby contribution to effective nanomaterials OHS regulation.

A network manager is an actor (group) that functions as point of intersection in a collaborative network and that takes up responsibility naturally over time in the process of cooperation. Network management is a form of steering on the meta-level to promote cooperative strategies, which may be directed at facilitating interaction among actors (Friend et al. 1974), or at creating or changing structures to facilitate improved coordination (Scharpf 1978). But network management can also be useful for building and improving trust-relationships among actors (McGuire 2006; Huxham 2003). Thus, management from the network perspective refers to mediating and guiding interaction among actors (Kickert et al. 1997).

Based on the theoretical discussion in chapter 4 and the empirical results of chapters 6 and 7, we can derive four characteristics that appear decisive for a network manager in order to be able to successfully facilitate rule development (see Table 9.10).

Table 9.10. Characteristics of a suitable network manager.

What a network manager should possess
1. ability to participate in debates on a scientific and political level (i.e. be a relevant actor in the context of nanomaterials OHS)[130],
2. being independent (i.e. not have 'hidden', or biased interests in the debate),
3. having a central position in the network (i.e. have connections to all actors), and
4. being trusted by most actors in the network (i.e. can facilitate open exchange of ideas).

Considering these characteristics, in the ACC Nano Panel network, a suitable network manager would be NIOSH. The Institute is independent and has participated in the scientific and political debates on nanomaterials OHS in the US, and globally, since the establishment of its Nanotechnology Research Center (NTRC) in 2004 (NIOSH 2012). In this respect, NIOSH has established relationships with the collaborators of the ACC Nano Panel and beyond (on global level). Among all NNI participating agencies, NIOSH is the most valued by stakeholders and is identified as lead agency for gaining information on EHS issues (GAO 2012). NIOSH can thus be considered as already having a central position in the network. Furthermore, the Institute appears to be trusted by the actors in the collaborative network.

However, certain companies (especially SMEs) continue to be skeptical whether the Institute is a trustworthy partner because there may be the potential that NIOSH could share

[129] See section 4.2 (p. 61).

[130] 'Relevant' actors in the context of nanomaterials OHS, with the challenges of making risk assessment applicable to nanomaterials, are those who bring the resources 'knowledge and data' or 'decision-making authority' into the collaboration (see section 4.3).

sensitive information with OSHA who, in turn, could use this information for its enforcement activities (Interviewee 5, federal research institute; 4, industry). Yet, over the years, and based on its commitment to convincing companies that they act in their best interest, this study suggests that NIOSH has not merely gained the trust of industry but a much larger set of stakeholders (Interviewee 10, academia; 8, law consultancy; 5, federal research institute; 4, industry).

In the VCI network, a suitable network manager could be BAuA. Comparable to NIOSH, the BAuA is independent and has participated in scientific and political discussions on nanomaterials OHS in Germany since 2003. Since 2005, nanomaterials have been part of the strategic program of the BAuA (under the heading chemical safety). The Institute has taken a central position in the German network around nanomaterials OHS by actively engaging in the organization of various workshops, seminars, and surveys and through having pushed (jointly with the BfR and UBA) for the organization of the NanoDialog. BAuA's central position in the German OHS landscape is also reflected in its joint development of guidance material and in its administration of the AGS. Furthermore, the Institute appears to be trusted by the actors in the network including industry and specifically SMEs (BAuA 2008; VCI 2005, 2007b). No evidence of distrust was found in this research.

Against this backdrop, it appears that federal research institutes, i.e. BAuA and NIOSH, would be suitable network manager that can generally facilitate the development of rules to make collaborative structures sustainable and/or to provide support on how to conduct risk assessment for nanomaterials.

More specifically, it is recommended that NIOSH and BAuA could act as network managers each with specific key tasks as emerging from the characteristics of the two collaborative networks. In the US network, a suggested task for NIOSH would be to further strengthen trust, especially between the ACC and academia.[131] And also to overcome concerns among companies as to the handling of their data. The Institute has already engaged in this task implicitly. By explicitly acknowledging this role of NIOSH, e.g. through ascribing the Institute a formal position within the NNI, the exchange of knowledge and the generation of new facts relevant for ensuring health and safety at workplaces where nanomaterials are handled could be facilitated.

In Germany, network management could, and should, focus on maintaining the collaborative structures and relations among actors that have been established in the context of nanomaterials OHS. These structures can be utilized and leveraged in order to continue contributing to the effective regulation of nanomaterials. In addition, the Institute could accompany the process of rule development (including the update of existing rules) for nanomaterials OHS. BAuA seems to already fulfill this task, albeit in an informal manner.

The analysis of institutional learning in the VCI network has shown (see section 7.2.1), that a progression from soft to hard(er) rules for nanomaterials OHS is taking place. BAuA had, and still has, an important role in this development. It has, jointly with the VCI, developed the Guidance for Handling and Use of Nanomaterials at the Workplace (2007) as well as its updated version Empfehlung für die Gefährdungsbeurteilung bei Tätigkeiten mit Nanomaterialien am Arbeitsplatz (2012). Certain aspects of the two guidelines have become further hardened through the Hazardous Substances Committee, which is administered by BAuA. The Committee had referred to, and used, these guidelines as resources in the development of its Announcement on Hazardous Substances 527 (2013).

Through the Institute's continuous involvement, it can be ensured that rules are developed, which are useful from both a scientific and political point of view and which can be complied with by all companies in the chemical sector, independent of their size. In this respect, whether or not it is desirable to formalize BAuA's position as a network manager is

[131] See, section 6.2.2 (pp. 103-104).

debatable because the Institute appears to already provide useful support to the collaborators through this informal position.

Against this backdrop, it shall be important to learn, through empirical research beyond the two networks, whether we can speak of federal research institutes more generally as suited bodies for the management of private-public collaborative networks in the context of nanomaterials. This may be important because, depending on the characteristics of a network, a managing entity must fulfill tasks of different nature. For instance, network management can be a solution when actors are not aware with whom they are linked, or they cannot agree on common (regulatory) goals (McGuire 2006; Goldsmith & Eggers 2004; Huxham 2003). In this respect it shall be necessary to acknowledge that while federal research institutes may be willing to fulfill such tasks, capacity problems related to questions such as ‘who is going to pay for it?’ may hinder active engagement. One possibility, specifically in Europe, could be to finance network management through public funding schemes for research projects on the responsible research and innovation (RRI) of new and emerging technologies.

9.3 Discussion and outlook for future research

The goal of this thesis was to find conditions, including relations between them, under which collaborative business association activities that involve regulators contribute to effective regulation through learning processes. Due to the tentative character of this research, and the selection of certain scope conditions (see chapter 5), the results of this study cannot be readily transferred to other regulatory contexts beyond Europe and the US. Nevertheless, this thesis has demonstrated that the collaborative activities of two business associations in Germany and the US can have an impact on effective nanomaterials OHS regulation.

In this context it shall be acknowledged that the field of nanomaterials is highly dynamic. The scientific knowledge base on specific nanomaterials is constantly developing, new knowledge becomes available and old knowledge quickly becomes obsolete. This thesis provides a snapshot on issues in the regulation of nanomaterials OHS that appeared important at the time of research (2011-2014). In the future other issues, for example aspects of enforcement, may be more significant in aiming to ensure effective nanomaterials OHS regulation. It shall be important to see how the field of nanomaterials develops in the future and how regulators will deal with emerging issues as science progresses.

Nevertheless, based on these findings we can define some hypotheses to be studied in future research on co-regulation among business associations and regulators under conditions of scientific uncertainty. As such, four hypotheses have been formulated:

H_1: Business associations share specialized knowledge with regulators and engage in joint deliberation processes that result in the generation of new scientific knowledge when relations are based on limited trust.

H_2: Associations are willing to exchange more valuable scientific knowledge and data when relationships among business associations and regulators are based on strong trust.

H_3: Joint development of rules among business associations and regulators, based on knowledge exchange and the generation of new scientific facts, is likely when the collaborator relationships are based on strong trust.

H_4: Overall, co-regulatory arrangements involving business associations and regulators are more successful in contributing to effective regulation when interaction and interests are managed by a trusted, independent body that has connections to all collaborators and operates at the intersection of science and policymaking.

Testing these hypotheses in a broader population of cases shall yield new, and useful, insights on the particular conditions under which the collective capacity of associations can be leveraged by regulators to the advancement of (existing) regulation.

Such research will contribute to the literatures on (decentered) regulation and co-regulation involving industry and public actors.

In the effective regulation of new technologies characterized by high scientific uncertainty, with nanomaterials being an example of such a technology, it is useful to diverge from the traditional perspective on effective regulation. Complementary to focusing on the outcome of rule compliant behavior in order to determine the effectiveness of regulation, it is useful to investigate processes of learning that prepare for rule compliance. The empirical analysis in this thesis is a preliminary step towards building a theory of learning in collaborative networks that can support regulatory process effectiveness under circumstances of scientific uncertainty.

The empirical research has provided us with insights into understanding how certain conditions of the three types of learning (i.e. substantive, strategic, and institutional learning) work in the practice of the two cases. In order to build a theory on regulatory process effectiveness the next steps are to explain the necessary conditions under which these indicators are met. This includes also exploring the identified (causal) relations between the three types of learning.

This thesis has found indications that rule development seems to be facilitated when collaborators show strong trust in each other. Conducting further research on the possibility for trust to influence rule development is important in view of the regulatory process (i.e. rule setting, implementation including rule compliance, and enforcement) (Black & Baldwin 2010; Levi-Faur 2010; Scott 2010; Black 2002; Scott 2002). More specifically, if trust influences rule development when private and public actors are involved, this has implications for the preparing compliance.

So far, regulatory studies have not strategically approached the issue of trust among regulators (public actors) and regulatees (private actors) in the effective regulation of new technologies. Empirical research on how to build, and maintain, trust among co-regulators can be useful in order to understand and to support the longevity of co-regulation among a multitude of collaborators. Since business regulation is said to increasingly emanate from the private sector and multi-stakeholder public-private operations (Eberlein et al. 2014), researching the role of trust shall be important.

In this context, it shall be necessary to understand under which specific circumstances trust builds up, or declines, and how co-regulators can be supported in trusting each other. More specifically, as this study has suggested different types of meetings–i.e. long-term, medium-term, or short-term meetings–may support the development of trust among collaborators. It is therefore important to better understand under which circumstances which types of meetings can facilitate trust building most favorably; or, whether long-term meetings are to be preferred by default.

It shall also be necessary gain a better understanding of the influence of disagreement on trust within these relationships. In this study we have seen that experiences of disagreement can strengthen trust, but likewise such experiences can lead to the decline of trust. As such, it may be important to distill the specific circumstances under which disagreement likely furthers trust in the relationships of collaborators.

Finding answers to these questions shall be crucial in the context of understanding the effectiveness of co-regulation. In this respect, the literature on trust in the field of inter-organizational studies can provide useful points of entry.

Learning in collaborative networks in the context of political systems

The possibilities for developing trust among regulators and industry, and more generally the possibilities for learning, may also be influenced by certain key characteristics of the political system in which the collaborations take place. In this respect, it has been indicated that business association activities and their contribution to regulation can be influenced by the characteristics of the political system in which they are embedded (see section 3.2). Rather than intending to characterize the US, or German, political system as such, we want to highlight certain aspects that are related to learning in collaborative activities. Considering specific characteristics of political systems helps to understand why we have observed certain differences in the learning articulated in section 9.1.

More specifically, after the comparison of learning in the VCI and ACC Nano Panel collaborative networks, learning in the latter network seemed to be limited in view to the conditions that were met. However, as the discussion of learning in the context of the US political systems in this section will show, learning in the case of the ACC in relation to certain characteristics of US political system can be regarded differently.

Political systems are embedded in a specific pattern of orientations to political action (Almond 1956). From this viewpoint, the Anglo-American political system is said to be homogeneous and pragmatic in the atmosphere of a game in which political outcomes are uncertain and in which policy-making is characterized by adversarial approaches (ibid). Adversarial political systems determine winners and losers and are not directed at creating compromise, which increases distrust and conflict among actors in the system (Weible & Sabatier 2009).

More specifically, in the US the relationship between regulators and industry has been described by many as adversarial, meaning decisions by regulatory agencies are often challenged in court by dissatisfied actors (see, for example, Von Mehren & Murray 2007; Kagan 2001). Industry and advocacy groups hire scientists and lawyers to challenge agency decisions within the courts. Legal defensiveness often impedes constructive collaboration (Weible & Sabatier 2009). Policymaking often happens in cycles of mistrust and litigation. Understanding industry-regulator relationships in this light indicates, in the US, it tends to be uncommon for the parties to collaborate based on relationships of trust, to share information and jointly generate knowledge based on which rules are jointly developed.

The adversarial character in the relationship among industry and regulators is visible particularly in the way how US industry shares scientific data with regulators. In this respect, industry has tried to avoid submitting data to regulators by designating such information as confidential business information (CBI) (GAO 2005). Of those claims that actually were reviewed, in 1992, half or more CBI claims were found to be illegitimate and of those claims that were challenged nearly all claims were withdrawn by companies (GAO 2005: 33; EPA 1992).[132]

In the specific case of nanomaterials, there appears to be a general tendency by industry to be hesitant in voluntarily sharing scientific data with regulators. For instance, the NGO EDF found evidence indicating industry does provide information that nanomaterials are used, but insufficient details as to their characteristics (e.g. names, toxic effects etc.) were submitted since industry claims such information to be CBI (EDF 2009).

Against the backdrop of the Anglo-American political system, collaboration among industry and regulators in the form of data/knowledge sharing and development of new scientific facts (substantive learning), as well as joint rule development (institutional learning) appears unusual. Nevertheless, substantive learning was visible in the case of the ACC Nano Panel and OSHA on matters of nanomaterials OHS. Furthermore, the relationship between the Panel and OSHA appeared to be characterized by trust, which tends to be uncommon in the US political system. This was visible in that collaborators exchanged knowledge with the Agency, based on which new scientific facts have been generated that are relevant for making risk assessment applicable for nanomaterials. These facts have not been used for the development of soft regulation (institutional learning); they appear, instead, to have been employed to support and sustain the lobbying activities of the association. This appears in line with what we would have expected from the general characteristics of the political system in the US.

While this must be acknowledged, overall, it can be argued that a window of opportunity for collaboration among industry and regulators (including other parties) has been opened in the context of nanomaterials OHS in the US. This is why certain conditions were met (knowledge sharing/generation and trust), which appear uncommon in view of key characteristics of the US political system. How long this window will stay open is still in question.

In comparison to the US, the political system in Germany shows different key characteristics. In most Western European democracies, policymaking implies to combine political and expert judgment and consult with the affected parties (Brickmann et al. 1985). As such, policy-making is typically characterized by collaborative approaches (Newman & Bach 2004). Collaborative approaches to policy-making are characterized by efforts to create win-win and voluntary solutions to policy problems (Weible & Sabatier 2009). The aim is to achieve consensus based on joint fact-finding that integrates scientists and non-scientists in decision-making processes (Sabatier et al. 2005). Since conflicts are typically mitigated to intermediaries collaborators are likely to engage in joint knowledge generation, based on mutual understanding and trust, during which learning is likely to occur (Sabatier & Jenkins-Smith 1993).

In Germany there is a tradition for collaboration among industry and government and it is not uncommon for these parties to jointly develop and implement policy (Lane & Bachmann 1997). Relationships between industry and regulators tend to be oriented at constructive cooperation and coordination with the aim to agree on a joint course of action

[132] The EPA has not conducted any recent studies on the appropriateness of CBI claims (GAO 2005: 32-33).

(Newman & Bach 2004). Thus, overall, the private and public sectors appear to consider each other more as partners rather than adversaries.

Considering these characteristics of the German political system, one would expect relationships of a collaborative character among policy-makers and business associations. The analysis of the VCI activities in collaboration with regulators (and other actor groups) on matters of nanomaterials OHS support this. Thus, the collaborators have exchanged and generated knowledge on the basis of mutual trust, and we have observed joint rule development these parties. Thus, the VCI collaborative activities seem to be an example of the traditional characteristics of the German political system.

In this part we have seen that national political systems show certain endemic features that are unique and that may shape interaction among collaborators. In this context, industry may have a certain position in the coordination and organization of policies. At the same time, interaction among a multitude of actors is shaped by their own personal interests and the strategies to satisfy these interests. The limits, or rules of the game, for collaboration between industry, regulators and others are anchored in the political system and its characteristics. While varieties in approaches to policy-making exist across jurisdictions we may also speak of varieties of business associations. Approaches to policy-making and business associations need to fit into one another to be able to coexist.

Although business associations can make important contributions to effective regulation, it needs to be acknowledged that these bodies, in the US and Germany, show fundamental differences in view of their typical strategies related to knowledge exchange and generation in co-regulatory arrangements. While associations in both jurisdictions show an interest, their strategies in deploying the resource knowledge may be fundamentally different. In the US, associations seem to use knowledge in order to influence regulation through stalemate (passive stance). In Germany, associations appear to use knowledge in order to influence regulation by participating in the development of soft regulation (active stance). In this respect it shall be necessary to conduct additional case studies of business association activities in other jurisdictions. Doing so shall help to understand whether we can differentiate other strategies in regard to knowledge deployment within co-regulatory arrangements and whether certain strategies are more, or less, common.

Co-regulation and network governance

Lastly, this thesis has shown that it is useful to approach co-regulation from a network governance perspective. The network governance literature provides various empirical examples of issues that are relevant for the field of regulation and governance. Thus, this thesis agrees with network governance scholars, who argue that cooperation in networks is advantageous for the involved parties. At the same time the supposed disadvantages of networks need to be considered.

In this respect, it was indicated that collaborative networks involving industry and regulators can bear the risk of capture due to close cooperation of these parties over a period of many years. While measures can be put in place in order to forestall capture (e.g. through formalizing collaboration or applying forms of tri-partism) the risk of capture may be, to a certain extent, inherent to collaboration in networks. Other points of critique are that networks are often not opaque and constitute a threat to accountability (Milward 1996) and the democratic legitimacy of government performance (Marsh & Rhodes 1992). Therefore it is necessary to investigate how crucial regulatory principles, e.g. transparency, accountability, and legitimacy, can be achieved in co-regulatory arrangements. The installment of a network manager, that possesses the four characteristics identified in section 9.2, may help to address these issues.

A more general disadvantage that may need to be accounted for is the high transaction costs in order to manage interaction in networks that are complex and large in size; involved actors must be able and motivated to invest in interaction. It shall therefore be useful to further explore the limits and opportunities that a network governance perspective may bring to the field of regulation.

A network governance perspective fits well with Black's decentred approach to regulation, characterized by notions of complexity, fragmentation, 'ungovernability', interdependencies, and the rejection of a clear distinction between public and private (Black 2002). The network governance literature points to an element we may want to include: uncertainty in the interaction among actors. While Black acknowledges 'complexity' in interactions between actors and/or systems with diverse identities in society that are in constant tension between stability and change, network governance approaches speak of uncertainty as deriving from the presence of multiple actors each having own perceptions, goals and strategies in view to the collaboration. Interaction occurs in unpredictable games of collaboration during which actors pursue individual, as well as broader network goals. While we can never eliminate this element of uncertainty in the interaction among multiple actors, network governance has taught us that we can deploy specific strategies by which we can steer interactive processes. It may be useful to explore these strategies in the field of regulation.

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Appendices

Appendix 1

Table 1. Overview interviews.

Interviewees	Organization	Date of interview	Type of interview	Representing
1	Organisation for Economic Co-operation and Development (OECD)	12 March 2014	Phone	Industry
2	Nanotechnology Industry Association (NIA)	3 March 2014	Phone	Association
	Case study American Chemistry Council			
3	International Life Sciences Institute (ILSI)	3 Aug. 2014	Face-to-face	Research institute
4	QD Vision Inc.	21 Jan. 2014	Phone	Industry
5	National Institute for Occupational Safety and Health (NIOSH)	14 Jan. 2014	Phone	Federal research institute
6	Centre for Progressive Reform (former employee Environmental Protection Agency , EPA)	9 Jan. 2014	Phone	NGO
7	Vireo Advisors	9 Jan. 2014	Phone	Consultancy
8	Bergeson & Campbell	6 Dec. 2013	Phone	Consultancy
9	Occupational Safety and Health Agency (OSHA)	5 Dec. 2013	Phone	Regulator
10	University of Massachusetts Lowell	5 Dec. 2013	Face-to-face	Academia
11	Chemical Heritage Foundation (CHF)	3 Dec. 2014	Face-to-face	NGO
12	Univ. of Pennsylvania	3 Dec. 2013	Face-to-face	Academia
13	Former employee Occupational Safety and Health Agency (OSHA)	2 Dec. 2013	Phone	(Former) Regulator
14	Member American Chemistry Council Nano Panel/ Evonik	26 Nov. 2013	Phone	Industry
15	Member American Chemistry Council Nano Panel/ DuPont	26 Nov. 2013	Phone	Industry
16	American Chemistry Council (ACC)	19 Nov. 2013	Face-to-face	Association
17	Harvard University	14 Nov. 2014	Face-to-face	Academia

	Case study German Chemical Industry Association (VCI)			
18	European Commission, DG Employment, Social Affairs, and Inclusion	16 Apr. 2014	Phone	Regulator
19	European Chemicals Agency (ECHA)	3 Apr. 2014	Phone	Regulator
20	Chair VCI AK Responsible Production and Use of Nanomaterials/ Bayer	14 Mar. 2014	Phone	Industry
21	German Chemical Industry Association (VCI)/ Member VCI AK Responsible Production and Use of Nanomaterials	14 Mar. 2014	Phone	Association
22	Committee on Hazardous Substances (AGS)/ Hamburg Advice Centre on Work and Health	28 Feb. 2014	Phone	Labor union
23	Industriegewerkschaft Bergbau, Chemie, Energie (IG BCE)	26 Feb. 2014	Phone	Labor union
24	Verband Chemiehandel (VCH)	14 Feb. 2014	Phone	Association
25	Society for Chemical Engineering and Biotechnology (DECHEMA)	13 Feb. 2014	Face-to-face	Association
26	Member VCI AK Responsible Production and Use of Nanomaterials/ Institute of Energy and Environmental Technology (IUTA)	13 Feb. 2014	Face-to-face	Academia
27	Member VCI AK Responsible Production and Use of Nanomaterials/ EMPA	12 Feb. 2014	Face-to-face	Academia
28	Federal Institute for Risk Assessment (BfR)	11 Feb. 2014	Phone	Federal research institute
29	German Chemical Industry Association (VCI)	11 Jan. 2014	Phone	Association
30	BÜFA Gelcoat Plus GmbH & Co. KG	26 Mar. 2013	Phone	Industry
31	Sachtleben Chemie GmbH	6 Mar. 2013	Face-to-face	Industry
32	Sachtleben Chemie GmbH	6 Mar. 2013	Face-to-face	Industry
33	German Chemical Industry Association (VCI)	16 Feb. 2013	Face-to-face	Association
34	German Chemical Industry Association (VCI)	16 Feb. 2013	Face-to-face	Association
35	Federal Institute for Occupational Safety and Health (BAuA)	28 Nov. 2012	Face-to-face	Federal research institute
36	DSM	21 Sep. 2012	Face-to-face	Industry
37	Arbo Unie	10 Apr. 2012	Face-to-face	Consultancy
38	BASF	15 Feb. 2012	Phone	Industry

Appendix 2

Table 2. Interview Guide.

Actor analysis - **Substantive learning** (scientific expertise)	1. How do you perceive business association activities, which take place over a longer period of time, to contribute to nanomaterials OHS regulation? 2. In your view, which business association activities have been main contributions to nanomaterials OHS regulation? 3. Which scientific issues/challenges have been discussed accordingly? 4. In the context and process of these activities, has there been formulated a common problem or work definition towards nanomaterials OHS and or risk assessment for nanomaterials? 5. Have there been differences in opinion as to the problem definition? 6. What kind of resources have you brought into the collaboration 7. Are those resources brought into the collaboration distinctively by you, or have there been other actors with the same resources? 8. Did from this collaboration emerge a common level of new scientific knowledge into what the problems of conducting risk assessment for nanomaterials are & what proposed solutions could be? 9. Have there been formulated commonly agreed upon, new facts for nano risk assessment?
Game analysis - **Strategic learning** (trust)	1. Did the collaboration take place on a permanent/regular basis or over a longer period of time (month, years)? 2. Where did you meet usually and who takes the lead in organizing these meetings? 3. Has there been an exchange/sharing of scientific (risk?) data on nanomaterials? 4. As a result, have there been generated new scientific facts? 5. With regard to the process of collaboration, could you realize your own goals against the background of the goals of other actors? 6. Did the pursuit of your own goals lead to any form of disagreement in the interaction with others? How had the disagreement been dealt with/solved? 7. How did the relations between all involved or particular actors have changed over time? (e.g. deepened, shallow, loosened, dismissed) 8. Would you say you can rely on (certain) actors in the network and the arrangements you make with them? 9. Did the collaboration result in additional collaborative activities relevant for nanomaterial risk assessment?
Network analysis - **Institutional learning** (rules)	1. During the process of collaboration have there been agreed on & developed any ad hoc agreements or (binding/non-binding) rules as to the conduction of risk assessment for nanomaterials? 2. In your view which agreements/rules were most significant? 3. Have these agreemens/rules been communicated to all members? 4. Have involved parties formally committed to these agreements/rules? 5. Have the agreements been included/mentioned in regulatory process on nanomaterials OHS regulation and/or legislation?
Backup/additional questions **Business association membership**	1. Which general advantage does the membership in the business association offer? 2. Which individual services are offered/used regarding nanomaterials OHS/risk assessment? 3. Which of these services are used commonly?
Other	1. As regards the collaborative activities you are most actively involved in, do you have any publicly available documents that would be of interest to me? 2. Are there other important people who were involved in the collaboration and to whom I should talk?

Appendix 3

Table 3. Activities directed at nanomaterials OHS by the ACC Nano Panel.

TIME	ACTIVITY
2005	Establishment of the ACC Nanotechnology Panel (ACC n.d.)
	Publication of a Joint Statement of Principles for nanomaterials (together with the Environmental Defense Fund, EDF) (EDF & ACC 2005)
2006	Issuance of Comments on the EPA Nanotechnology White Paper External Review Draft' (ACC 2006)
2007	Statement before the National Nanotechnology Coordination Office (NNCO) (ACC 2007a)
	Comments on the Draft Environmental Defense/DuPont Nano Risk Framework for Responsible Nanotechnology' (ACC 2007b)
	Comments on the Scientific Opinion of the EC Scientific Committee on Emerging and Newly Identified Health Risks (SCENIHR) on the Technical Guidance Documents of the chemicals legislation, for the risk assessment of nanomaterials (ACC 2007c)
	Conduction of a survey among ACC member companies (ACC 2007d)
2009	Became a member of the Business and Industry Advisory Committee (BIAC) Nanotechnology Committee that advises the OECD Working Party on Manufactured Nanomaterials (WPMN) (OECD 2009)[133]
2011	Comments on the Environmental Health and Safety Strategy of the National Nanotechnology Initiative (NNI) (ACC 2011a)
	Comments on the NIOSH draft Current Intelligence Bulletin (CIB) Occupational Exposure to Carbon Nanotubes and Nanofibres (ACC 2011b)
	Comments on the relevance of the NNI on safe work and use of nanotechnology (ACC 2011c)
	Comments on NIOSH's updated strategic plan for identifying and prioritizing nanotechnology research (ACC 2011d)
	Co-sponsor of the the NanoRelease Consumer Products research project (ILSI 2011)
2012	Comments on the EPA Office of Inspector General's Report on Nanotechnology (ACC 2012a)
	Comments on EPA's proposed significant new use rules (SNURs) (ACC 2012b)
	Organization of a workshop on Strategies for Setting Occupational Exposure Limits for Engineered Nanomaterials' was initiated (ACC 2012c)
2013	Publication of a Comparative assessment of nanomaterial definitions and considerations (ACC 2013e)
	Comments on NIOSH's draft strategic plan for nanotechnology research (ACC 2013f)
	Comments on the draft NNI Strategic Plan 2014 (ACC 2013g)

[133] The ACC Nano Panel has been a member of BIAC at least since March 2009 (OECD 2009); there is no data available from publicly available documents that points to an earlier engagement.

Appendix 4

Table 4. Activities directed at nanomaterials OHS by the VCI.

TIME	ACTIVITY
2003	Founding joint working group (with DECHEMA) Responsible Production and Use of Nanomaterials (DECHEMA & VCI 2007)
2005	Workshop Nanomaterials at the workplace l (VCI 2005)
2006	Survey I on OHS aspects in the production and handling of nanomaterials (collaboration with BAuA) (Plitzko et al. 2007)
2007	Feedback on the EDF/DuPont Nano Risk Framework (VCI 2007a)
	Workshop Nanomaterials at the workplace ll (VCI 2007b)
	Roadmap for Safety Research on Nanomaterials (DECHEMA & VCI 2007)
2007	Guidance for Handling and Use of Nanomaterials at the Workplace (collaboration with BAuA) (VCI & BAuA 2007)
	Strategy Paper of the German Chemical Industry on the Standardization of Nanomaterials (in the context of ISO/TC 229) (VCI 2007c)
2008	Guidance 'Anforderungen der REACH-Verordnung an Stoffe, welche auch als Nanomaterialien herge-stellt oder eingeführt werden' (VCI 2008a)
	Guidance for a Tiered Gathering of Hazard Information for the Risk Assessment of Nanomaterials (VCI 2008b)
	Guidance for the Passing on of Information along the Supply Chain in the Handling of Nanomaterials via Safety Data Sheets (VCI 2008c)
	Guidance Responsible Use and Production of Nanomaterials (VCI 2008d)
	Guidance 'Umsetzung von Responsible Care® für eine verantwortliche Herstellung und Verwendung von Nanomaterialien' (VCI 2008e)
	Workshop 'Verantwortlicher Umgang mit Nanomaterialien' (collaboration with IG BCE) (VCI & IG BCE 2008)
2011	Guidance 'Tiered approach to an Exposure Measurement and Assessment of Nanoscale Aerosols Released from Engineered Nanomaterials in Workplace Operations' (IUTA et al. 2011)
	Survey II on occupational health and safety aspects in the production and handling of nanomaterials in Germany (in collaboration with BAuA) (Plitzko et al. 2011)
2011	Reaction to EC definition of a nanomaterial (VCI 2011a)
	Reaction to a report on nanomaterials risks by the German Advisory Council on the Environment (VCI 2011b)
2012	Revised Guidance 'Empfehlung für die Gefährdungsbeurteilung bei Tätigkeiten mit Nanomaterialien am Arbeitsplatz' (2007/2012) (VCI & BAuA 2012)
	Reaction to EC Communication on the 2nd Regulatory Review on Nanomaterials (VCI 2012a)
2013	VCI/VCH-Position zum Gesamtbericht der Europäischen Kommission zu REACH vom 5. Februar 2013 (VCI & VCH 2013)

Appendix 5

Table 5. New scientific facts established by the RPUN through NanoCare.

Nanomaterial [134]	New scientific facts						
	Hazard	**Exposure**		**Toxicology**			
				Uptake via lung		**Behaviour**	
						Uptake in somatic cells	**Blood-brain barrier**
		In vitro	***In vivo***	***In vitro***	***In vivo***	***In vitro***	***In vivo***
Titanium dioxide (TiO_2)	No indicators of increased risk for workers to incur cancers (particles released during TiO_2 powder filling mostly are larger than 450nm, thus are not considered nanoparticle	The vitality of cells was reduced only after administration of very high doses (50 µg/cm^2) of different variants of TiO_2. That concentration is far above the concentration as industrial TiO_2 is used. Besides, TiO_2 tends to strongly agglomerate. The concentration of free nanoparticles thus is reduced accordingly. Human lung cells were exposed to TiO_2 for two and four hours, respectively. None of the applied concentrations was found to	A five-day inhalation study has revealed that inhaled TiO_2 particles are deposited in the lung as agglomerates and can get into the lung-associated lymph nodes. They are mostly found in phagocytes. In addition, instillation studies applying low (0,6 mg/lung) and	Only very high doses (50 µg/cm^2) of different variants of TiO_2 were found to have caused losses in vitality. To simulate the formation of dust, the cells were exposed to TiO_2 particles for two and four hours, respectively, using the	TiO_2 particles that are deposited in the lungs of the subjects may trigger temporary inflammatory reactions (see, section 'Exposure').	TiO_2 particles are not transported through monolayer cells. Besides, exocytosis, a process where substances are transported from the cell interior to the cell environment, does not take place according to *in vitro* tests.	---

[134] All information is retrieved from DaNa 2.0 (see http://nanopartikel.info/en/nanoinfo); only such information is included in the table, which has been the result of NanoCare, i.e. is referenced as such according to the NanoCare Final Scientific Report (BMBF 2009), and which is new scientific knowledge, i.e. results that presumably have not been published before and that are pointing out new findings rather than confirming other studies.

	s	decrease the vitality of the exposed cells or cause acute cytotoxicity.	high doses (4,8 mg/lung) showed a slight dose-dependent increase in the number of macrophages.	Karlsruhe Exposure System. None of the applied concentrations was found to have caused losses in the cell vitality or signs of acute cell cytotoxicity.			
Carbon Black	---	Not any of the eleven cell lines of different origins tested in layers containing up to 10 µg of carbon black particles per cm^2 exhibit stress symptoms nor did carbon black cause any cell-damaging effects. Moreover, a test for cell culture apoptosis proved negative. Further experiments on human lung cells proved that the latter do not get stressed before being exposed to high doses of 25 µg particles per cm^2 cell layer. The cell vitality was observed to decrease strongly at and above such particle concentrations.	---	---	---	---	---
Cerium dioxide **(CeO_2)**	---	A threshold concentration of at least 25 µg CeO_2 particles per cm^2 cell culture area was determined by means of *in vitro* tests on the human lung epithelial cell line A549. At this concentration as the lowest one that triggers an effect, cells were found to become	In short-time inhalation studies (six hours daily over five days) on rats the inhaled particles were detected in the lung and in the lung-associated lymph nodes. No	---	Inhaled particles can be detected in the lung. However, no long-time studies are available to confirm findings.	---	No particles could be found in the brains of rats during *in vivo* tests.

		stressed while inflammation markers and reactive oxygen species (ROS) were produced. In some cell lines, lower CeO_2 doses were not able to trigger any detectable effects anymore. Co-cultures react more sensitively to the CeO_2 than monocultures and communication between different cells may increase such effects.	particles were found in the liver, the kidneys, the spleen, or the brain with attached olfactory nerve. Lung liquid examination after CeO_2 exposure showed that inhalation markers occurred and increased with the dose of particles applied.				
Doped Cerium dioxide **(CeO_2)**	nda	nda	nda	nda	nda	nda	nda
Boehmite (AIOOH)	---	AIOOH particles are among the low-toxicity materials. Excessive, overloading concentrations of 60-120 µg particles per 106 macrophages were observed to damage the cells but did not lead to the formation of harmful reactive oxygen species (ROS). Damage due to realistic doses of Al particles is not expected.	Two different types of boehmite particles (primary particle sizes of 10 and 40 nm) were scrutinized. The experiments on rats that were made to inhale up to 28 mg/m^3 of the particles five days a week over a period of four weeks showed that inflammation of the lungs due to strongly agglomerated particles only occurred in the presence of the highest	---	---	---	---

			concentration. Inflammations in the lungs occurred at inhaled particle doses of more than 1 mg per lung. Similar results were obtained from instillation experiments: Instillation of more than 1,2 mg of boehmite particles per lung in the respiratory tracts of the test animals caused damage to the lungs. In these studies, the NO(A)EL amounts to 0,6 mg.				
Mixed Titanium – Zirconium oxide (Ti-Zr-Mixed oxide)	nda	nda	nda	nda	nda	nda	nda
Mixed Titanium-Aluminide-Zirconi-um Oxide (Ti-Al-Zr Mixed oxide)	nda	nda	nda	nda	nda	nda	nda
Zirconi-um dioxide (ZrO_2)	---	Three different modifications of zirconium dioxide were used. Furthermore a threshold	---	---	---	---	---

		concentration of at least 50 µg ZrO_2 particles per cm^2 cell culture area was determined by means of in vitro tests on the human lung epithelial cell line A549. At this concentration as the lowest one that triggers an effect, cells were found to become stressed. Investigations with 11 different cell lines from different derivations and up to 10 µg particles per cm^2 cell culture area used, none of the cell lines showed indications of stress or zirconium dioxide caused other cell-damaging effects. Likewise, a test on apoptosis was negative with cell cultures. Within co-culture systems, particles also showed no adverse effects.					
Zinc oxide (ZnO)	---	Studies on eleven different cell lines of different origins show that these cell lines are differently sensitive to the ZnO particles. Here, a relatively high toxicity was found already at low concentrations in some cell lines (LOEL from 5 g/cm^2 or approximately 16 µg/ml). For some cells, the threshold values for *in vitro* apoptosis tests were in the range of 7,5-10 µg/cm^2. In co-culture systems ZnO particles were found to cause increased levels of	---	---	---	---	---

		inflammation markers.					
Barium sulphate ($BaSO_4$)	---	*In vitro* experiments performed on human lung cells have shown that these cells get stressed and lose their vitality only after administration of very high doses of 50 µg particles per cm^2 cell lawn. This dose is not only far above the dose of natural exposure but also above the one occurring during correct use of barium sulfate. Tests on ten different cell lines of different proveniences with up to 10 µg particles per cm^2 cell lawn revealed that only embryonic stromal cells of mice were suffering from reduced cell vitality and stress. To any of the other cell lines, $BaSO_4$ did not cause effects damaging the cells. In co-culture systems barium sulfate particles did not trigger any biological effects and the cells were found to remain vital. Based on the so-called vector model representing some of the elementary cell functions it was proven that $BaSO_4$ causes the least effects of all materials tested. A concentration of more than 120 µg particles per 106 macrophages (total overload for the cells) was found to lead to damage of the cells. Although that dose is ultra-high, reactive	Both intratracheal instillation tests and inhalation experiments were performed on rats. Neither the instilled nor the inhaled barium sulfate particles showed any biological effects in the different organs of the animals examined subsequently.	---	---	---	No barium sulphate ($BaSO_4$) particles were found in brains of rats during *in vivo* studies.

		oxygen species (ROS) were not detected in the cells.					
Stronti-um carbonate ($SrCO_3$)	---	*In vitro* experiments with two differently modified, well-characterised variants of strontium carbonate that were applied to human lung cells have shown that only high doses of at least 25 µg/cm^2 of the hydrophobic particles can cause stress in cells and a decrease in the cell vitality after 72 hours. No effects were caused by the hydrophilic variant with particles of almost identical primary particle size. No negative effects on the cells were observed during studies with ten different cell lines of different origins treated with up to 10 µg particles/cm^2. Using the so-called vector model it was proven that $SrCO_3$ has little or no effects at all. Excessive, overloading concentrations of at least 120 µg particles per 106 phagocytes were observed to damage the cell function and lead to the formation of reactive oxygen species (ROS).	Intratracheal instillation tests were carried out. A particle suspension was instilled in the pharynx of the animals and different cell markers were analysed subsequently. During this experimental approach, the strontium carbonate particles did not reveal any biological effects.	---	---	*In vitro* studies have shown that strontium carbonate particles in principle can be taken up by different cell types. The uptake mechanism has not yet been investigated for these special particles.	---