

Risk Management of Nanotechnologies within German Legislation

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‘There are the rushing waves...
mountains of molecules,
each stupidly minding its own business...
trillions apart
...yet forming white surf in unison.

...

Deep in the sea,
all molecules repeat
the patterns of another
till complex new ones are formed.
They make others like themselves...
and a new dance starts.

Growing in size and complexity...
living things,
masses of atoms,
DNA, protein...
dancing a pattern ever more intricate.

Out of the cradle
onto dry land...
here it is standing...
atoms with consciousness
...matter with curiosity.

Stands at the sea...
wonders at wondering... I...
a universe of atoms...
an atom in the universe.’¹

Richard Phillips Feynman (11 May 1918 – 15 February 1988)

¹ ‘The Value of Science’, addressed to the National Academy of Sciences (Autumn 1955); published in *The Pleasure of Finding Things Out: The Best Short Works of Richard P. Feynman* (1999) edited by Jeffrey Robbins.

Abstract^{2, 3}

Nanotechnologies allow for the production of completely new materials in a wide range of industries and technical fields and are also recognised as one of the most important technological sectors for the future. The growing nanotechnological industry is rapidly generating new forms of materials; however, little is known about the behaviour of these substances, in particular their particle form and their impact on different ecological systems and the life within them. Concerns have been raised about the safety and regulation of nanomaterials, following a number of studies that indicated that some nanomaterials are able to cause adverse effects on living objects. This data, as well as increasing production volumes and commercialisation, the capability of crossing biological barriers and the increased physico-chemical activities of nanoparticles, when compared to their bulk counterparts, have triggered concern (Baró et al., 2001; Kear et al., 2012) about their impacts on health and safety.

In Germany, nanoparticles, nanotechnological products, their production processes and their disposal are generally subject to the prevailing law of the German legal system, especially with respect to the authorization of equipment, permissions regarding chemicals and other product groups, and the protection of employees and the environment. With regard to nanotechnologies, however, the question arises as to whether the present legal regulations are adequate, and/or whether regulative gaps occur because of specific new products, materials or process characteristics. Accordingly, based on the analysis of the relevant state-of-the-art technology and science, and an evaluation of existing, as well as projectable, future national legislation on this matter, this work aims to identify regulative gaps in the relevant standardisation procedures and to point out possible adjustments.

Although nanomaterials are covered by the general scope of many of the existing legislative frameworks, it is often unclear if current regulation is actually applicable for specific questions of nanomaterials and their diverse applications. In particular, there is a lack of sufficient knowledge of the risks, which could lead to imbalanced legal protection against any threats that may arise. However, it is recognised that adjustments are needed, and legal amendments have been repeatedly proposed by expert committees, policymakers, industry members and non-governmental organisations (European Parliament, 2009). Nonetheless, very few revisions have been made to date, so the existing regulations are not considered adequate to deal with all kinds of nanomaterials in both the short and long term. Current legislation needs to be adapted immediately to reflect the challenges posed by current nanomaterials and their applications.

² This thesis will be available for download under <http://www.tu-cottbus.de/einrichtungen/en/welcome-to-icmc.html>

³ Keywords: Compliance, German, Law, Legal, Legislation, Nano, Nanotechnology, Regulation, Right, Risk.

Abriss^{4, 5}

Nanotechnologien ermöglichen die Herstellung völlig neuer Materialien in einem breiten Spektrum von Branchen sowie technischen Bereichen und werden als einer der wichtigsten Technologiebereiche der Zukunft angesehen. Die wachsende nanotechnologische Industrie erzeugt immer neue Formen von Materialien; dagegen ist wenig über deren Verhalten bekannt, insbesondere ihre Auswirkungen auf Ökosysteme sowie auf die Dinge, die darin leben. Eine Reihe von Studien äußert Bedenken über die Sicherheit der Regulierung von Nanomaterialien, von denen behauptet wird, nachteilige Auswirkungen auf Organismen zu verursachen. Neben diesen sind steigende Produktionsmengen und zunehmende Vermarktung, die Fähigkeit biologische Hürden zu überschreiten sowie die erhöhte physikochemische Aktivität im Vergleich zu makroskopischen Substanzen, Gründe zur Besorgnis (Baró et al., 2001; Kear et al., 2012).

In Deutschland unterliegen sowohl Nanopartikel, nanotechnologische Produkte und deren Produktionsprozesse als auch ihre Entsorgung grundsätzlich den geltenden Bestimmungen des deutschen Rechtssystems, insbesondere bei der Genehmigung von Anlagen, der Zulassung von Chemikalien und besonderen Produktgruppen und dem Schutz von Mitarbeitern und Umwelt. Bei Nanotechnologien stellt sich nun jedoch die Frage, ob die vorliegenden Rechtsvorschriften bereits hinreichend zutreffen, und/oder ob Regelungslücken auftreten, die aus den neuartigen, individuellen Produkten, Materialien oder Prozesseigenschaften resultieren. Dementsprechend soll diese Arbeit, basierend auf einer Analyse des relevanten Stands der Technik und Wissenschaft sowie einer Bewertung des bestehenden und künftig absehbaren Rechtsrahmens, Regelungslücken identifizieren und mögliche Anpassungen aufzeigen.

Obwohl im Ergebnis Nanomaterialien vielfach durch den bestehenden Rechtsrahmens eingefasst sind, ist oftmals noch unklar, ob Einzelregelungen tatsächlich anwendbar sind. Es herrscht vor allem ein Mangel an ausreichender Kenntnis der Risiken, welche zu einem unzureichenden rechtlichen Schutz gegen die auftretenden Gefahren führen könnte. Es wird zwar erkannt, dass Anpassungen erforderlich sind, und von Fachausschüssen, politischen Entscheidungsträgern, Mitgliedern der Industrie und NGOs wurden wiederholt Gesetzesänderungen vorgeschlagen (European Parliament, 2009). Doch wurden tatsächlich bisher nur sehr wenige Modifikationen vorgenommen, so dass die bestehenden Vorschriften als nicht ausreichend erachtet werden müssen, um mit allen Arten von Nanomaterialien sowohl kurz- als auch langfristig umgehen zu können. Der aktuelle Rechtsrahmen muss sofort angepasst werden, um die Herausforderungen der inzwischen gebräuchlichen Nanomaterialien und deren Anwendungen widerzuspiegeln.

⁴ Diese Dissertation wird downloadbar unter <http://www.tu-cottbus.de/einrichtungen/en/welcome-to-icmc.html>

⁵ Schlagworte: Compliance, German, Law, Legal, Legislation, Nano, Nanotechnology, Regulation, Right, Risk.

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Abbreviations & Terms⁶

ADR

European Agreement concerning the International Carriage of Dangerous Goods by Road *is derived from the French name for the treaty: Accord européen relatif au transport international des marchandises Dangereuses par Route*

Afssaps

Agence française de sécurité sanitaire des produits de santé *French Agency for Sanitary Safety of Health Products*

AGS

Ausschuss für Gefahrstoffe *Committee on Hazardous Substances*

AIMDD

Active Implantable Medical Devices Directive *is intended to harmonise the laws relating to active implantable medical devices within the European Union*

AIST

National Institute of Advanced Industrial Science and Technology *is managed to integrate scientific and engineering knowledge to address socio-economic needs*

ANSES

Agence nationale de sécurité, de l'alimentation, de l'environnement et du travail *French Agency for the Safety of Health Products*

ANSI-NSP

American National Standards Institute's Nanotechnology Standards Panel *focuses on the development of standardisation documents concerning nanotechnologies in the US*

ArbSchG

Arbeitsschutzgesetz German Occupational Health and Safety Act

ASTM

American Society for Testing and Materials *is an international standards organisation that develops and publishes voluntary consensus technical standards for a wide range of materials, products*

BAFU

Schweizer Bundesamt für Umwelt *Swiss Federal Office for the Environment*

BAuA

Bundesanstalt für Arbeitsschutz und Arbeitsmedizin *Federal Institute for Occupational Safety and Health*

BCC Research

Business Communications Company *is a publisher of technology market research reports, reviews, and technical newsletters*

BfR

Bundesinstitut für Risikobewertung *Federal Institute for Risk Assessment*

BImSchG

Bundes-Immissionsschutzgesetz *Federal Immission Control Act*

BImSchV

Bundesimmissionsschutzverordnung *German Federal Immission Control Ordinance*

BioStoffV

Biostoffverordnung *Ordinance on Biological Agents*

BMBF

Bundesministerium für Bildung und Forschung *Federal Ministry of Education and Research*

BMEL

Bundesministerium für Ernährung und Landwirtschaft *Federal Ministry for Food and Agriculture is a cabinet-level ministry of the Federal Republic of Germany*

BMU

formerly Bundesministerium für Umwelt, Naturschutz und Reaktorsicherheit *now Bundesministerium für Umwelt, Naturschutz, Bau und Reaktorsicherheit (BMUB)*

BMUB

Bundesministerium für Umwelt, Naturschutz, Bau und Reaktorsicherheit *Federal Ministry for the Environment, Nature Conservation, Building and Nuclear Safety*

BREF

Best Available Technique Reference Documents *is a term applied with regulations on limiting pollutant discharges with regard to the abatement strategy*

BSI

British Standards Institution *is the national standards body of the United Kingdom*

BSI NT1

British Standards Institution Nanotechnologies Standardisation Committee *focuses on the development of standard documents concerning nanotechnologies in the UK*

⁶ The meanings of used, but not listed abbreviations can be found at <http://www.oxforddictionaries.com>

BUND

Bund für Umwelt und Naturschutz Germany
Friends of the Earth Germany

BVerwG

Bundesverwaltungsgericht *Federal
Administrative Court*

BVL

Bundesamt für Verbraucherschutz und
Lebensmittelsicherheit *Federal Office of
Consumer Protection and Food Safety*

CAGR

Compound annual growth rate *is a business and
investing specific term for the geometric
progression ratio that provides a constant rate of
return over a time period*

CAS

Chemical Abstracts Service *is a division of the
American Chemical Society and is a source of
chemical substance information*

CASRN

Chemical Abstracts Service Registry Number *is a
unique numerical identifier assigned by Chemical
Abstracts Service (CAS) to every chemical
substance described in the open scientific
literature*

Cefic

Conseil Européen de l'Industrie Chimique
European Chemical Industry Council

CEN

Comité Européen de Normalisation *is a major
provider of European Standards and technical
specifications*

CENELEC

Comité Européen de Normalisation
Électrotechnique *European Committee for
Electrotechnical Standardization*

CEP

Royal Commission on Environmental Pollution
*in the UK was created in 1970 to advise the
Queen, Government, Parliament and the public
on environmental issues. It was closed on 1 April
2011, as part of the Coalition Government's
spending cuts*

CH

Confoederatio Helvetica *is a federal republic in
Europe. It consists of 26 cantons, and the city of
Bern is the seat of the federal authorities*

CIEL

Center for International Environmental Law *is a
public interest, not-for-profit environmental law
firm founded to strengthen international and
comparative environmental law and policy
around the world*

CLP Regulation

Regulation on Classification, Labelling and
Packaging of Substances and Mixtures *aligns the
European Union system of classification,
labelling and packaging chemical substances and
mixtures to the Globally Harmonised System
(GHS)*

CMR

Substances carcinogenic, mutagenic or toxic to
reproduction *are chronically toxic and have very
serious impacts on health*

CNT

Carbon nanotubes *are allotropes of carbon with a
cylindrical nanostructure. These molecules have
unusual properties, which are valuable for
nanotechnology, electronics, optics and other
fields of materials science and technology*

CRN

Center for Responsible Nanotechnology *is
addressing the crucial policy issues in advanced
nanotechnology*

DaNa

Data and knowledge on Nanomaterials *is an
umbrella project aiming at collecting and
evaluating scientific results in an
interdisciplinary approach with scientists from
different research areas*

DE

Deutschland Germany
*is the main constituent country of the Kingdom
of the Netherlands. It is a small, densely
populated country located in Western Europe
with three island territories in the Caribbean 33*

DEFRA

Department for Environment, Food and Rural
Affairs *is the government department responsible
for environmental protection, food production
and standards, agriculture, fisheries and rural
communities in the United Kingdom*

DMEA

Dutch Ministry of Economic Affairs *is
responsible for Economics, Industry, Mining,
Trade, Energy policy, Agriculture, Fishery and
Tourism*

DNA

Deoxyribonucleic acid is a molecule that encodes the genetic instructions used in the development and functioning of all known living organisms and many viruses

E numbers

Europe numbers are codes for substances that can be used as food additives for use within the European Union and Switzerland

e.g.

exempli gratia for the sake of example

EC

European Commission is the executive body of the European Union (EU) responsible for proposing legislation, implementing decisions, upholding the EU treaties and managing the day-to-day business of the EU

ECETOC

European Centre for Ecotoxicology and Toxicology of Chemicals is a scientific, non-profit, non-commercial and non-governmental association. Its main objective is to identify, evaluate, and through such knowledge help industry to minimise any potentially adverse effects on human health and the environment that may arise from the manufacture and use of chemicals, biomaterials and pharmaceuticals

ECHA

European Chemicals Agency is an agency of the EU which manages the technical, scientific and administrative aspects of the implementation of REACH (Regulation (EC) No 1907/2006)

ECHA-NMWG

European Chemicals Agency (ECHA) Nanomaterial Working Group is a forum for discussing scientific and technical aspects related to nanomaterials under REACH

ECJ

European Court of Justice officially just the Court of Justice, is the highest court in the European Union in matters of EU law

EEA

European Environmental Agency is the agency of the European Union that provides independent information on the environment

EEB

European Environmental Bureau is a federation of over 140 environmental citizens' organisations based in all 28 European Union Member States, potential Member States and some neighbouring countries

EEE

Electrical and Electronic Equipment is defined as equipment which is dependent on electric currents or electromagnetic fields and equipment for the generation, transfer and measurement of such

EFSA

European Food Safety Authority is an agency of the European Union that provides independent scientific advice and communication on existing and emerging risks associated with the food chain

EDGE

European Group on Ethics in Science and New Technologies is an independent, pluralist and multidisciplinary body which advises the European Commission on ethical aspects of science and new technologies in connection with the preparation and implementation of legislation or policies

EHS

Environmental, Health and Safety Issues for example, fire, explosion and release of harmful substances into the environment or the work area

EINECS

European Inventory of Existing Commercial Chemical Substances is an inventory of substances that were deemed to be on the European Community market between 1 January 1971 and 18 September 1981

ELINCS

European List of Notified Chemical Substances was used by the European Union to identify commercially available chemical substances

ELSA

Ethical, Legal and Societal Aspects Ethical, Legal and Societal Aspects (of nanotechnologies)

EMA

European Medicines Agency is a European Union agency for the evaluation of medicinal products

ENVI Committee

Committee on the Environment, Public Health and Food Safety is responsible for sustainable development, deals with public health, and tackles food safety issues

EP

European Parliament is the directly elected parliamentary institution of the European Union (EU). Together with the Council of the European Union (the Council) and the European Commission (EC), it exercises the legislative function of the EU

EPA

Environmental Protection Agency is an agency of the US federal government which was created for the purpose of protecting human health and the environment by writing and enforcing regulations based on laws passed by Congress

ETSI

European Telecommunications Standards Institute seeks to produce the telecommunications standards that will be used throughout Europe and beyond

EU

European Union is a politico-economic union of 28 member states that are located primarily in Europe

EUV

Extreme ultraviolet lithography is a next-generation lithography technology using an extreme ultraviolet wavelength, currently expected to be 13.5 nm. EUV is currently being developed for high volume use by 2020

EWC

European Waste Catalogue replaced by the List of Wastes; refers to a set list of wastes that are derived from both households and businesses inside the European Union, corresponding statistical classification is the European Waste Classification for Statistics, version 3 (EWC-STAT 3)

FAO

Food and Agriculture Organization of the United Nations leads international efforts to defeat hunger

FDA

Food and Drug Administration is an agency of the United States Department of Health and Human Services, one of the United States federal executive departments

FICA

Federal Immission Control Act regulates parts of the environmental law and is the most important practice-relevant regulation in this field as long as there is no uniform German environmental law

FIFRA

Federal Insecticide, Fungicide and Rodenticide Act is a United States federal law that sets up the basic US system of pesticide regulation to protect applicators, consumers, and the environment

FOEN

Swiss Federal Office of Public Health is part of the Federal Department of Home Affairs in Switzerland

FOPH

Swiss Federal Office of Public Health is responsible for public health in Switzerland and for developing national health policy

FP7

Seventh Framework Programme for Research Initiative was the European Union's Research and Innovation funding programme for 2007–2013. The current programme is Horizon 2020

FPS

Belgian Federal Public Service is a Federal public service of Belgium on health, food chain safety and the environment

Omnibus bill

for everything is a proposed law that covers a number of diverse or unrelated topics. It is a single document that is accepted by a legislature but packages together several measures into one or combines diverse subjects

Prima facie

at first sight is used to signify that upon initial examination, sufficient corroborating evidence appears to exist to support a case

FSA

Food Standard Agency is a non-ministerial government department of the Government of the UK protecting public health in relation to food

GefStoffV

Gefahrstoffverordnung German Hazardous Substances Ordinance

GGBefG

Gesetz über die Beförderung gefährlicher Güter Act on the transportation of hazardous goods

GMO

Genetically modified organism is an organism whose genetic material has been altered using genetic engineering techniques

GMR

Giant magnetoresistance is a quantum mechanical magnetoresistance effect observed in thin-film structures composed of alternating ferromagnetic and non-magnetic conductive layers

HMWEVL

Hessian Ministry of Economics, Energy, Transport and Regional Development is a state institution of the German State of Hesse. It has its headquarters in the state capital of Wiesbaden

i.e.

id est that is to say

IEC

International Electrotechnical Commission is a non-profit, non-governmental international standards organisation that prepares and publishes International Standards for all electrical, electronic and related technologies – collectively known as ‘electrotechnolog’

IED

Industrial Emissions Directive is a EU directive which commits European Union member states to control and reduce the impact of industrial emissions on the environment

IEEE

Institute of Electrical and Electronics Engineers is dedicated to advancing technological innovation and excellence

IFST

Institute of Food Science and Technology is a British, independent qualifying body for food professionals in and around Europe

IG BCE

Industriegewerkschaft Bergbau, Chemie, Energie Mining, Chemical, and Energy Industrial Union

IHK

Industrie und Handelskammer Chamber of Industry and Commerce

in vitro

in glass studies are performed with cells or biological molecules studied outside their normal biological context

in vivo

within the living studies are those in which the effects of various biological entities are tested on whole, living organisms usually animals including humans, and plants

INCI

International Nomenclature of Cosmetic Ingredients is a system of names for waxes, oils, pigments, chemicals, and other ingredients of soaps, cosmetics, and the like, based on scientific names and other Latin or English words

IOMC

Inter-Organization Program for the Sound Management of Chemicals was established in 1995 to strengthen cooperation and increase coordination in the field of chemical safety

IRGC

International Risk Governance Council works to improve the understanding, management and governance of emerging systemic risks that may have significant adverse consequences for human health and the environment

ISO

International Standards Organization is an international standard-setting body composed of representatives from various national standards organisations

ITF

Innovation Task Force is a multidisciplinary group by the European Medicines Agency that includes scientific, regulatory and legal competences

ITRI

Industrial Technology Research Institute is a taiwanese nonprofit R&D organisation engaging in applied research and technical services

IUPAC

International Union of Pure and Applied Chemistry is an international federation of national adhering organisations that represents chemists in individual countries

IVDD

In Vitro Diagnostic Medical Devices Directive is intended to harmonise the laws relating to in vitro diagnostic medical devices within the European Union

JISC

Japanese Industrial Standards Committee is a standards organisation and is the International Organization for Standardization member body for Japan

JNIOOSH

Japan National Institute of Occupational Safety and Health is the only comprehensive research institute for occupational safety and health in Japan

JRC

Joint Research Centre is a scientific and technical research laboratory and an integral part of the European Commission

JWC

Joint Working Committee is a body of one or more persons that is subordinate to a deliberative assembly

JWG

Joint Working Group is an ad hoc group of subject-matter experts working together to achieve specified goals

LAI

Länder-Arbeitsgemeinschaft für Immissionschutz *Joint Working Group on air pollution of the Federal States*

LASI

Länderausschuss für Arbeitsschutz und Sicherheitstechnik *Commission for occupational health and safety technology*

LED

Light-emitting diode *is a two-lead semiconductor light source. It is a p–n junction diode, which emits light when activated, is a two-lead semiconductor light source. It is a p–n junction diode, which emits light when activated*

lex lata

also called *de lege lata is a Latin expression that means 'the law as it exists'*

LFGB

Lebensmittel- und Futtermittelgesetzbuch *German Food and Feed Code*

LKV

Los-Kennzeichnungs-Verordnung *Lot labelling regulation*

LOI

Loss on Ignition *is a test used in inorganic analytical chemistry, particularly in the analysis of minerals*

LOW

List of Wastes *is meant to be a reference nomenclature providing a common terminology throughout the European Union with the purpose to improve the efficiency of waste management activities*

MDD

Medical Devices Directive *is intended to harmonise the laws relating to medical devices within the European Union*

MDEG

Medical Devices Experts Group *is an expert body of the Commission and includes representatives of competent authorities of Member States, standardisation and industrie bodies*

MEDDEV

Medical Devices Guidelines *are part of a set of guidelines relating to questions of application of EU Directives on medical devices*

MEMS

Microelectromechanical systems *is the technology of microscopic devices, particularly those with moving parts. It merges at the nano-scale into nanoelectromechanical systems (NEMS) and nanotechnology*

METI

Ministry of Economy, Trade and Industry *is a ministry of the Government of Japan*

MHRA

Medicines and Healthcare Products Regulatory Agency *is responsible for ensuring that medicines and medical devices work and are acceptably safe in the UK*

MRAM

Magnetoresistive Random Access Memory *is a non-volatile random-access memory technology under development. Unlike conventional technologies, data is not stored as electric charge or current flows, but by magnetic storage elements*

MSDS

Material Safety Data Sheet *is intended to provide workers and emergency personnel with procedures for handling or working with a substance in a safe manner, and includes further detailed information*

MWCNT

Multiwall Carbon Nanotubes *are members of the fullerene structural family and consist of multiple rolled layers (concentric tubes) of graphene*

NB

Notified Body *in the European Union, is an organisation that has been accredited by a Member State to assess whether a product meets certain preordained standards*

NEMS

Nanoelectromechanical systems *are a class of devices integrating electrical and mechanical functionality on the nanoscale. They form the logical next miniaturisation step from so-called microelectromechanical systems, or MEMS devices*

NemV

Nahrungsergänzungsmittelverordnung *Dietary supplement regulation*

NICNAS

National Industrial Chemicals Notification and Assessment Scheme *is the Australian government's regulatory body for industrial chemicals*

NIOSH

National Institute for Occupational Safety and Health *is the US federal agency responsible for conducting research and making recommendations for the prevention of work-related injury and illness*

NL

Netherlands is the main constituent country of the Kingdom of the Netherlands. It is a country located in Western Europe with three island territories in the Caribbean

nm

nanometre is a unit of length in the metric system, equal to one billionth of a metre

NNI

National Nanotechnology Initiative is a U.S. Government research and development initiative

NSMP

Nanoscale Materials Stewardship Program provides a scientific foundation for regulatory decisions by the development of key scientific information and improved risk management practices for nanoscale substances

OECD

Organization for Economic Cooperation and Development is an international economic organisation of 34 countries founded in 1961 to stimulate economic progress and world trade

OHS

Occupational Health and Safety is an area concerned with protecting the safety, health and welfare of people engaged in work or employment

OLED

Organic light-emitting diode is a light-emitting diode (LED) in which the emissive electroluminescent layer is a film of organic compound that emits light in response to an electric current

PBT

Persistent, Bioaccumulative and Toxic is a chemical substance that is persistent, bioaccumulative and toxic according to the criteria in Annex XIII of the REACH Regulation in accordance with its Art. 57d

PET

Polyethylene terephthalate is the most common thermoplastic polymer resin of the polyester family and is used mostly in fibres for clothing, containers for liquids and foods, and thermoforming for manufacturing

PNEC

Predicted No Effect Concentration is the concentration of a chemical which marks the limit at which below no adverse effects of exposure in an ecosystem are measured

PVC

Polyvinyl chloride is the world's third-most widely produced synthetic plastic polymer, after polyethylene and polypropylene

RCEP

Royal Commission on Environmental Pollution in the UK was created to advise the Queen, Government, Parliament and the public on environmental issues

REACH

Registration, Evaluation, Authorisation and Restriction of Chemicals addresses the production and use of chemical substances (i.e. everything made of atoms), and their potential impacts on both human health and the environment

RoHS

Restriction and Use of Certain Hazardous Substances in Electrical and Electronic Equipment

RS & RAE

Royal Society & the Royal Academy of Engineering carried out an independent study of likely developments and whether nanotechnology raises or is likely to raise new ethical, health and safety or social issues

SAC TC 279

National Technical Committee on Nanotechnology of Standardization Administration of China focuses on the development on standardisation documents concerning nanotechnologies in China

SCCNFP

Scientific Committee on Cosmetic Products and Non-Food Products Intended for Consumers mandates scientific and technical questions concerning consumer health relating to cosmetic products and non-food products intended for the consumer especially substances used in the preparation of these products, their composition, use as well as their types of packaging

SCCP

Scientific Committee on Consumer Products mandates questions concerning the safety of consumer products (non-food products intended for the consumer

SCCS

Scientific Committee on Consumer Safety *is one of the independent scientific committees managed by the Directorate-General for Health and Consumer Protection of the European Commission, provides scientific advice on issues related to non-food and is the successor to both the SCCP and the SCCNFP.*

SCENIHR

Scientific Committee on Emerging and Newly Identified Health Risks *provides opinions on broad, complex or multidisciplinary issues requiring a comprehensive assessment of risks to consumer safety or public health and similar related issues*

SME

Small and Medium Enterprises *are companies whose personnel numbers fall below certain limits*

SNUR

Significant New Use Rules *are notifications asked from companies in case of any significant new use of existing chemicals*

SRU

Sachverständigenrat für Umweltfragen *German Advisory Council on the Environment*

TC 113

Technical Committee 113 (IEC) *aims at standardisation of technologies relevant to electrical and electronic products and systems in the field of nanotechnologies*

TC 229

Technical Committee 229 (ISO) *has the scope of standardisation in the field of nanotechnologies*

TC 352

Technical Committee 352 (CEN) *aims at developing standards for methodologies for the characterisation of nanomaterials in the manufactured form and for a voluntary labelling in products*

TEC

Treaty establishing the European Community *is the renamed and amended Treaty establishing the European Economic Community (TEEC)*

TEEC

Treaty establishing the European Economic Community *is an international agreement that led to the founding of the European Economic Community (EEC) on 1 January 1958. Upon the formation of the European Union (EU) in 1993, the EEC was incorporated and renamed as the European Community (EC). In 2009 the EC's institutions were absorbed into the EU's wider framework and the community ceased to exist*

TFEU

Treaty on the functioning of the European Union *is the renamed and amended Treaty establishing the European Community (TEC)*

TLV

Threshold limit value of a chemical substance *is a level to which it is believed a worker can be exposed day after day for a working lifetime without adverse health effects*

TMR

Test Method Regulation *and its subsequent amendments, define tests testing of chemicals for the REACH Regulation. They are based on the OECD Guidelines for the Testing of Chemicals*

TOC

Total organic carbon *is the amount of carbon bound in an organic compound and is often used as a non-specific indicator of water quality or cleanliness of pharmaceutical manufacturing equipment*

TRGS

Technische Regeln für Gefahrstoffe *Technical Rules for Hazardous Substances*

TSCA

Toxic Substances Control Act *is a United States law that regulates the introduction of new or already existing chemicals*

UBA

Umweltbundesamt *German Environment Agency*

UK

United Kingdom of Great Britain and Northern Ireland, *is a sovereign state in Europe*

UNITAR

United Nations Institute for Training and Research *is an autonomous body within the United Nations with a mandate to enhance the effectiveness of the United Nations through training and research*

US

United States of America *commonly referred to as the United States (US) or America, is a federal republic composed of 50 states, a federal district, five major territories and various possessions*

VAwS

Verordnung über Anlagen zum Umgang mit wassergefährdenden Stoffen *Regulations concerning installations handling water hazardous substances*

VCI

Verband der Chemischen Industrie e. V. *German Council of Chemical Associations*

vPvB

very Persistent and very Bioaccumulative *is a chemical substance that is very persistent and very bioaccumulative according to the criteria in Annex XIII of the REACH Regulation in accordance with its Art. 57d*

VwVwS

Verwaltungsvorschrift wassergefährdender Stoffe *Administrative Regulation on Substances Hazardous to Water*

WEEE

Waste Electrical and Electronic Equipment *is the collection, recycling and recovery targets for all types of electrical goods, with a minimum rate of 4 kilograms per head of population per annum recovered for recycling by 2009 (Directive 2012/19/EU)*

WFD

Water Framework Directive *is a European Union directive which commits Member States to achieve good qualitative and quantitative status of all water bodies (including marine waters up to one nautical mile from shore) by 2015*

WG

Working Group *is domain-specific and focus on discussion or activity around a specific subject area*

WHC

German Water Hazard Class *is either classified as non-hazardous to water or assigned to one of three classes with increasing water hazard: WGK 1, WGK 2, and WGK 3*

WHO

World Health Organization *is a specialised agency of the United Nations that is concerned with international public health*

WPMNs

Working Party on Manufactured Nanomaterials *focuses on issues related to nanomaterials impacting human and environmental health and safety*

WRMG

Wasch- und Reinigungsmittelgesetz *German Detergents Act*

A. Introduction^{7, 8, 9}

The prefix ‘nano’ is derived from the Greek *νᾶνος* [*nános*]: ‘dwarf’.

Nanotechnologies allow for the production of completely new substances and materials in a wide range of industries and technological sectors. Due to the multiplicity of their possible applications, nanotechnologies are typically a very heterogeneous field. Thus, most scientists speak of nanotechnologies, instead of ‘the’ nanotechnology (Führ et al., 2006b).

Nanotechnologies are not just a new field of science and engineering, but a completely new approach to technology (NNI, 2012; Catenhusen, 2008) and are considered one of the most important global future technologies (Breiner et al., 2009). Although they promise much, substantial uncertainties exist regarding the potential risks occurring at any stage of the life cycle of nanotechnological products (Führ et al., 2006b). In Germany, nanotechnological products and their production processes are generally subject to the legal system, especially with respect to their production equipment and plant, permissions regarding substances or formulations, and the protection of employees or the environment (Eisenberger et al., 2010; Calliess, 2001). Nevertheless, it is currently unclear whether existing legislation is already adequately applicable or whether hazards brought about by specific new products, materials or process characteristics could result in legislative gaps. Thus, it is important to consider the extent to which a mostly single substance-related legislation is able to meet the size-specific properties of nanomaterials.

While the first nanotechnological products are already in existence, few politico-legal regulations attempt to handle the special characteristics of nanomaterials; the commercial use of nanotechnologies is subsidised by large amounts of public development funding. However, only 4% of these funds are spent on risk research (BMBF, 2012a). The question is whether this is sufficient to ensure that products meet certain requirements before becoming available on the market. Generally, the potential of nanotechnologies is highly valued; however, the risks remain unclear. The possibility of a distinct legal framework for nanotechnologies has been hotly debated, but there has been no definitive result. This thesis thus attempts to construct a comprehensive legislative framework (theoretically) for all the existing and potential risks of nanotechnologies, in particular those in the foreseeable future.

⁷ The documentation follows the ISO 690 standard for bibliographic referencing.

⁸ Male and Female notations are to be considered as equal.

⁹ The *duplex* (both sided) printing of this thesis should benefit the environment – thereto, the author is aware of the violation of the custom and the tradition to deliver standard academical works single side printed. To accommodate notes, however, extra-large margins were considered.

A.1. Thematic status quo

It can be fundamentally stated that nanotechnology is promoted very strongly economically. Products are already merchandised and being used. The potential of nanotechnology is highly valued – the risks, however, remain relatively unclear. Therefore, the question of a distinct legal framework needs to be discussed; a clear opinion has not yet been developed.

Nevertheless, consciousness of the relevance of nanotechnologies and regulation seems to be gradually growing; in 2006, the German federal government initiated a dialogue – the ‘NanoKommission’ – to investigate the usability and risks of nanotechnologies (NanoKommission, 2011). Since then, in the different institutions of the European Union, intensive discussions regarding the proper legal framework for nanomaterials have been taking place. There seem to be efforts to regulate nanotechnologies more strictly in the future, e.g. in the context of REACH and in the Cosmetics Directive. Similarly, the Novel Food regulation is intended to examine the specific characteristics of nanoparticles with reference to the EU’s food sector.

At an international level, the Organization for Economic Cooperation and Development (OECD) created the ‘Working Party on Manufactured Nanomaterials’ in 2006 (OECD, 2012a). This committee’s activities include the observation of current politico-legal and industrial developments, the investigation of the state of research and remaining research gaps, the examination of available testing guidelines for nanomaterials, and international exchange on the current conditions for relevant and necessary risk research. Additionally, international standardisation committees, such as the International Standards Organization (ISO), are currently developing a standardised nomenclature and physico-chemically based standardisation of nanoscaled objects and procedures (ISO, 2008). In 2011, the latest activity took place: a report on environmental legislation within the field of nanotechnologies, as well as a listing of products already present on the market, were submitted to the European Commission (EC). The report implies that both regulators and users are struggling to manage the risks of nanotechnologies, which remain essentially unquantifiable (Milieu and AMEC, 2011).

A.2. Objectives

Although it is recognised that adjustments are needed, and they have been repeatedly proposed by expert committees of policymakers, industry members and non-governmental organisations, very few amendments have actually been made (Führ et al., 2006b). This leads to the question of whether sufficient regulatory handling of the opportunities and risks of nanotechnologies is possible on the basis of the current legal situation.

Based on an analysis of the relevant state of the art of technology and science, and an assessment of national (German) and European (particularly REACH) legislation on nanotechnologies, the aim of this present work is to examine whether there are gaps in the aforementioned current legislation and, if so, how to close them. The objective is to propose possible adjustments to the legislation regarding the special risks and hazards of nano-sized technologies. This will be done with the help of certain adjustments to the existing legislation that take into account present, as well as foreseeable future, risks based on the author's experience of current trends in nanotechnologies. However, they must be considered as emerging technologies developing rapidly into various scientific and industrial sectors (Kearnes et al., 2006).

To summarise, the risk assessment, the evaluation of current legislation and the development of appropriate legal control mechanisms must take into account current and foreseeable developments in nanotechnologies. Thus, this thesis aims to investigate the adequacy of existing and future regulation of nanotechnologies, to explore the feasibility of legislating for possible future risks with existing laws and, finally, to provide recommendations on the legislation of nanotechnologies in order to adequately protect human health and the environment.

A.3. Methodology

In order to properly outline the appropriate framework for nanotechnologies, current and expected nanotechnological developments must be taken into account. Additionally, legislation must be considered in its present and future forms. Before discussing the risks of nanotechnologies/nanomaterials and the suitability of current legislation, it is important to clarify the terminology used. The term 'nano' has not always been consistently used (Paschen et al., 2003). The first step will thus be to define the relevant characteristics of nanotechnologies.

Subsequently, a basis of technological understanding will be obtained, and the proper handling of the 'chance/risk' discrepancy of nanotechnologies will be discussed. Further investigations will proceed using a two-step analysis: firstly marking out fields in which regulatory deficits exist and, secondly, pointing out methods for amendments reducing these deficits.

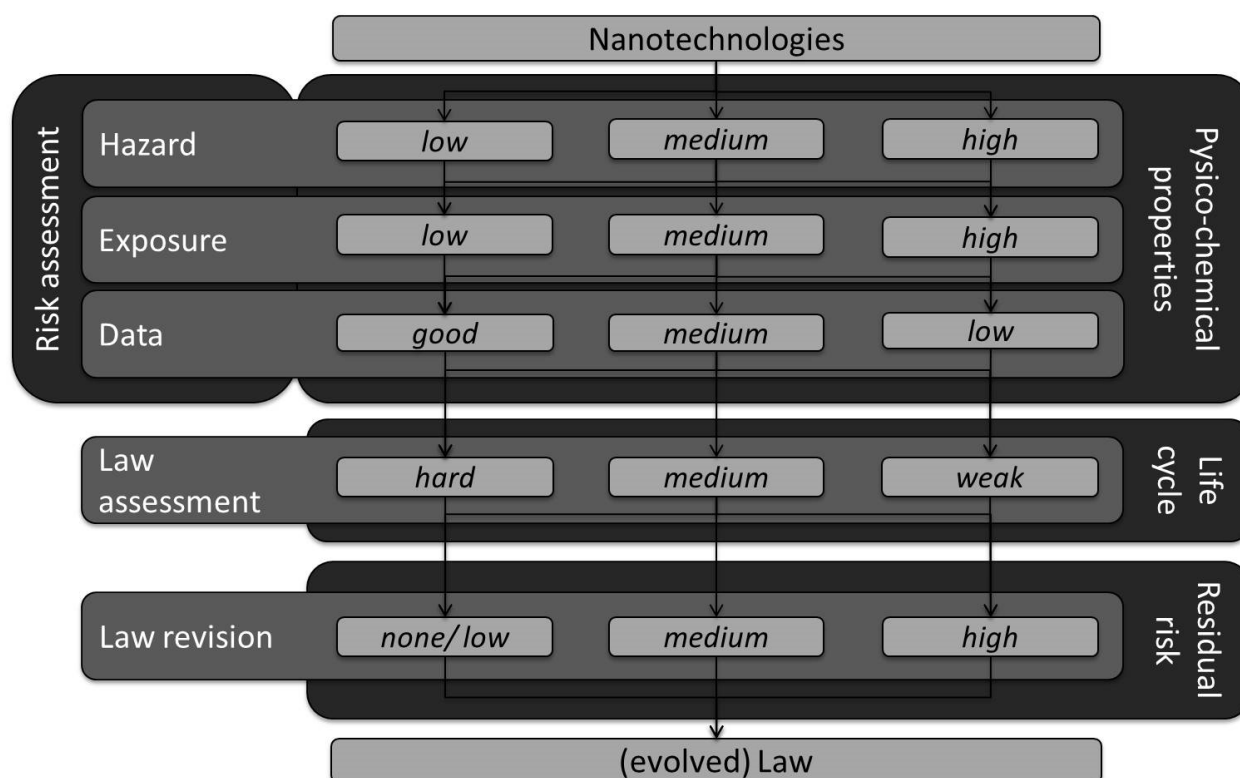
Due to the absence of explicit regulations, a normative orientation in the form of an evaluation benchmark is required in order to formulate the requirements for appropriate legal management of nanospecific risks. This orientation can often only be established if the legislation's orientation in a similarly treated field is compared to the present case. Considering these two findings in parallel should reveal the gaps between risk and appropriate regulation. This procedure is based on the fundamental compatibility and comparability of single laws within the German and the European legal system (SRU, 2011).

A.4. Outline

After a brief general overview in part A of this work, part B will consider the fundamental technological basics. Here, the terminology of nanotechnologies and nanomaterials will be defined, in addition to an introduction to the various forms of nanoparticles and their production processes. The subject ‘risks and hazards’ will be discussed in depth due to the fact that this matter is fundamentally important in understanding the role of the relevant legislation. After establishing this basic technological framework, part C gives an initial characterisation of the conflict with the introduction of some general legal objectives. This could be understood as an initial introduction to a better understanding of the characteristic legal difficulties.

The legislative basics will follow in section D. Here, the role and function of the pertinent legislation will be explained. Moreover, legislation will be assessed by taking into account the nanospecific risks and hazards in present and future applications. In the same section, the possible legislative amendments will be discussed in detail for each hazard or risk in the possible life cycle of nanotechnological products.

Finally, in the concluding section E, the achieved aims will be briefly reviewed. Additionally, a short commentary on present and future developments is provided. Here, some comments are made concerning the complex issues around the technical development of nanomaterials.



A.1. Overview of methodology.

B. Technological basics

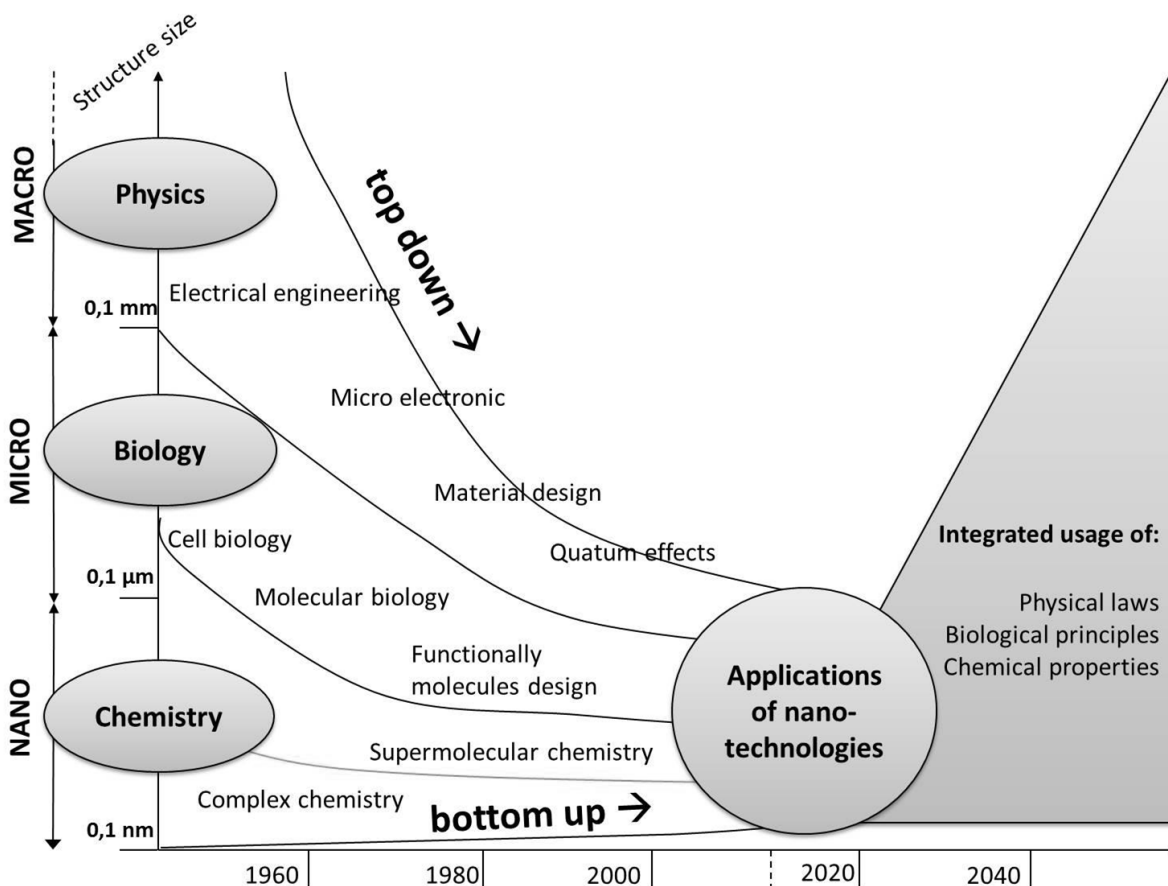
Nanotechnology is an umbrella term covering a wide range of technologies that have one thing in common: structures and processes at the nanometre scale. A nanometre is one billionth (10^{-9}) of a metre and denotes a border range in which the behaviour of matter cannot be described by the laws of classical physics, mathematics or chemistry. For that reason, quantum physical effects increasingly play a role. At this stage, there is talk of ‘induced size functions’ (Paschen et al., 2003). The guiding vision of nanotechnologies: the manipulation of matter at the atomic level, was first formulated in 1959 by the Nobel laureate in physics Richard P. Feynman.

The crucial features of nanotechnologies are that they represent a multidisciplinary interaction of numerous specialised fields of science and have now reached a point at which the boundaries of different disciplines (physics, chemistry and biology) have blurred. Nanotechnologies are therefore also known as a ‘convergent technology’ (IHK Köln, 2010).

Nanotechnologies include research in cluster and solid state physics, surfaces and other areas of chemistry, molecular biology, food technology, cosmetics, pharmaceuticals, and also, with limited scope, some areas of engineering, as well as, occasionally, other areas. The basic principles of nanotechnologies are, in the main, their quantum-mechanical behaviour and their enlarged surfaces, in combination with their molecular recognition ability. However, nanoparticles are also formed in a natural way, although usually in another form. Their weathering products found in nature come together to form larger particles, whereas technical nanoparticles are usually preserved against agglomeration by special coatings or solvents (BMBF, 2011).

Some nanomaterials are already used in commercial products; others are important model systems for chemical, physical and materials science research. Physics plays a major role in nanotechnologies in terms of the construction of microscopes and for the laws of quantum mechanics. For the desired structure of matter and atomic arrangements, chemistry is used. Medicine will use targeted nanoparticles against diseases, and structures constructed from DNA (e.g. two-dimensional crystals in the nanometre scale) can be manipulated with already existing techniques (e.g. polymerase chain reaction) using genetic or bioengineering. Further applications involve the coating of surfaces and the production of filling materials. Applications use the fact that nano filling materials do not behave like amorphous substances but have the properties of a liquid. Medical researchers are developing customised nanoparticles the size of molecules that can deliver drugs directly to diseased cells. In food science, applications range from how food is grown to how it is packaged (University Kiel, 2010a).

Nanoelectronics are important; however, their affiliation to nanotechnologies is not seen uniformly in scientific and political practice (Krüger, 2010). Typical products include ‘quantum dots’; microprocessors have structures that are smaller than 100 nm and, therefore, could be referred to as nanotechnologies, although this is not commonly done as they are made with conventional lithographic techniques (University Kiel, 2010b). Similarly, another development direction can be seen in the expansion of microtechnology. However, due to the requirements of a further reduction of micrometre structures, unconventional new approaches are being used. For example, nanochemistry often follows the opposite approach: sub-nanometre dimensions are commonly used in molecular work, and the final substances are made by multiplying individual units to form larger molecular nanoscale composites (Wendorff, 2009; Ajayan et al., 2003).



B.1. Blurring of technologies (BMBF, 2012c).

B.1. Defining terminologies

A generally in law accepted definition of nanotechnologies does not exist to date; however, several differing definitions can be found (HMWVL, 2010). For this reason, a suitable definition of nanotechnologies must be discussed. The term ‘nanotechnology’ was first used in 1974 by Norio Taniguchi, University of Tokyo (RS & RAE, 2004). He described the precise engineering of materials at the nanometre level. Nanotechnologies could thus be understood as the design and fabrication of materials, devices and systems at nanometre dimensions.

So the essence of this technology is size and control, as they relate to tools, methods and applications. Nonetheless, all nanotechnologies share the common feature of control at the nanometre scale. Putting forward a common, all-embracing definition of nanotechnologies has, however, been quite challenging. Conceptually, nanotechnologies refer to science and technology at the nanoscale of atoms and molecules, and to the scientific principles and new properties that can be understood and mastered when operating in this domain. Such properties can then be observed and exploited at the micro- or macro-scale. Because of the diversity of its applications, some scientists prefer the plural term ‘nanotechnologies’ (SRU, 2011). The term ‘nanotechnologies’ will be used in this thesis as a collective term, encompassing the various branches of nanosciences, nanomaterials and nanoparticles. Although the wording differs, most definitions specify that a nanomaterial must fulfil two of the follow criteria:

- ∞ Structure in at least one dimension in the approximate range of 1–100 nm (nanostructure);
- ∞ This nanostructure must lead to properties differing from the bulk properties;
- ∞ Must not occur through natural processes (manipulation of individual nanostructures).

The first criterion characterises the relevant size range. Stricter definitions can be found in the literature, e.g. that nanotechnologies deal with structures that are in at least two dimensions less than 100 nm in size. This definition is not used here because it excludes the entire range of thin films and coating techniques (Paschen et al., 2003). Accordingly, a definition that is too narrow should not be chosen.¹⁰ Systems greater than 100 nm that have novel properties should considered as nanostructured materials (NanoKommission, 2011).

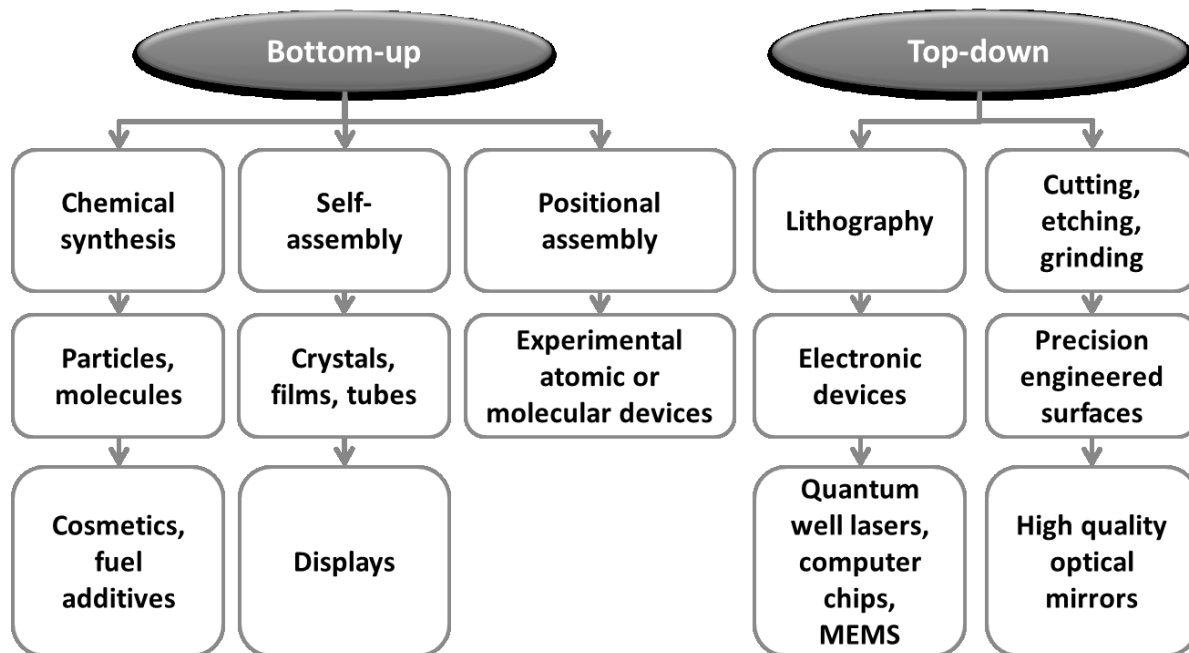
The second criterion makes it very clear that both the geometry and the utilisation of new effects and features are constitutive for nanotechnologies. This means, for example, that the production and use of DNA chips is in a narrow sense not included within nanotechnologies. However, they are included in the definition of nanotechnologies found in this work because they are closely linked to various fields of its development. The third and final criterion is primarily important for the field of life sciences. It differs from those activities that make natural processes on the nanometre scale advantageous. This includes, for example, the bio-based (with the aid of micro-organisms) production of enzymes. The natural world also contains many examples of nanoscale structures, from milk (a nanoscale colloid) to sophisticated nano-sized and nanostructured proteins that control a range of biological activities, such as flexing muscles, releasing energy and repairing cells. Observational activities are not considered; however, they relate to individual nanostructures (Paschen et al., 2003).

¹⁰ Commission Recommendation 2011/696/EU of 18 October 2011 on the definition of nanomaterial (OJ L 275, 20.10.2011, p. 38–39).

Although this definition is broad, this does not make it diffuse. For a given material or system, one can individually determine whether it involves nanotechnologies (Hansen et al., 2007). Generally, the literature also takes a pragmatic approach in defining the terminology of nanotechnologies (BSI, 2007b; BSI, 2007a; ISO, 2008; ISO, 2015). This means that even if an application does not follow the definition used strictly enough, it may nevertheless be considered on an individual basis (e.g. if it is generally recognised that some approaches will continue to develop into nanotechnologies) (Paschen et al., 2003). Thus, nanotechnologies also are defined via the convergence of chemistry, biology, physics and engineering (BMBF, 2012c).

B.2. General production methods

There are a wide variety of techniques that are capable of creating nanostructures with various degrees of quality, speed and cost. These manufacturing approaches fall into two categories: ‘bottom-up’ and ‘top-down’. In recent years, the limits of each approach, i.e. of the features, size and quality that can be achieved, have started to converge. A diagram illustrating some types of materials, their production process and the products that these two approaches are used for is shown below (RS & RAE, 2004).

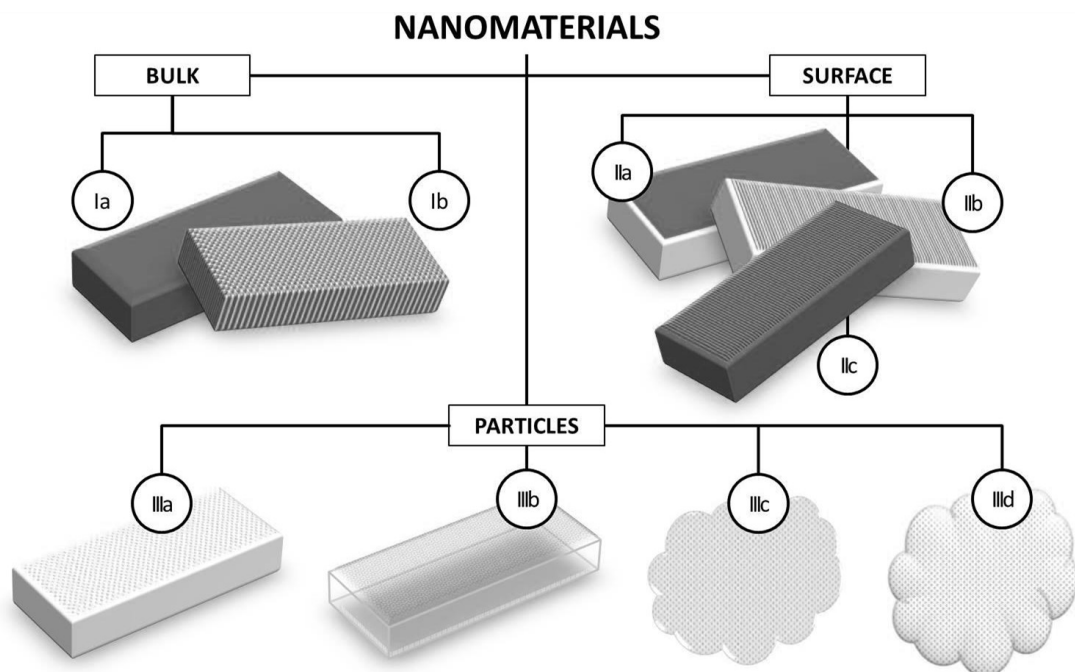


B.2. Bottom-up and top-down approaches (RS & RAE, 2004).

The figure shows the two different approaches in nanotechnologies. However, it is an explanatory model and is not completely comprehensive. The named end products are examples of possible products. A third approach would be to use both strategies at the same time (ICON, 2006). The dimensions that can be controlled by either approach are of a similar order, and this is leading to exciting new hybrid methods of manufacturing. This is, without question, an indication that science in this area still has potential (RS & RAE, 2004).

B.3. Kinds of nanomaterials

The following framework for nanotechnologies will be limited to materials that have been humanly engineered intentionally – henceforth referred to as engineered nanotechnologies – and does not include nanomaterials that are either naturally occurring or unintentionally human-generated nanoparticles (Oberdörster et al., 2007). Nowack and Bucheli also propose dividing nanoparticles into ‘natural’ and ‘anthropogenic’ particles, depending on their origin (Nowack et al., 2007). In the same way, this thesis focuses on anthropogenic nanomaterials only, as legislation usually only focuses on controls for this kind of emission source. A procedure for dividing nanomaterials into relevant subcategories has been developed (Hansen, 2007) in order to facilitate hazard identification and to focus risk assessment procedures; the findings of this procedure are shown in the following diagram.



B.3. Kinds of nanoproducts (Hansen et al., 2007).

Description of the nanomaterials in the figure: Ia: One phase. Ib: Multi phase. IIa: Film. IIb: Structured film. IIc: Structured surface. IIIa: Surface bound. IIIb: Suspended in solids. IIIc: Suspended in liquids. IIId: Airborne.

A major benefit of the proposed categorisation framework is that it provides a tool for dividing nanosystems into identifiable parts and thereby facilitating evaluations of, for instance, relevant exposure routes or analysis of effect studies, according to the relevance of the material tested (Hansen, 2009).

When using this kind of framework for categorising nanotechnological systems, it should be noted that it is possible for a system to consist of nanostructured elements belonging to different categories, e.g. car catalysts containing nanoparticles bound to a surface (IIIa) as well as a support material (surface) that is a nanoporous material mixture (Ib) (Chorkendorf et al., 2003).

B.4. Potential and possibilities

Nanotechnologies as ‘enabling technologies’ come into play early on in the value chain, as they are used to design smaller, faster, more powerful and ‘intelligent’ system components for products, with the effect of significantly improved (UBA, 2006) and, in some cases, entirely new functionalities. When it comes to maintaining a strong economy and securing jobs, nanotechnologies are a key crosscutting technology and are of enormous importance worldwide (Smalley, 2004). The innovation potential of nanotechnologies, in fact, reaches far beyond that (BCC Research, 2010; BCC Research, 2012; BCC Research, 2013). The potential of nanotechnological discoveries to solve global issues is considered very promising. For example, nanotechnologies may be used to increase energy supplies, conserve natural resources through resource savings, and to expand comprehensive preventive and medical care (Steinfeldt et al., 2004). Beyond that, many applications affect not only industrial use but also contribute to everyday life. For example, the lotus effect enables self-cleaning surfaces. Global consumption of advanced and nanoscale ceramic powders will rise from \$9 billion in 2013 to \$12.1 billion in 2018. Global consumption of nanocomposites is expected to grow in unit terms from nearly 225,060 metric tonnes in 2014 to nearly 584,984 metric tonnes in 2019, reaching a compound annual growth rate (CAGR) of 21.1% for the period of 2014 to 2019 (BCC Research, 2014).

Nearly 450 economic agents in the field of SMEs and large companies were identified in Germany. Between 50,000 and 100,000 jobs in Germany in the year 2009 depended directly or indirectly on nanotechnologies (BMBF, 2012d). In addition, it is expected that throughout 2015 almost all industries – in Germany and worldwide – will be affected by the development of nanotechnologies. Moreover, 10% of all existing jobs will be based directly on the manufacture of nanoproducts, with both large corporations and small businesses being involved (BMBF, 2012d).

To summarise, the current and future applications of nanotechnologies are very widespread, impacting nearly all technical fields and markets. In the future, no sector will be without the direct or indirect impact of nanotechnologies. Despite the fact that nanoproducts are now reaching the point where they can be of use in the industrial or private sector, the potential of future applications is remarkable. Consequently, due to the almost infinite number of possible applications and operational areas, only a fraction of possible applications can be shown in the table below. However, this data should demonstrate the general economic potential of nanotechnologies and should additionally show the extent of civil and economic benefits (Becker et al., 2009).

| | | | | |
|-----------------------|---|--|---|---|
| Civil Security | <ul style="list-style-type: none"> Chemical/Biological (C/B) decontamination systems on nanoparticle basis Security tags on the basis of nanoparticles and nanopigments | <ul style="list-style-type: none"> Protection systems on the basis of nanofluids reinforcing pressure impact Lab-on-Chip-Systems for C/B diagnostics Electronic noses for the detection of C/B-substances | <ul style="list-style-type: none"> Super-absorbing gels for the neutralisation of radioactive residues C/B-filter systems on the basis of nanocatalytic or nanostructured materials Nanotube-reinforced protection systems | <ul style="list-style-type: none"> Self-healing protection materials Early diagnosis on the basis of cross-linked nanosensors/NEMS Biomonitoring systems with integrated molecular diagnostics and medication |
| Construction | <ul style="list-style-type: none"> Dirt-resistant coating and paint IR-reflecting nanolayers for heats-absorbing glasses Photocatalytic coatings for roof tiles, awnings, PVC-profiles Nanobased sealing coatings | <ul style="list-style-type: none"> Antibacterial paints Multifunctional ceramic wallpapers Fire-protected glasses and construction materials Aerogel facades, vacuum insulation panels Switchable glasses | <ul style="list-style-type: none"> Nanoporous insulation foams Large-area flexible solar cells as facade elements OLED-illumination Ultra-high-performance concrete Nanooptimised asphalt mixtures | <ul style="list-style-type: none"> Ultra-light construction material on CNT-basis Multifunctional adaptive facade elements (energy recovery, shading, illumination) Construction material with self-repair mechanism |
| Environment | <ul style="list-style-type: none"> Nanostructured catalysts Nanolayers for corrosion and wear protection Nanomembranes for wastewater treatment Anti-reflection layers for solar cells | <ul style="list-style-type: none"> Nanooptimised micro fuel cells/batteries Photocatalytic air and wastewater treatment with nanoTiO₂ Heat-protection for turbines Groundwater sanitation with iron-nanoparticles | <ul style="list-style-type: none"> Large-area polymer solar cells Nanosensors for environmental monitoring Thermo-electric waste heat utilisation Efficient hydrogen generation through nanocatalysts Selective pollutant separation | <ul style="list-style-type: none"> Artificial photosynthesis High-effective quantum dot solar cells Resource saving production through self-organisation Efficient power supply lines with CNT-cables |
| Textile | <ul style="list-style-type: none"> Dirt-repellent textiles through nanoparticles Antibacterial textiles through nanosilver Scent-impregnated textiles on the basis of nanocontainers (e.g. cyclodextrine) | <ul style="list-style-type: none"> UV-protected textiles Thermal protection clothing with aerogels Abrasion-resistant fibres through ceramic nanoparticles Nanooptimised technical textiles | <ul style="list-style-type: none"> Active thermal regulation through phase-change materials Electrically conductive textile fibres for Smart Textiles Textile-integrated OLED Textile-integrated power generation (e.g. solar) | <ul style="list-style-type: none"> Textile-integrated sensors/actors for active movement support control of body functions etc. Textile-integrated digital assistance systems (Human Interfaces) |
| Automotive | <ul style="list-style-type: none"> Nanostructured exhaust catalysts Admixtures for tires Nanocoated Diesel-Injectors Anti-reflection layers for displays Magneto-resistant sensors Scratch-resistant lacquers | <ul style="list-style-type: none"> Nanoparticles as Diesel-additives LED-headlights Nanohard layers for polymer disks Nanostructured light-construction composites Nanooptimised Li-ion batteries | <ul style="list-style-type: none"> Thin-film solar cells for car roofs Nanooptimised fuel cells Thermoelectric waste-heat utilisation Ferrofluids for adaptive shock absorbers Nanoadhesives in production | <ul style="list-style-type: none"> Switchable, self-healing lacquers Adaptive bodysell for optimum air resistance Intelligent drive assistance and traffic detection Connected cars |
| Chemistry | <ul style="list-style-type: none"> Nanopowder/dispersion Nanostructured industrial carbon black Active agents and vitamins Polymer dispersions Effect pigments Ferrofluids | <ul style="list-style-type: none"> Fullerene, Carbon Nanotubes Nanopolymer composites Organic semiconductors Semiconductor quantum dots Inorganic/organic hybrid composites Dendrimers | <ul style="list-style-type: none"> Nanoporous foams Switchable adhesives Functionalised nanomembranes Artificial spider silk Electro spun nanofibres | <ul style="list-style-type: none"> Self-healing materials Self-organising complex materials/ composites Molecular machines Adaptive multifunctional materials |
| Optics | <ul style="list-style-type: none"> Nanolayers for scratch-proof plastic lenses Ultra-precision optics Anti-reflection layers LED diode lasers | <ul style="list-style-type: none"> Optical microscope with nanoresolution Organic light-emitting diodes CNT-field emission displays 2D-photonic crystals | <ul style="list-style-type: none"> EUV lithography-optics Quantum-dot lasers Quantum cryptography 3D photonic crystals | <ul style="list-style-type: none"> All Optical Computing Optical meta-materials for 'Magic Cap Applications' Data transmission through surface plasmons |
| Electro | <ul style="list-style-type: none"> Hard-disk storage units with GMR-reading heads Silicon electronics Flash-storage Polymer electronics | <ul style="list-style-type: none"> Silicon-electronics 32 nm structures CNT-field emission displays MRAM-memories Phase-change memory | <ul style="list-style-type: none"> MEMS-memory ('Millipede') CNT-data memory Silicon-electronics 22nm structures CNT-interconnects in circuits | <ul style="list-style-type: none"> Molecular electronics Quantum computing Spintronic logics DNA-computing |
| Medicine | <ul style="list-style-type: none"> Nanoparticles as contrast medium in diagnostics Nanoscale drug carriers Biochips for in-vitro diagnostics Nanomembranes for dialysis | <ul style="list-style-type: none"> Nano cancer therapy Nanostructured hydroxylapatite as bone substitute Quantum-dot markers Drug release for implants | <ul style="list-style-type: none"> Bio-compatible, optimised implants Nanoprobes and markers for molecular imaging/diagnostic Selective drug carriers | <ul style="list-style-type: none"> Artificial organs trough Tissue Engineering Theranostics Neuro-coupled electronics for man-machine-interfaces and active implants |
| | Established | Market entry | Prototype | Concept |
| | Commercialisation in: | | | |
| | 0-3 years | 4-10 years | >10 years | |

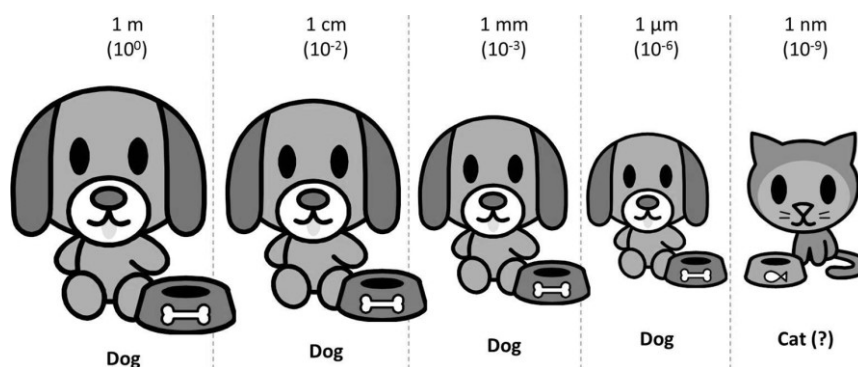
B.1. Examples of possible nanotechnological developments (BMBF, 2009).

B.5. Hazards and risks

In scientific risk assessment, ‘hazard’ and ‘risk’ are distinctly different concepts (BfR, 2009a; Cefic, 2003; IPCS, 2004; Jonen, 2007; Kaplan et al., 1993). A ‘hazard’ is the potential of a substance or situation to cause adverse effects when an organism, system or (sub) population is exposed to it. ‘Risk’, on the other hand, denotes the probability of an adverse effect on an organism, system or (sub) population with exposure to a substance or situation under specified conditions (BfR, 2009b). In the presentation of the hazards and risks of nanotechnologies, it is hardly possible to address every aspect of the many different products and procedures in detail. Instead, the specific characteristics of nanotechnologies and their products will be addressed, in addition to the potential risks and hazards resulting from them (Allianz Versicherung-AG, 2005).

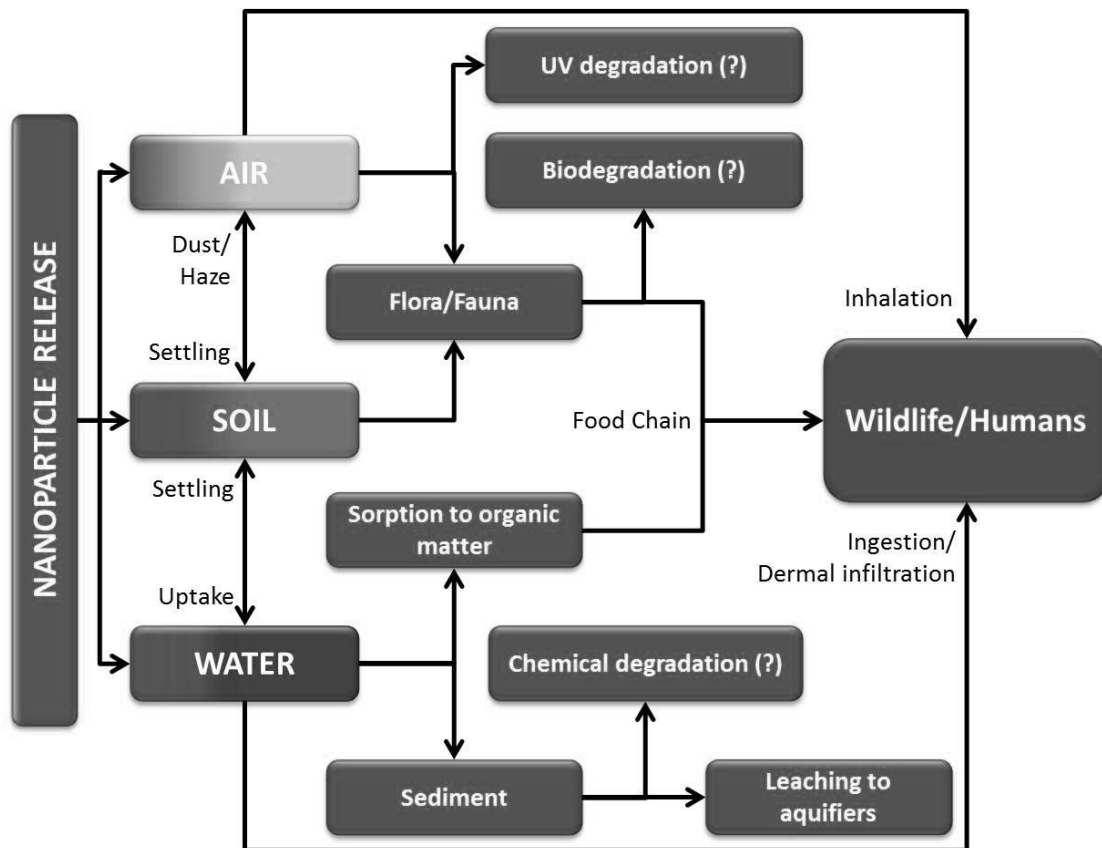
So far, little is known about the exposure of nanoparticles with regard to human health and the environment (BAuA, BfR and UBA, 2007; BMU, 2008; Dreher, 2004; HCN, 2006; Hoet et al., 2004; UBA, 2006). However, concrete evidence is available that there are interactions between nanoparticles and biological systems (Berry et al., 2003; Cheng, 2004; Hund-Rinke et al., 2006; Köhler et al., 2008; Xia et al., 2004). Moreover, most of these scientific publications show that nanoparticles may pose a risk because of their special properties (Biswas et al., 2005; Gottschalk et al., 2009; Boxall et al., 2007). These studies on the risk assessment of nanomaterials can indeed provide the first clues as to specific hazards. However, generalised statements on whether a threat emanates principally from nanomaterials cannot be made. The nanometre range of the particles’ geometry alone does not indicate the properties of a substance or whether it is even (in each case) a hazardous substance (Führ et al., 2006b).

The following is worth noting with regard to small particle size: very small nanoparticles can overcome barriers that remain insurmountable for larger particles (Borm et al., 2006) and may also have other properties which differ from those of their macro counterparts. Additionally, crystal structure, surface condition and surface area are important when considering this change in properties leading to ‘nanospecific risks’ (Führ et al., 2006b; Bhushan et al., 2003).



B.4. Particle size and properties.

Based on exposure routes identified by Oberdörster et al. (2005) and Moore (2006), figure B.5. gives a good overview of the known potential pathways for nanomaterial translocation in the environment. The need for quantitative studies on the fate of nanoparticles released into the environment is highlighted. Many routes and sources are confirmed, and many more are possible, but the exact mechanisms of these particles' routes remain unknown – most of them could be connected to the end of the life cycle of nanomaterials and their (improper) disposal.



B.5. Routes of nanoparticles into the environment (O'Brien et al., 2008).

A generic name for all waste generated by nanomaterials, or created during their manufacturing processes, is 'nanopollution' (Buzea et al., 2007). Since most human-made nanoparticles do not exist in nature, living organisms may not have the appropriate means to deal with nanowastes or their degradation products. As a result, one of the greatest challenges nanotechnologies could be facing is how to deal with nanopollutants, nanowastes and their disposal (Fulekar, 2010).

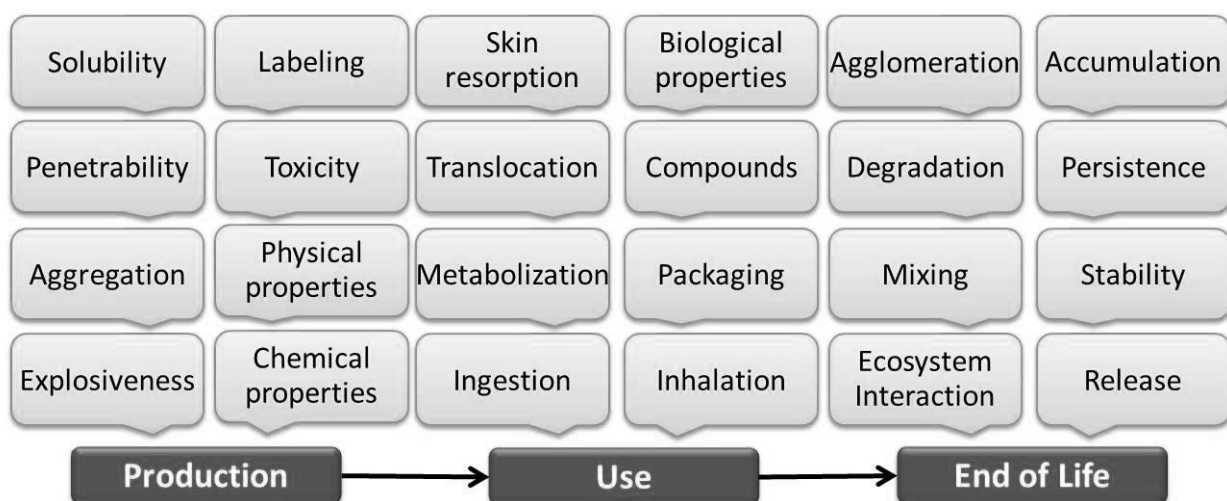
The release of nanomaterials into the environment justifies a special assessment as nanoparticles present novel (new) environmental impacts. Scrinis (2007) raises concerns about nanopollution and argues that it is not currently possible to 'precisely predict or control the ecological impacts of the release of these nanoproducts into the environment.' Ecotoxicological impacts of nanoparticles and the potential for bioaccumulation in plants and microorganisms remain to be researched (Scrinis, 2007). The capacity for nanoparticles to function as a transport mechanism also raises concern about the transport of heavy metals and other environmental contaminants.

A UK (United Kingdom) report (DEFRA, 2007) noted concerns about the (eco) toxicological impacts of nanoparticles in relation to both hazard (fate and behaviour in the environment (Behra et al., 2008)) and exposure (incomplete understanding of sources). The report recommended comprehensive toxicological testing and independent performance tests of fuel additives. According to the Centre for Biological and Environmental Nanotechnology, nanoparticles are accumulating in living organisms (CBEN, 2002). Even though this is not necessarily harmful (Naica-Loebell, 2010), it gives rise to some concern.

The possible effects on humans (e.g. absorption of nanomaterials through the human gastrointestinal tract) are, however, less well known (Hillyer et al., 2001). Absorption of nanomaterials through the skin may also be problematic (Alvarez-Roman et al., 2004; Baroli et al., 2007; Cross et al., 2007). Additionally, the inhalation of nanomaterials may potentially be hazardous to human health (Auclair et al., 1983; Lee et al., 1997; Williams et al., 1974; Woo et al., 2001; Baggs et al., 1997; Borm, 2002; Elder et al., 2006; Fujitani et al., 2008).

Naturally occurring nanoparticles have, however, existed in the habitual environment of humans for a long time. Additionally, anthropogenic-produced nanomaterials have been in existence for hundreds of years. Problems are likely to arise when the human body is faced with an unprecedented and ever-growing volume and diversity of nanoparticles (Mae-Wan, 2010).

In the following, current knowledge of the environmental and health risks of nanomaterials will be summarised. The aim is not a comprehensive representation of all available study results but the inclusion of all possible aspects that are particular to a risk assessment. To illustrate the different exposure scenarios, the life cycle of nanomaterials from their entrance into the world at production, to their use and their disposal are described. In each step, different exposure scenarios can be expected. It is also possible that the material itself changes during its life cycle.



B.6. Identification of risks; based on (Helland, 2004).

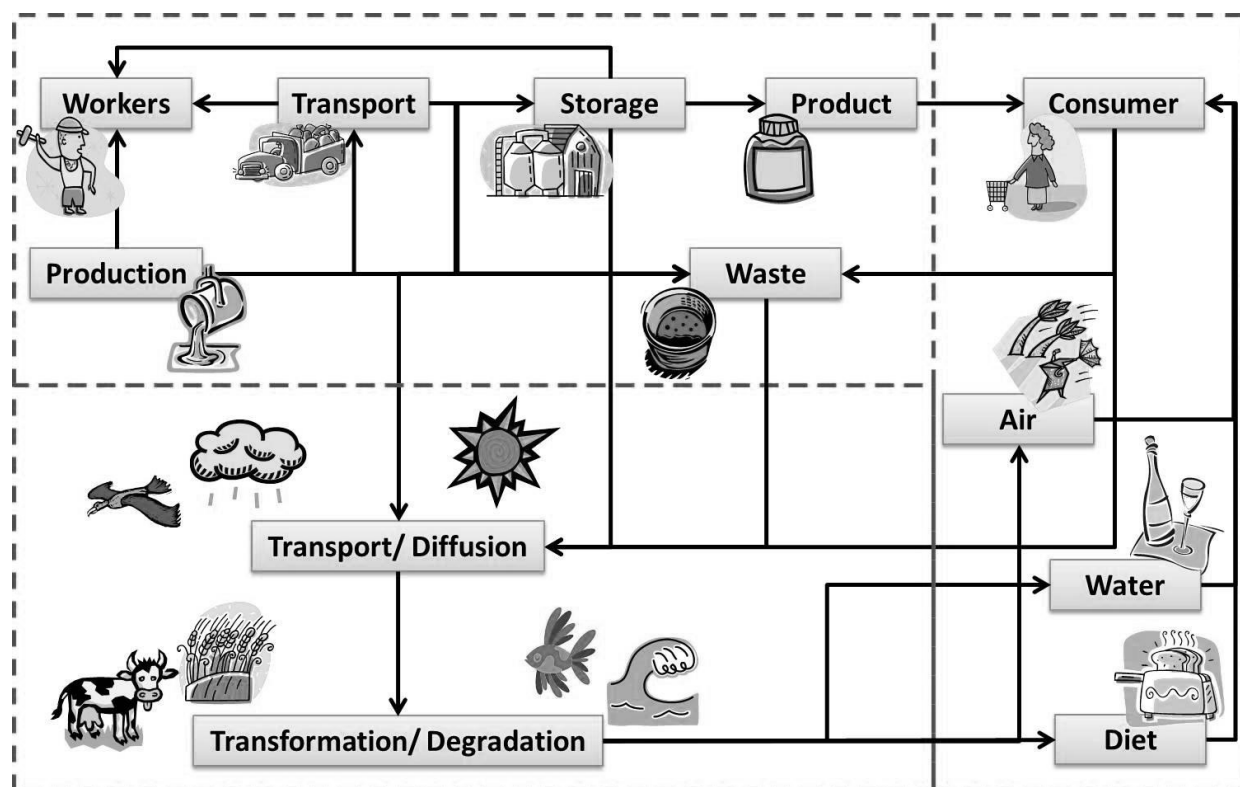
In the diagram above, possible focus areas for risk assessments during the life cycle of a typical nanomaterial are depicted. Although they are not conclusive, this illustrates the number of possible ways that a hazard could be exposed to humans or their environment. However, a particular challenge lies in dealing with nanomaterials whose risks have not yet been researched. This raises the question of whether it is even possible to evaluate these materials in terms of environmental or health risks at a time where nothing or very little is known about their toxicity, ecotoxicity and possible exposures (SRU, 2011; Warheit, 2008; Warheit, 2006).

Exposure to nanomaterials could occur during their development, manufacture, use (here mostly as point sources) or following disposal (mostly diffuse sources). Too little is known to predict the environmental fate of nanomaterials, and feasible documentation of environmental dispersion through monitoring is not expected in the short term (Helland, 2004).

Exposure is a key element in the risk assessment of nanomaterials because it is a precondition for the potential toxicological and ecotoxicological effects to take place. Hence, if there is no exposure, there is also no risk. According to the European JRC's Technical Guidance Document, exposure assessment involves '...an estimation of the concentrations/doses to which human populations (i.e. workers, consumers and man exposed indirectly via the environment) or environmental compartments (aquatic environment, terrestrial environment and air) are or may be exposed' (EC JRC, 2003).

Completing a full exposure assessment requires extensive knowledge of manufacturing conditions, production levels, industrial applications and uses, consumer products and behaviour, and environmental fate and distribution. Such detailed information is not available, and no full exposure assessment has been published thus far. This may be partly due to difficulties in monitoring exposure in the workplace (Maynard et al., 2004) and the environment, and partly due to the fact that the biological and environmental pathways of nanomaterials are still largely unexplored (CCA, 2008). Some efforts have been made to assess occupational, consumer and environmental exposure, both with regard to assessing the level of exposure and also the applicability of current exposure assessment methods and guidelines (Hansen, 2009).

For risk characterisation, being at the end of the line, the sum or maybe even all of these limitations are conveyed to calculating risk quotients for nanoparticles. Considerable work is still required if future risk assessment is to be relevant and reliable. Despite some attempts to respond to the limitations of risk assessment and uncertainty, coordinated action seems to be slow in emerging (EEA, 2001). However, there is no sufficient knowledge to predict the environmental fate of nanomaterials. Feasible documentation of environmental dispersion through monitoring is also not expected in the short term (RS & RAE, 2004).

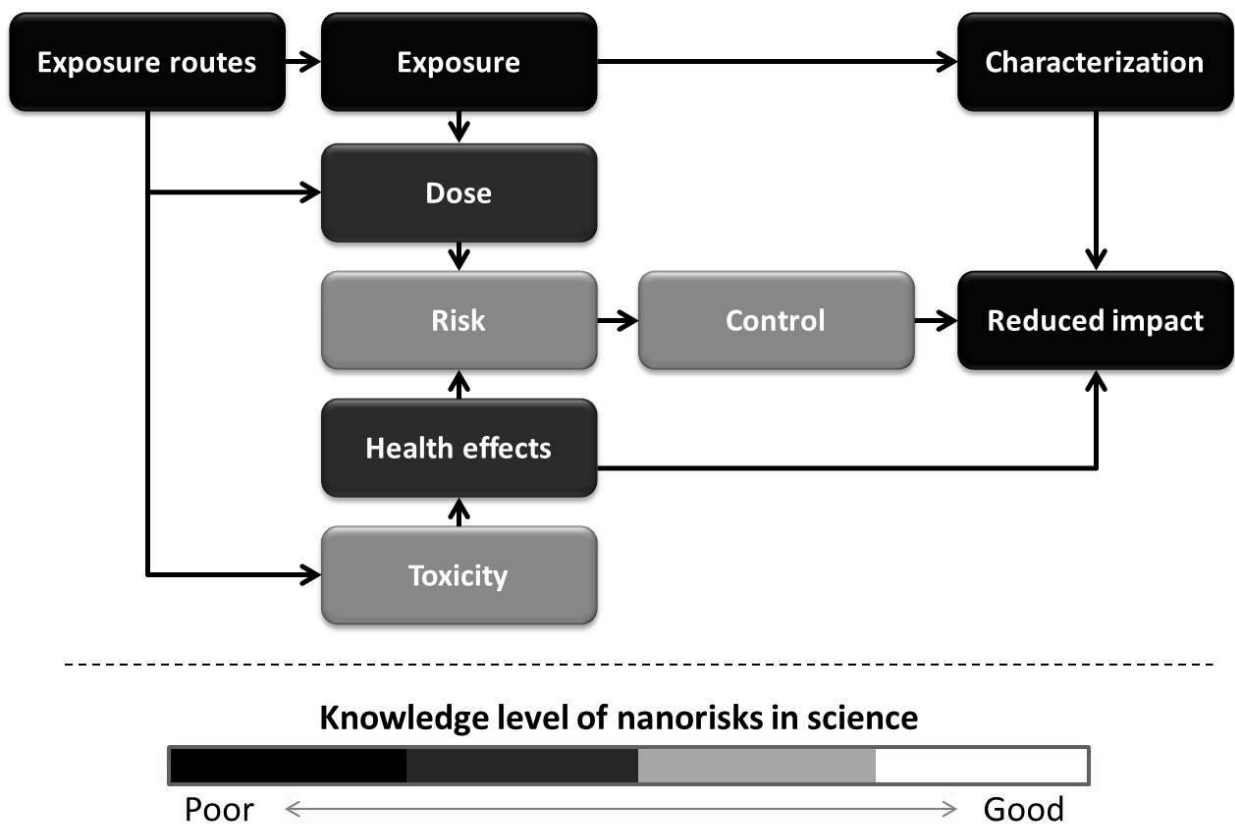


B.7. Exposure routes of nanomaterials; based on (RS & RAE, 2004).

Too little is known to be able to predict the environmental fate of nanomaterials. In the above figure, some possible exposure scenarios are shown. However, more research needs to be done to draw verified conclusions on the basis of a fact-based exposure and risk assessment.

A number of reports make specific recommendations on developing such responsive research strategies (Oberdörster et al., 2005; Maynard, 2006; Moore, 2006; Tsuji et al., 2006). Calls for proposals in the Seventh Framework Programme (FP7) reflect some of these recommendations, while countries like Australia are beginning to develop integrated environment, safety and health research programmes. In the US, the nanotechnological risk-research portfolio looks impressive on paper, although it only accounts for 1–4% of the total R&D budget (Maynard, 2006). There are a number of additional problems when it comes to the risk assessment of future nanomaterials, their application and their variety – especially when the pace of technological development is considered (Hansen, 2009).

In 2001, a report written by the European Environment Agency (EEA) on avoiding repeating the mistakes of previous technological development recommended looking out for ‘warning signs’, such as materials exhibiting novelty, persistency, ready dispersibility, bioaccumulation, or leading to irreversible action (EEA, 2001). These characteristics resonate with many nanomaterials (RCEP, 2008), some of which have novel properties, are capable of being incorporated into highly diverse products, may be transported to places in new ways and may be designed to be persistent (Hansen, 2009).



B.8. Knowledge level of nanorisks; based on (Maynard, 2007).

The need to assess the risks of nanoparticles on a case-by-case basis is often mentioned as a means of taking the unique properties of nanomaterials into consideration (SCENIHR, 2007; Environmental Defense and DuPont, 2007). An official in charge of regulatory aspects of nanotechnologies at the European Commission has even been cited as stating that product authorisation must also be conducted ‘on a case-by-case basis’ (EurActiv, 2008). While chemical risk assessment is based on the fact that chemical identity governs the fate and effects of a chemical, the situation for nanomaterials may be somewhat different; by definition, the properties of nanomaterials cannot be determined by their chemical composition alone, and hazard identification of nanomaterials has come under intense scrutiny in recent years. However, much of what needs to be done is still in the discovery stage (SCENIHR, 2006).

Many governments, however, still call for more information as a substitute for action, and there are indications that understanding and managing the risks of engineered nanomaterials is being paralysed by analysis. It is clear that more scientific information is needed, but we need to act on what we know now in order to enable industry to produce and market nanotechnological-enabled products that are as safe as possible (Hansen, 2009).

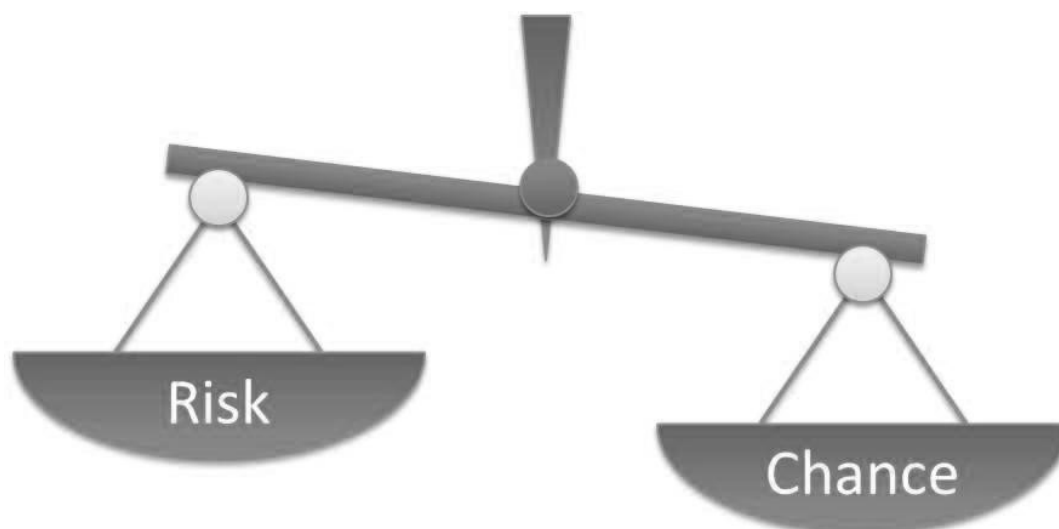
Applying current knowledge to nanotechnological oversight will not solve every problem, but it will help prevent basic mistakes being made while the knowledge needed for more effective oversight is developed (Hansen et al., 2008).

C. Characterisation of the conflict

Nanotechnologies are being strongly promoted commercially; products are already merchandised and being used. Nanotechnologies' potential is valued very high and the commercial use of nanotechnologies is being subsidised by large amounts of public development funding. While the first nanotechnological products have already been created, few politico-legal regulations address the special characteristics of nanomaterials and only 4% of public development funding goes towards risk research (BMBF, 2009). As a result, the risks of nanotechnologies remain relatively unclear; a distinct legal framework has not yet been developed.

This may result in problems with the general public similar to those that arose in relation to genetic engineering; in that case, it was a mistake not to develop a clear usage strategy and bring consumers into the dialogue (Zimmer et al., 2008). Thus, GMO is widely rejected today. To prevent this happening to nanotechnologies, the development of a strategy and the inclusion of the public would be fundamental (CIEL, 2009; Stirling et al., 2000).

However, consciousness of the relevance of this topic seems to be gradually growing. Furthermore, standardisation and self-regulation initiatives are playing an important role in the short and medium term to deal with the current uncertainties and ambiguity about the regulatory situation for nanotechnologies. (Private) standards and self-regulation approaches can support disclosure and sharing of information, the definition and dissemination of guidelines and best practices, provide common principles and values, facilitate trust between different current and potential stakeholders, and thus facilitate an environment where more knowledge about the risks of nanotechnologies can be generated, alleviating current levels of ignorance (SRU, 2011).



C.1. Compromise risk/chance.

C.1. International politics

Internationally, the US, Canada and Australia are most active regarding the regulation of nanotechnologies; in the US, the Environmental Protection Agency (EPA) has, as part of the Toxic Substances Control Act (TSCA – the US regulatory provision for chemical substances), taken dedicated action on the regulation of nanomaterials (Mantovani et al., 2011).

As with other regulations, nanomaterials are not explicitly mentioned in this statute. However, a series of actions have been put in place in recent years to ensure the notification and registration of nanomaterials. In particular, ‘Significant New Use Rules (SNUR)’, a notification given to companies in the case of any significant new use of existing chemicals, has been issued for some specific nanomaterials (e.g. fullerenes). The EPA is planning to adopt such procedures on a regular basis for a number of nanomaterials in order to gather detailed information about their use, characteristics and safety issues before they are put on the market (EPA, 2012).

The EPA, under the FIFRA statute (Federal Insecticide, Fungicide and Rodenticide Act), is carefully reviewing pesticide products containing nanosilver. A new policy is expected that will require reporting and provision of safety information about nanoscale materials used as ingredients in pesticides (Mantovani et al., 2011).

A task force has been active within the Food and Drug Administration (FDA) since 2007. The general approach of the FDA is that existing regulation adequately covers nanoforms of substances, although a careful review of nanotechnological products is usually carried out. In June 2011, the Agency issued short draft guidance on ‘Considering Whether an FDA-regulated Product Involves the Application of Nanotechnology’, with consideration of a definition of nanotechnologies (FDA, 2012). The National Institute for Occupational Safety and Health (NIOSH) updates a series of authoritative guidelines on occupational health and safety (OHS) nanomaterials issues on a regular basis (NIOSH, 2012).

A joint commitment between the US and the EU to promote transatlantic cooperation in regulation and safety issues related to nanotechnologies has been established and has led to the establishment of bilateral research activities on these matters (OECD, 2012b).

In Canada and Australia, EHS and regulatory issues are increasing the level of resources within their national strategies for nanotechnologies, and the need to adopt a precautionary approach is explicitly stated. There is growing involvement on the part of the authorities in different sectors that are working to develop regulatory, product-specific guidance documents for nanomaterials. A definition of nanomaterials is considered one of the key gaps in enabling regulatory actions (Mantovani et al., 2011).

Health Canada held a consultation on the 'Interim Policy Statement on Canada's Working Definition for Nanomaterial', and the document is now in the review phase. The main scope is to establish a working definition of nanomaterials and provide a means of gathering information on the use, characteristics and safety issues of nanomaterials entering the market. The policy statement, once finalised, will be applied under all of Health Canada and Environment Canada's regulations that are relevant to nanomaterials, including chemicals, cosmetics, drugs, foods, pesticides and medical devices (NanoPortal, 2012; Health Canada, 2012).

In Australia, the National Industrial Chemicals Notification and Assessment Scheme (NICNAS) has developed a specific strategy for the regulation of nanomaterials, supported by an in-depth stakeholder consultation concluded at the beginning of 2010. Based on this consultation, a working definition for 'industrial nanomaterials' has been agreed with stakeholders and was officially adopted at the end of 2010. A series of amendments have been introduced into existing chemical regulation, ensuring pre-market evaluation of new nanomaterials. These requirements have been in force since January 2011, accompanied by guidance documentation, and monitoring of concrete implementation is currently ongoing (OECD, 2012b; NICNAS, 2012).

Other authorities are also active with regard to nanotechnologies regulation, as they review existing regulation and increase the knowledge base through specific research programmes. In particular, Safe Work Australia has launched a programme to develop appropriate tools and methods related to occupational and health issues. These include the 'work health and safety assessment tool for handling engineered nanomaterials' and draft guidance to introduce nanomaterials into Safety Data Sheets and labelling procedures (Safe Work Australia, 2012).

With regard to Asia, the countries considered were China, Japan, India, Taiwan, Korea and Thailand (OECD, 2012b; Mantovani et al., 2010). Seemingly, none of these countries are planning specific regulatory action regarding nanotechnologies but are looking at legislation developed in Europe and the US as a benchmark for the development of their own standards. They are paying particular attention to the debate on REACH and nanomaterials. Nevertheless, the Asian countries mentioned above are generally quite active in the field of standardisation and all have initiatives and research programmes at institutional level on nanomaterials, in particular regarding OHS aspects (Mantovani et al., 2011).

In Japan, the Ministry of Economy, Trade and Industry (METI) has been supporting a voluntary gathering initiative relating to the risk management of nanomaterials at industry level since 2008 (the last periodic report was published in March 2010). Research reports on OHS nanomaterials issues have been published (the last in December 2010) by the National Institute of Occupational Safety and Health, Japan (JNIOSH) (Mantovani et al., 2011).

South Korea is developing a ‘National Nanosafety Strategic Plan (2011–2015)’ and published ‘Guidance on Safe Management of Nanotechnology-based Product’ in 2011. Moreover, a specific ‘Risk Management Platform Technology for Nanoproducts (2009–2013)’ was developed, aiming to provide a certification system for nano-related products. Several research programmes on EHS and ELSA are in progress (Mantovani et al., 2011).

In Taiwan, within the framework of their Strategic Plan for Responsible Nanotechnology (2009–2014), the Nanomark Certification System (coordinated by ITRI, the Industrial Technology Research Institute) has been active since 2004. This is a voluntary reporting and certification scheme that aims to increase public confidence in nanotechnological products (nanoMark, 2012).

In Thailand, safety is among the priorities of the national policy on nanotechnologies. A first strategic safety plan was proposed to the government by the National Nanotechnology Center in 2011. This includes plans for the creation of an industrial standards certification for nano-related products (called NanoQ, (NanoTec, 2012)). While there are some movements to regulate nanotechnologies more strictly, a genuine approach is not yet underway in the aforementioned countries (Working Group 3 of the NanoKommission, 2010).

C.2. Politics of the EU

Current EU regulations provide the most important framework for activities in this field at national level by the EU member states (Gehring et al., 2007). In general, national regulatory agencies must align with EU regulations, with the possibility of implementing specific (more detailed or tighter) regulations at a national level (Mantovani et al., 2011). In addition, many European countries, in particular those more active in nanotechnologies, have also started their own activities in relation to the regulation of nanomaterials. These are mainly concerned with occupational health and safety aspects, chemicals, and foods (Mantovani et al., 2011).

Research on EHS issues and regulatory aspects are included as a priority in all countries that have a nanotechnologies development strategy/plan. Among them, the most active are France, Germany, the Netherlands and the UK (Mantovani et al., 2011). Almost all the other countries surveyed¹¹ have at least some initiatives on these matters and are linked to activities at EU level through participation in working groups at the institutional level (such as the different technical Committees of member states, the OECD WPMNs or the Nanosafety Hub of the European Commission). In particular, guidelines regarding occupational health and safety issues are being developed (Mantovani et al., 2011).

¹¹ The countries surveyed, selected based on their activity on nanoregulation have been: Austria, Czech Republic, France, Italy, Germany, UK, The Netherlands, as well as non-EU Switzerland and Norway (EFTA).

Regarding chemicals, the way nanomaterials are considered in REACH will strongly influence regulatory actions at national level. In particular, France, Germany, Austria, Belgium and Italy are considering introducing notification and registration mechanisms for nanomaterials, although they would generally prefer to avoid any duplication of REACH procedures (OECD, 2012b; Mantovani et al., 2010). On this issue, relevant initiatives have been undertaken lately by France, which is moving forward with a compulsory reporting scheme (declaration) for nanomaterials. The scheme will be devoted to specific types of nanomaterials (Tomazic-Jezic et al., 2001) and requires a declaration of identity, quantity and use of these substances. A public consultation on the decree issued on this by the Environmental Ministry ended in February 2011. A definitive version of the decree is expected (French Ministry of Ecology, Sustainable Development, Transport and Housing, 2011; Mantovani et al., 2011).

France is also publishing a series of technical guidance documents relating to nanotechnologies (OHS aspects of nanomaterials in general), including a control banding tool, carbon nanotubes, medicinal products and medical devices (ANSES, 2012; ANSES, 2011; Afssaps, 2012).

In Germany, the need to develop appropriate regulation and standards for nanotechnologies is included as a priority in the Nano Action Plan 2011–2015 (BMBF, 2012b) promoted by the federal government. In September 2010, the German NanoKommission Dialogue Initiative (BMUB, 2012) (involving more than 100 key nanotechnological stakeholders) provided the German government with an analysis of EU/national regulation and the concrete application of the precautionary principle (Calliess, 2009), as well as considerations on a definition of nanomaterials and the creation of a nanoproducts register (Mantovani et al., 2011). The report suggested a series of amendments aiming to explicitly include nanomaterials in existing regulatory provision, though stressing the need for a coherent approach between German and EU regulation (Mantovani et al., 2011).

Several documents and suggestions have been published in recent years by the German authorities and stakeholders on EHS issues and nanotechnologies, and the German Federal Institute for Occupational Safety and Health is running a second survey (the first was in 2006) on worker protection in the production and handling of nanomaterials (BAuA, 2012).

In terms of regulation, the United Kingdom supports European initiatives (UK Government, 2010; DEFRA, 2012; NRSF, 2012). However, it is promoting a ‘case-by-case’ approach to assess the risk and suitable use of individual nanomaterials in food and food contact materials. The UK Food Standards Agency monitors the regulatory situation of these products on a regular basis (FSA, 2011).

The UK Government has confirmed its commitment toward EHS research with new studies on the safety issues of specific nanomaterials (iron nanomaterials, nanosilver, CNT) and a bilateral call for research projects on environmental issues with the US (OECD, 2012b; DEFRA, 2007; MHRA, 2012; FSA, 2011). The British Standards Institution (BSI) will be publishing three new standards documents on nanotech (including a guide for SMEs on nano-regulation) (BSI, 2012).

The Netherlands have a clear commitment towards responsible innovation, and the principles of precaution, inclusiveness, transparency and risk/benefit balance are clearly set out in its nanotech development strategy (Mantovani et al., 2011). Various guidance materials are being developed on issues such as regulation, the precautionary principle, risk management, information sharing, consumer information and societal dialogue (DMEA, 2012; Wijnhoven, 2012). Research on safety issues is considered a priority, with relevant funding allocated in national research activities. In response to the EC recommendation on a code of conduct for nanotechnologies, the Netherlands introduced a contractual obligation to comply with this code in its national funding guidelines (Mantovani et al., 2010; OECD, 2012b; Nanocode Project, 2012).

In Switzerland (closely related to the EU – EFTA), a joint effort between different authorities has led to the publication of the ‘precautionary matrix’, the ‘guidelines for safety data sheets’ and reports on ‘nanoparticles at workplaces’ and ‘nano waste management’, relating to synthetic nanomaterials. As planned in the action plan on risk assessment and risk management of synthetic nanomaterials, Switzerland continues to strictly monitor the regulatory situation and provide technical guidelines to support the implementation of existing regulation, as well as consumer and stakeholder awareness on safety issues (BAFU, 2012). At the end of 2010, the results of an initiative promoted by the Swiss Federal Office of Public Health (FOEN) and key stakeholders were published (NANO Dialogue Platform, with a focus on consumer information (FOPH, 2012)). Issues related to the need for a definition of nanomaterials, labelling within foods, cosmetics and chemicals, and waste regulations were considered. As in the German case, there was unanimous agreement on the need for a coherent approach across Swiss and EU regulation (Mantovani et al., 2011).

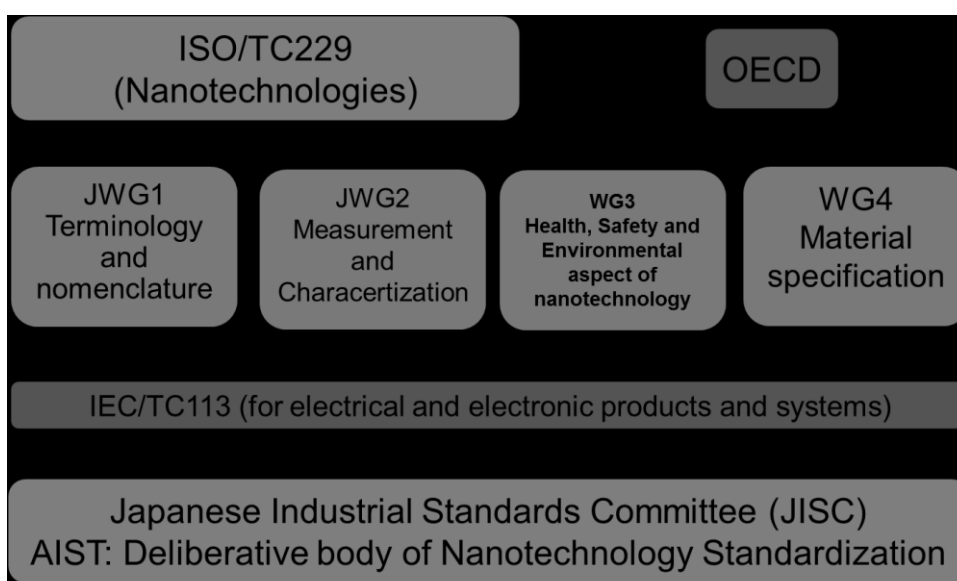
C.3. Standardisation activities

The availability of appropriate standards is pivotal to implementing appropriate regulation for nanotechnologies-related products (Mantovani et al., 2011). However, due to the innovative production processes enabled by nanotechnologies and the peculiar behaviour of matter at the nanoscale, the system of written and physical standards established for the macroscopic and microscopic world cannot easily be scaled down to the nanoscopic world (Hansen, 2009).

The International Standards Organization (ISO) Technical Committee 229 (TC 229), in conjunction with the International Electrotechnical Commission (IEC) TC 113 (and other national standards bodies), has been directing activities on nanotechnologies standards since 2004 (Hatto, 2007). European standards activities are coordinated by the European Committee for Standardization Technical Committee on nanotechnologies (CEN TC 352). There is a strong connection between CEN TC 352 and ISO TC 229. Where possible, CEN will follow the developments at international level (Mantovani et al., 2011).

Various national standards bodies, such as BSI NT1 in UK, SAC TC 279 in China, ANSI-NSP in the US and Standard Developing Organisations such as ASTM and IEEE have all produced standards relevant for nanotechnologies. Most of these activities are in liaison with ISO TC 229 and IEC TC 113, and are mirrored by work in the following European standards bodies: the European Committee for Standardization (CEN), European Committee for Electrotechnical Standardization (CENELEC) and the European Telecommunications Standards Institute (ETSI).

In 2010, the Commission drafted mandate M461 for the development of standards in the broad area of nanotechnologies and nanomaterials. At the end of 2010, CEN, CENELEC and ETSI decided to accept the mandate. For the execution of the mandate, which covers a large range of topics, it was decided to ask CEN TC 352 to coordinate the programme. TC 352 was given the task of liaising with all the relevant European and international committees and to ask them to start work on topics in their area of interest, as identified by the mandate. Currently, this extensive programme is being initiated, and the committees involved are at varying stages of progress (European Commission, 2007). ISO TC 229 is organised into four working groups that focus on issues crucial for the development of an effective regulation for nanotechnologies-related products (FPS, 2012).



C.2. Working groups of the ISO TC 229; based on (FPS, 2012).

In 2011, the Joint Research Centre (JRC) of the EC launched a nanomaterials repository within the activities related to the OECD WPMN sponsorship programme, providing standards samples for different nanomaterials and setting up the NanoHub database on safety issues (FPS, 2012).

OECD has engaged with other international bodies active in the field of nanomaterials safety. Several meetings and workshops on these issues have been held in the framework of the Inter-Organization Program for the Sound Management of Chemicals (IOMC) (IOMC, 2012). In particular, the Food and Agriculture Organization of the United Nations (FAO), the United Nations Institute for Training and Research (UNITAR) and the World Health Organization (WHO) have initiated work on nanotechnologies, with a focus on increasing awareness of potential risks and benefits in developing countries (OECD, 2012b; UNITAR, 2012). WHO is developing guidelines on ‘Protecting Workers from Potential Risks of Manufactured Nanomaterials’, mainly for low- and medium-income countries (WHO, 2012).

The matter of nanostandardisation is, however, far from settled.¹² Nevertheless, the legislature is able to take over from private standards. As in almost all fields of German environmental law, the use of standards and thresholds is commonly practised. Necessary for systematic and reasonable execution, it is necessary to define applicable legal terms or giving functional thresholds to users. The German Federal Constitutional Court has, however, set some requirements to allow the adoption of private standards (BVerfGE 49, 89 – Kalkar I).¹³

C.4. Voluntary programmes

Self-regulation initiatives play an important role in the short and medium term when it comes to dealing with the current uncertainties and ambiguity about the regulatory situation for nanotechnologies. They can support the disclosure and sharing of information, the definition and dissemination of guidelines and best practices, provide common principles and values, and facilitate trust between different current and potential stakeholders. As stated in the general objectives of most of these initiatives, their aim is not to replace regulation or any other legislative requirement but rather to complement them. Codes of conduct, risk management systems and reporting schemes are measures that can have an important role in coping with current uncertainties about the impact of nanotechnologies and during the redefinition of existing hard regulation. They address key issues for the application of responsible practices (e.g. risk evaluation or sharing of information (Hansen, 2009)).

¹² One document for example could be ISO 31000:2009, Risk management – Principles and guidelines, ed. 1, published 15.11.2009, ISO copyright office, Geneva Switzerland.

¹³ Federal Constitutional Court’s Decisions (*Federal Constitutional Court decision (BVerfGE) Vol. 49, p. 89 – Kalkar I, decision 2 BvL no. 8/77 from 8.8.1978.*

Some stakeholders at the industrial level are developing their own risk management systems, defining best practices and procedures for safety control and the handling of nanomaterials in occupational settings, as well as certification tools that help to evaluate and monitor performance in risk management. In parallel, there have been several attempts from government agencies to develop (voluntary) reporting/data gathering schemes on nanomaterials since 2007, as complementary actions to regulation. As described above, these generally come under the remit of the authorities in charge of regulating chemicals. A relevant example of a code of conduct is the EC ‘Code of Conduct for responsible nanoscience and nanotechnologies research’, providing principles and guidelines to lead research activities (European Commission, 2008a).

The EC is actively promoting this code of conduct and strongly recommends that all member states implement it. A specific project (Nanocode) of the FP7 has been funded to support its implementation and adoption, as well as its further revision (Nanocode Project, 2012).

| | |
|--|--|
| Codes of Conduct/ Practice | CoC of EC for Responsible Research (EC) |
| | German NanoKommission ‘Principles’ (DE) |
| | Responsible Nanocode (UK) |
| | Code on nanotechnologies (DE, global) |
| | IG-DHS- Swiss Retailer Association Code (CH) |
| Risk Management Systems | Responsible Care Global Charter (ICCA) |
| | DuPont NanoRisk Framework |
| | Bayer, Royal DSM, Evonik risk management systems |
| | Cenarios (CH) |
| | AssuredNano (UK) |
| | Stoffenmanager Nano (NL) |
| Reporting/ Data Gathering Schemes | UK (DEFRA), Germany (BAuA), Norway (Climate and Pollution Agency) |
| | US (EPA, FDA), Australia (NICNAS), Japan (METI), Taiwan (Nanomark, ITRI) |

C.1. Voluntary programmes and measures (OECD, 2012b; Nanocode Project, 2012).

This and other initiatives aim to complement existing regulation (or prepare the ground for new regulation), helping to gather detailed information on the introduction and use of nanomaterials and nano-related products on the market (among the data generally provided/requested are their type, use, quantity and safety aspects). However, their voluntary nature has some drawbacks. When endorsed by public/government bodies, they have received a poor response. For example, some codes suggested that reporting schemes be made mandatory, as is occurring in France and Canada. However, when promoted by private companies, these measures are treated by some stakeholders with suspicion and are considered to be of little value (Mantovani et al., 2011).

Nevertheless, voluntary measures can play an important, constructive role in the present state of nano-regulation. They can also build a knowledge base to support policy and regulatory decisions, and on nanotechnologies oversight. Therefore, they should be retained, and ways found to overcome their limitations and make people use them without changing their nature (Mantovani et al., 2011).

C.5. General handling of emerging risks

The use of nanotechnologies (NanoKommission, 2011) can already be legitimised by the constitution;¹⁴ the technological prospects can fund constitutionally sound public interests and fundamental rights, including those under Basic Law for the Federal Republic of Germany (GG) Art. 2 para. 2, Art. 12, Art. 14 and Art. 20a. From the same basic legal references, protection perspectives can also be derived.¹⁵ Moreover, recourse to primary legislation is made, in particular to Art. 191 para. 2 of the Treaty on the Functioning of the European Union (TFEU¹⁶) (with the principles of precaution, polluter pays and preventive action), supplemented by the objective definition in the preamble and the horizontal clause in Art. 11 TFEU (Führ, 2009).

The sections on the technological and political foundations of this work show that, due to the large variety of materials and their applications, it is difficult to make general claims about adequate regulation. Nevertheless, the following is a review of the general principles of the existing legal framework. In addition to appropriate guidelines for design options, the legislature already has conventional capabilities in the field of ‘new technologies’. This section provides a brief overview of the possibilities of handling upcoming nanorisks in a very general way.

The precautionary principle states that if an action or policy has a suspected risk of causing harm to the public or to the environment, in the absence of scientific consensus that the action or policy is not harmful, the burden of proof that it is not harmful falls on those taking the action. The principle is used by policymakers to justify discretionary decisions in situations where the likelihood of harm is unknown because extensive scientific knowledge on the matter is lacking. In the legal system and the law of the European Union, the application of the precautionary principle has been made a statutory requirement in some areas of law (SRU, 2011).

¹⁴ Basic Law for the Federal Republic of Germany (*Grundgesetz – GG*) in the revised version published in the Federal Law Gazette Part III, classification number 100-1 (promulgated by the Parliamentary Council on 23 May 1949), as last amended by the Act of 11 July 2012 (Federal Law Gazette I p. 1478).

¹⁵ The in Article 20a of the German Basic Law and Article 191 para 2 of the Treaty on the Functioning of the European Union enshrined precautionary principle legitimises the legislature to effective action when necessary.

¹⁶ Consolidated versions of the Treaty on European Union and the Treaty on the Functioning of the European Union – Consolidated version of the Treaty on the Functioning of the European Union – Protocols – Annexes – Declarations annexed to the Final Act of the Intergovernmental Conference which adopted the Treaty of Lisbon, signed on 13 December 2007 – Tables of equivalences (Official Journal C 326, 26.10.2012 p. 47–390).

The precautionary principle is already applied in other areas of law, for example the Federal Immission Control Act (*Bundes-Immissionschutzgesetz – BImSchG*) (Rengeling, 1982; Lübbecke-Wolff, 1998), the Atomic Energy Act (*Atomgesetz – AtG*)¹⁷ (Breuer, 1978; Schreiber, 1996), as well as the Law of Genetic Engineering (*Gentechnikgesetz – GenTG*)¹⁸ (Gill et al., 1998). Details of the precautionary principle and corresponding prevention structures are also found in the law on environmental impact assessment (Erbguth et al., 2000; Hoppe et al., 2000), in the field of water law (Volken, 1993; Breuer, 1986), as well as in waste disposal law (Diedrichsen, 1998; Kunig, 2000). In addition to making appropriate mention of design options, the legislature already has conventional capabilities in the field of ‘new technologies’ (e.g. nuclear and genetic engineering legislation (Paschen et al., 2003)).

Overall, political science has observed a shift over many years – at least of degree – towards new forms of governance (Holzinger et al., 2006; Lyall et al., 2005; Mayntz, 1996; Rhodes, 1996).

The hierarchical control of influence by governments and administrations over many cooperative coordination and control processes involving both governmental and non-state bodies is eroding. Consequently, for many authors, nanotechnologies are an exemplary field of application for such new forms of governance (Gammel et al., 2009; Kearnes et al., 2006; Barben et al., 2007; Kurath, 2009; Renn et al., 2006a; Maynard et al., 2006; Renn et al., 2006b; WHO, 2012).

C.6. Duty of care and general liability

There are two regulative fields fitting the overall approach of controlling risks that can generally be applied to liability and due diligence in the field of nanotechnologies. The general duty of care, understood as a thorough approach in which all essential aspects, such as all the rules of the art (*lege artis*), the state of the art or the state of the science, are emphasised, must be considered in the production or commercialisation of nanomaterials. Art. 276 para. 2 of the German Civil Code (*Bürgerliche Gesetzbuch – BGB*)¹⁹ states that those who act negligently are those who do not take the necessary care (Spindler, 2009). According to Art. 276 para. 1 sent. 1 of the BGB, however, the law differentiates between intention and negligence.

¹⁷ Atomic Energy Act (*Atomgesetz – AtG* (Act on the Peaceful Utilisation of Atomic Energy and the Protection against its Hazards) *Gesetz über die friedliche Verwendung der Kernenergie und den Schutz gegen ihre Gefahren*) of 15 July 1985 (Federal Law Gazette I p. 1565), last amended by Art. 1 of the law of 20 November 2015 (Federal Law Gazette I p. 2053).

¹⁸ Genetic Engineering Law (*Gentechnikgesetz – GenTG* (Law Regulating Genetic Engineering) *Gesetz zur Regelung der Gentechnik*) of 16 December 1993 (Federal Law Gazette I p. 2066), last amended by Art. 55 of the Directive of 31 August 2015 (Federal Law Gazette I p. 1474).

¹⁹ German Civil Code (*Bürgerliches Gesetzbuch – BGB*) of 2 January 2002 (Federal Law Gazette I, p. 42, 2909 and 2003, p. 738), last amended 20 November 2015 (Federal Law Gazette I p. 2018).

Intent is the knowledge and the will of the wrongful success: The actor must have foreseen it and included it in his will. The predictability of risk is a prerequisite for negligence. It refers only to the statements of facts of liability, but not to the further development of the damage. The general foreseeability of harmful success is sufficient. The actual sequence does not need to be predictable in detail; however, the debtor must take the necessary precautions for possible faults.

It is not possible to make arrangements for all conceivable theoretical risks; rather, there must be a reasonably proximate possibility of damage. It is not necessary for this to have been desired or intended. However, the mere observance of all codes of practice and relevant legislation does not automatically preclude negligence, at least if their inadequacy was apparent on closer examination by experts. The same applies in cases in which rules and practices have been proven to be insufficient, and this is known or could and should have been known to the person concerned (Spindler, 2009). In such cases – which have ex ante maximum uncertainty about the risk – public law is invoked in the form of the precautionary principle to create conditions in which the manufacturers and plant operators are encouraged to increase their knowledge (Spindler, 2009). However, if the manufacturer does not have sufficient knowledge of which actions regarding duty of care need to be taken, a liability for risks or harms will not provide any further incentives to implement measures designed to avoid harm (Hansen, 2009).

The question of negligence is therefore the question of whether the manufacturer could have been able to foresee, or could and should have recognised, that his technical knowledge and skills were not sufficient to make an assessment. Therefore, in the individual case, the question is not whether an entire branch of technology – such as nanotechnologies – can be classified as a risk, but rather whether the dangerousness of specific defective products could have been foreseen (Spindler, 2009).

It is possible that, for the relevant area of risk, a particular technical study at the time of the marketing of a product comes to the conclusion that there is no danger, and later – by new methods – it is shown that this result was wrong (Scherzberg, 1993). Generally, an assessment of nanotechnological products at this time will have to deal with a ‘foreseeable unknowability’ of risk (Führ, 2009); abstract awareness of danger is present, but the product is placed on the market anyhow (VCI, 2006; VCI, 2008). The development of products according to the state of the science could potentially provide (more) security regarding the necessary duty of care at this point. Thus, a concrete possibility of a potential harm would already trigger the necessity of precautions for the potential defect. Liability law is the classic tool to reallocate ‘externalised’ risks of products back to the perpetrator and so to ‘internalise’ them, to encourage manufacturers to produce safe products (Spindler, 2009).

If the product liability law of Directive 85/374/EEC concerning liability for defective products²⁰ (Bauer et al., 2010) and its transposition into German law – the Product Liability Law²¹ – is summarised, it appears that in principle the laws on nanotechnologies have no substantive special features (Burr et al., 2009), and so it is only for production failures (Meyer, 2010b), particularly in violation of the subsequent obligation of product monitoring by the manufacturers, where liability can be drawn (Hennig, 2008). In contrast, the indemnifications for development producer's errors are only likely to cause a weak incentive to create knowledge of risk. Here, only stricter obligations to conduct one's own research could provide a remedy, and these have, so far, experienced only a slight expression in German law (Spindler, 2009).

If the other conditions of liability law are considered in terms of causality, another reason for the reduced incentive to carry out research is highlighted: as in German law, very little liability can be drawn from the sheer chance of harm. The burden of ambiguity regarding the progress of the cause *de facto* must be carried by the victim, so that the economic calculus of both German civil law and product liability law does not incite manufacturers of nanotechnologies to increase the safety of products or to broaden their knowledge of risk. While this is true not only for nanotechnologies but also ultimately for all innovative technologies, this helps make it clear that, here, a mixture of regulation through precaution-oriented public law, particularly with regard to the burden of proof and *ex post* intervening, civil liability law regarding standardisation, and risk knowledge should apply (Spindler, 2009).

To summarise, civil law has considerable difficulties in compensating for the central problem of uncertainty around the impact of new technologies in the traditional legal doctrine and distribution of the burden of proof between the parties. In particular, the lack of knowledge of causal relations and lack of contact points to scientific and technical standards mean that any claims by victims are not executable or are procedurally not practicable. Similarly, the *prima facie* evidence in cases of the absence of knowledge fails over sequenced procedures of events. Without a corresponding burden of proof, there are thus insufficient incentives for manufacturers to obtain the necessary knowledge of the risks themselves. In this case, it is doubtful whether the current system is sufficient for the purpose of burden of proof. The operators of new technologies of risk are committed to carry out relevant research in the absence of knowledge, without having to take responsibility for the full proof of harmlessness (Spindler, 2009).

²⁰ Council Directive 85/374/EEC of 25 July 1985 on the approximation of the laws, regulations and administrative provisions of the Member States concerning liability for defective products (OJ L 210, 7.8.1985, p. 0029–0033).

²¹ Product Liability Law (*Produkthaftungsgesetz – ProdHaftG* (Act concerning liability for defective products *Gesetz über die Haftung für fehlerhafte Produkte*) of 15 December 1989 (Federal Law Gazette I p. 2198), last amended by Art. 180 der of the Directive of 31 August 2015 (Federal law Gazette I p. 1474).

D. Analysis and discussion of results

Nanotechnologies do not exist in an extralegal space in the European or German legal systems. Specific rules (addressing the nanotechnological properties directly, or taking them into consideration) are, however, rare and might not be effective (enough) given the present state of risk knowledge. A suggestion to improvise the legislative rules will be made in the following sections, under the auspices of precautionary principle. To summarise briefly, the main concern is the absence of a definition of nanotechnologies, partly due to branch-specific fields of applications, and, where a definition exists, it is questionable if it is consistent throughout different laws or rules. Even when a definition exists, its interpretation could be controversial. For example, the size definition of nanotechnologies in the cosmetics regulation states ‘0 to 100 nanometres’. At first glance, this might seem to be very precise. However, in practice, there are several analytic measurements²² for size distribution throughout different particles, every single one leading to (more or less) different results. As a result, ‘nano’ depends on the matrix and methods of measurement. Here, the lawmaker still needs more preliminary work from standards institutions on how to measure particles in a standardised and realistic way (proportionality principle). Only then will it be possible to administer nanomaterials not only in theory but also in practice. Applicable laws will only then be fully effective, or able to be written effectively.

In the following sections, the legal framework will be discussed and adjusted under the premise that the definition of nanotechnologies works in practice (as described above). The proposals for legal amendments will not aim for a zero-risk approach but for a risk/chance-oriented estimation. However, the determination of the level of residual risk is not only a technical process but also a political decision and must be worked out by society as a whole as technologies develop. This means that, even if the risks of a technology seem manageable on a technical level, the social debate could come to the opposite conclusion.

As nanomaterials are used in a wide selection of products and are able to find their way into the various environmental media via different paths, it would be inappropriate to develop a single regulatory regime for nanomaterials at either a national or European level. Regulation should – if possible – be based on the existing rules and add to them. This is particularly true for the areas in which it must first be ensured that nanospecific regulatory gaps are being closed. In addition, special instruments that are only valid for nanomaterials can be naturally integrated into the respective sector-specific regulations (Working Group 3 of the NanoKommission, 2010).

²² Exemplary measurement fundamentals for determining the size (diameter) or its distribution: geometrical diameter, aerodynamic diameter, hydrodynamic diameter, electrical mobility diameter, optical diameter, and so on.

D.1. Research and production

The legal framework is designed, as a rule, to provide research and development (R&D) with the greatest possible scope. From that perspective, R&D activities are the subject of legal regulation only in exceptional circumstances, as, for example, in the area of genetic engineering. The situation in the area of industrial safety (Stern et al., 2008) is different, since here the health of the employee is of prime concern (ENU, IOM, DTU, JRC-IHCP and IoN, 2009).

Therefore, special regulations on industrial installations in general take effect only when the laboratory scale and the phase of pilot plant facilities are overstepped in accordance with Art. 1 para. 6 of the 4th FICA Ordinance (4th BImSchV²³ (Böhm, 2014; Hansmann, 2007)).

Beyond that, installations listed in the Annex to the 4th BImSchV are subject to licensing; however, according to Art. 2 para. 3 of the 4th BImSchV, a simplified licensing procedure (excluding Art. 10 para. 2, 3, 4, 6, 7 sent. 2 and 3, para. 8 and 9 and Art. 11 and 14 of the Federal Immission Control Act (FICA)) applies in the case of ‘testing installations’. Material demands on testing installations do not differ from those on actual production installations, which is why reference can be made to both in the following sections of this thesis (Führ et al., 2007b).

Where a licensing obligation, according to Art. 4 ff. FICA,²⁴ is not in effect, laboratory and pilot-plant installations require planning approval and building permission. In the planning approval procedure, the demands contained in Art. 22 ff. FICA have to be examined (Roßnagel, 2007). In considering whether adverse effects on the environment from air impurity are to be expected, reference must also be made to ‘TA Luft’²⁵ and its specifications in No. 4 (Chapter 1), in addition, the 11th BImSchV²⁶ is of increasing importance (Führ et al., 2007b).

²³ 4th Ordinance on the Federal Immission Control Act (4. *Bundesimmissionsschutzverordnung – 4. BImSchV* (Fourth Ordinance implementing the Federal Pollution Control Act (Ordinance on installations requiring approval) *Vierte Verordnung zur Durchführung des Bundes-Immissionsschutzgesetzes (Verordnung über genehmigungsbedürftige Anlagen)* of 2 May 2013 (Federal Law Gazette I p. 973) last amended by Art. 3 of the Directive of 28 April 2015 (Federal Law Gazette I p. 670).

²⁴ Federal Immission Control Act (FICA) (*Bundes-Immissionsschutzgesetz – BImSchG (Gesetz zum Schutz vor schädlichen Umwelteinwirkungen durch Luftverunreinigungen, Geräusche, Erschütterungen und ähnliche Vorgänge)*) Act on the Prevention of Harmful Effects on the Environment caused by Air Pollution, Noise, Vibration and Similar Phenomena) of 17 May 2013 (Federal Law Gazette I p. 1274), last amended by Art. 76 of the Directive of 31 August 2015 (Federal Law Gazette I p. 1474).

²⁵ Administrative Circular on Air Quality Control (*Technische Anleitung zur Reinhaltung der Luft – TA Luft* (TA Air)) of 8 September 1964 (Joint Ministerial Gazette p. 433), last amended by the Directive of 24 July 2002 (Joint Ministerial Gazette p. 511).

²⁶ 11th Ordinance on the Federal Immission Control Act (11. *Bundesimmissionsschutzverordnung – 11. BImSchV* (Eleventh Ordinance implementing the Federal Pollution Control Act (Regulation on Emission Declarations) *Elfte Verordnung zur Durchführung des Bundes-Immissionsschutzgesetzes (Verordnung über Emissionserklärungen)*) of 5 March 2007 (Federal Law Gazette I p. 289) last amended by Art. 8 para 2 of the Directive of 2 May 2013 (Federal Law Gazette I p. 1021).

D.1.01 Air

Nanomaterials can be released into the surrounding atmosphere during production and processing, so the immission control law instruments are relevant to the regulation of nanomaterials. The mechanisms are listed in the Federal Immission Control Act (FICA – BImSchG) and its implementing regulations.²⁷ These principles are influenced by European law, in particular the IED Directive²⁸ (former IPPC),²⁹ the Seveso III Directive 2012/18/EU³⁰ and the Air Quality Directive 2008/50/EC,³¹ together with its daughter directives.^{32, 33, 34, 35} For dealing with air pollution from substances, there are two approaches: firstly, the construction, operation and significant change of equipment are regulated by special requirements, which are overseen. Key tools in this respect are the approval and conditioning of emissions (Art. 10 FICA) and subsequent orders (Art. 17), and the ordering of measurements (Art. 26–31). Secondly, the air quality is monitored so that when thresholds are exceeded, measures to reduce air pollution can be taken. These are aimed not only at plant operators but also to all issuers. The precautionary principle is implemented in the field of pollution control law, particularly through the authorisation requirement for systems and emission limits (SRU, 2011).

²⁷ See Federal Administrative Court BVerwGE 119, 329 [333] – Nanodust (*Nanostaub*): Whether in an uncertain causal relationship between environmental exposure and damage a danger or potential concern is likely depends on the state of knowledge about the likelihood of admission. The boundary between the third protective duty to protect and safe independent risk prevention in uncertainty about the harmfulness of environmental impacts on human health is not yet for all pollutants in a proceeding under Art. 48 BImSchG been established ... („*Ob bei ungewissem Kausalzusammenhang zwischen Umwelteinwirkung und Schäden eine Gefahr oder ein Besorgnispotential anzunehmen ist, hängt vom Erkenntnisstand über den Wahrscheinlichkeitseintritt ab. Die Grenze zwischen drittbeschützender Schutzpflicht und gefahrenunabhängiger Risikovorsorge bei Ungewissheit über die Schädlichkeit von Umwelteinwirkungen für die menschliche Gesundheit ist bisher nicht für alle Schadstoffe in einem Verfahren nach Art. 48 BImSchG festgelegt worden...*“).

²⁸ Directive 2010/75/EU of the European Parliament and of the Council of 24 November 2010 on industrial emissions (integrated pollution prevention and control) with EEA relevance (OJ L 334, 17.12.2010, p. 17–119).

²⁹ Directive 2008/1/EC of the European Parliament and of the Council of 15 January 2008 concerning integrated pollution prevention and control (OJ L 24, 29.1.2008, p. 8), repealed on 6 January 2014.

³⁰ Directive 2012/18/EU of the European Parliament and of the Council of 4 July 2012 on the control of major-accident hazards involving dangerous substances, amending and subsequently repealing Council Directive 96/82/EC (OJ L 197, 24.7.2012, p. 1–37).

³¹ Directive 2008/50/EC of the European Parliament and of the Council of 21 May 2008 on ambient air quality and cleaner air for Europe (OJ L 152, 11.6.2008, p. 1–44).

³² Council Directive 2004/107/EC of the European Parliament and of the Council of 15 December 2004 relating to arsenic, cadmium, mercury, nickel and polycyclic aromatic hydrocarbons in ambient air (Official Journal L 23, 26.1.2005, p. 3–16).

³³ Council Directive 1999/30/EC of the Parliament and of the Council of 22 April 1999 relating to limit values for sulphur dioxide, nitrogen dioxide and oxides of nitrogen, particulate matter and lead in ambient air (Official Journal L 163, 29.6.1999, p. 41–60).

³⁴ Council Directive 2000/69/EC of the European Parliament and of the Council of 16 November 2000 relating to limit values for benzene and carbon monoxide in ambient air (Official Journal L 313, 13.12.2000, p. 12–21).

³⁵ Directive 2002/3/EC of the European Parliament and of the Council of 12 February 2002 relating to ozone in ambient air (Official Journal L 67, 9.3.2002, p. 14–30).

The extent to which the instruments of the Federal Immission Control Act also apply to the production and use of nanomaterials in plants, in addition to the risks posed by these emissions (UBA, 2009b), remains to be discussed (Pache, 2009). Additionally, the lack of expertise of the competent authorities limits the overview of where and which nanomaterials are manufactured. Also, so far there are no laws specifically tailored to nanomaterials (Gantzer, 2004). Therefore, the substance-related instruments and requirements in specific areas of regulation need to be examined to ensure precautionary handling of nanomaterials (Art. 5 Para. 1 No. 2). First, however, it must be noted that most of the statements in the field of air quality regulation in general are transferable to soil and water. This is due to the fact that the FICA does not differ essentially amid discharges in various media, but begins with the general definition of emission.

As opposed to this, the 39th BImSchV³⁶ (former 22nd BImSchV)³⁷ serves to implement the air quality directives of the EU in German law. In addition to ambient air quality standards, it contains alarm thresholds – i.e. a value above which there is a risk to human health from brief exposure – and margins of tolerance – where these represent decreasing values in annual stages by which the exposure limit may be exceeded. The particulate limits of the 39th BImSchV apply to particles with an aerodynamic diameter of 10 (PM₁₀) and 2.5 (PM_{2.5}) micrometres, in weight units. However, mass-based limits are problematic for nanomaterials, because their harmful effects on the human respiratory tract are more likely to be dependent on particle volume and particle surface. Therefore, another criterion for measuring is advised. However, there is a lack of validated and standardised methods of measurement, and there is no meaningful parameter for specifying emissions of all possible nanomaterials (SRU, 2011).

The 39th BImSchV contains no specific limits for nanoparticles; a further differentiation of the ambient air quality standards is deemed necessary to improve air quality with regard to nanomaterials. Here, both the adoption of clean air plans for the permanent reduction of air pollutants as well as the preparation of action plans for short-term avoidance of excesses are linked to ambient air quality standards on the basis of Art. 47 FICA. In area-based pollution control, it is thus particularly evident that the instruments are focused on conventional pollutants.

³⁶ 39th Ordinance on the Federal Immission Control Act (*39. Bundesimmissionsschutzverordnung – 39. BImSchV* (Thirty-ninth Ordinance implementing the Federal Pollution Control Act (Regulation on Air Quality Standards and Maximal Amounts of Emissions) *Neununddreißigste Verordnung zur Durchführung des Bundes-Immissionsschutzgesetzes (Verordnung über Luftqualitätsstandards und Emissionshöchstmenge)* of 5 August 2010 (Federal Law Gazette I p. 1065), last amended by the Directive of 31 August 2015 (Federal Law Gazette I p. 1474).

³⁷ 22nd Ordinance on the Federal Immission Control Act (*22. Bundesimmissionsschutzverordnung – 22. BImSchV* (Twenty-second Ordinance implementing the Federal Pollution Control Act (Regulation on Emission Values for Pollutants in the Air) *Zweiundzwanzigste Verordnung zur Durchführung des Bundes-Immissionsschutzgesetzes (Verordnung über Immissionswerte für Schadstoffe in der Luft)* of 4 June 2007 (Federal Law Gazette I p. 1007), repealed on 2 August 2010.

To make this more concrete, the requirements of the Administrative Circular on Air Quality Control could be used (Jarass, 2010). This is especially true for the assessment of whether there are harmful environmental effects and for determining the safety requirements to be fulfilled by the operator. Operator obligations can be enforced by arrangements in individual cases (Schreiber, 1996). Should single or continuous measurements to determine the emissions need to be carried out, they can be enforced only if suspicion of danger is present. However, the intensity of intervention options is much lower, reinforcing the existing problems in the area of to-be-licensed installations. However, concerning Air Quality Control, the so-called BREFs have found application within the EC, where they are used as guidelines to ensure consistent implementation of the best available techniques. On the other hand, although there are general requirements to limit emissions under the Administrative Circular on Clean Air, including those for dust and total dust, no emission limits for nanomaterials exist. The reference to the ‘state of the science’ also offers no current basis for a normative threshold limit value (Dederer, 2010).

In addition, for the reporting of emissions, the extent of the selected parameter for the determination of emission limits for nanomaterials plays a crucial role. However, validated and standardised measurement methods for the determination of nanomaterial emissions are also lacking. As a result, if a normative threshold limit value for sufficient scientific evidence is lacking, an emission reduction needs to be implemented following No. 5.2.7 of the TA-Luft in the context of the precautionary principle (Dederer, 2010). Thereafter, emissions of substances that are carcinogenic, mutagenic or toxic for reproduction, or emissions that are difficult to break down, easily accumulative or highly toxic must be limited as much as possible in compliance with the principle of proportionality. Following this, the emission reduction requirement is not suitable for substances that contain other hazardous properties (SRU, 2011).

With regard to nanomaterials, therefore, two problems arise. Firstly, the vast majority of nanomaterials are not classified as harmful, so any enforceable emission ban would not be effective. Secondly, in addition, the competent licensing authority would have to develop its own standard of review for allowable emissions of nanoscale materials on the basis of its own scientific understanding. In the absence of normative limits, the authorities may establish them, although in individual cases, but then they would carry the burden of proof as to their appropriateness. The resulting problems can be explained by the circumstances on which the nanopowder decision³⁸ was based. The decision was taken with reference to a plant that produces in the order of 15 t/a ultrafine metal and ceramic powders with a particle size of 1–100 nm.

³⁸ Supreme Administrative Court (Bundesverwaltungsgericht – BVerwG) of 11 December 2003, 7 C 19.02, BVerwGE 119, 329 ff.

The authority responsible for allowing the set-up of the installation had no nanospecific limits other than those used in the TA-Luft for dust (mass concentration of 50 mg/m³). With recourse to the assessment criteria for carcinogenic effects developed in the study ‘Cancer Risk from Air Pollution’ by the Federal Committee for Immission Control (LAI, 1992) and taking into account an additional safety factor, the irrelevance limit for emissions by the nanomaterial-producing plant was determined. Below this limit, the principle of proportionality in accordance with a further limitation of emissions is regularly dispensed with (Dederer, 2010).

This type of determination of limits by the approval body has been found by the Federal Administrative Court to be free of arbitrariness due to the lack of scientifically detectable effect thresholds. This shows how authorities have to work if they want to make emission standards. If there are no set limits, the burden of proof lies with the authority. This, however, is neither compatible with the precautionary principle nor the immanent contradicting presumption of danger. Strictly speaking, a new standard of review must be developed for each individual case of a plant producing nanoparticles (Dederer, 2010). Particularly important are subsequent orders pursuant to Art. 17 FICA, which may be promulgated to statute directly and are at the discretion of the authority. Subsequent orders, as well as other decisions, fall under the subject of proportionality, which is problematic in the area of safety: if there are no limits on immissions, the burden of proof on the authority is increased even further (SRU, 2011).

As part of the monitoring of systems, arranging the taking of the correct measurements is particularly important. Thus, when there is a suspicion of danger, the competent authorities are able to trace emissions emanating from equipment into the environment, which is the case during commissioning or major changes of installations. The taking of individual measurements can be ordered at announced locations in a three-year cycle, or the continuous checking of emissions and pollutions can be arranged by the operator using recording gauges. The requirements for this are laid down in detail in the Administrative Circular on Air Quality. Also, the operator has to periodically submit an emission statement of information about the risks of his emissions in the scope of the 11th BImSchV, which lays down the requirements for declarations on emissions and emission reports. However, for this to be the case, the emitted substance must be either expressed or emanating from a plant, and its emissions must exceed (for most substances) 100 kg in the return period. However, insufficient data limits meaningful parameters for emissions and emission reporting. Validated and standardised measurement methods are thus difficult in the determination of emission parameters for nanomaterials. Since nanoparticles are not explicitly mentioned, emissions of less than 100 kg do not fall within the scope of the 11th BImSchV and, for that reason, no emission declaration must be completed for them (SRU, 2011).

According to Art. 52 of the FICA, the authorities have to regularly review pollution control permits and bring these up to date if there is evidence of adverse effects on the environment. However at present, when such a permit review is carried out, only conventional pollutants are considered due to the level of expertise of the authorities. However, contrastingly, in the ‘nano powder decision’³⁹ much more stringent requirements were adopted: in this decision of the Higher Administrative Court of the Federal State of Baden-Württemberg,⁴⁰ citing a number of diverse legal sources,^{41, 42, 43} the requirements of the Administrative Circular on Air Quality Control were interpreted in the case of an installation producing different nanopowders. Whether the operator was obliged by law to do so is unresolved even after the judgement, since an affected third party objected to the permit. Their action was, however, unsuccessful because it could not be proven that adverse effects on the environment and human health, pursuant to the law, emanated from the nanopowders in a certain concentration.

With the help of an expert opinion, it was shown during the court hearing that emission exposures at the plant would remain less than 1% of the emission value of diesel soot regarded as tolerable by the LAI (Hofmann, 2009). The resulting restriction – which was reduced in a disclaimer by the operator by a factor of 100 during the ongoing proceedings – remained unchallenged in the Federal Administrative Court decision: ‘Where a scientifically ascertainable effect threshold is lacking, it is free of arbitrariness, in the absence of better knowledge, when consideration of irrelevance is based for the purpose of orientation on the criteria for judging the carcinogenic effects of comparable substances evolved in the LAI study ‘Cancer risks from air impurities’ (LAI, 1992). Beyond such an irrelevance threshold, which marks the area of inevitable residual risk, the legal obligation of protection and preclusion related to emission control is meaningless. The outcome was that violation of the protection and preclusion obligation deriving from Art. 5 para. 1 no. 1 FICA (which merely protects third parties) had to be denied. To deduce from the judgement that present knowledge of the effects of nanomaterials is satisfactory or that the formulation of legislation on installations is not in need or capable of improvement would be excessive. The Federal Administrative Court merely observed that the decision of the authority was ‘free of arbitrariness.’

³⁹ Supreme Administrative Court (*Bundesverwaltungsgericht – BVerwG*) of 11 December 2003, 7 C 19.02, BVerwGE 119, 329 ff.

⁴⁰ Higher Administrative Court of Baden-Württemberg of 18 December 2001, 10 S 2184/99. See also the decision of the Federal Administrative Court: Supreme Administrative Court Decision (BVerwGE) 119, 329.

⁴¹ BImSchG Art. 5 para 1 no 1, no 2; Art. 48.

⁴² Administrative Circular on Air Quality Control (*Technische Anleitung zur Reinhaltung der Luft – TA Luft*) 1986.

⁴³ VwGO (Administrative Procedure Code (*Verwaltungsgerichtsordnung – VwGO*) of 19 March 1991 (Federal Law Gazette I p. 686), last amended by Art. 7 of the Law of 20 October 2015 (Federal Law Gazette I p. 1722).

It could be that emission-limiting measures were either too stringent or even, measured on the obligation for precaution (that excludes third-party protection), not far-reaching enough. Therefore, on the basis of material obligations on the part of installations, the authorities are quite able to respond to the specific dangers of nanoparticles released into the environment. However, they must determine and evaluate the risk independently (SRU, 2011).

As of yet, no support is to be found in non-statutory regulations. Authorities can merely use the interpretive support of the LAI on Administrative Circular on Air Quality Control. This allows risk-based analogous consideration without, however, addressing more precisely the specific effects of nanomaterials. This is problematic because the effects of nanomaterials on human health can by no means be restricted to their carcinogenic potential only. Finally, however, although nanomaterials currently pose particular problems in immission control law, the conventional instruments should be applied to control them (Franco et al., 2007).

To conclude, if the approval of title is concerned, the fact that the production and processing of nanomaterials are not universally approved is not acceptable in view of a precaution-oriented handling of nanomaterials. Führ (Führ et al., 2006a) proposes to make the use of nanomaterials approvable under the requirement of a licence, but then again, appropriate parameters for the definition of a threshold would have to be found. As such, they would need to suggest a unit that maps the surface activity of nanomaterials. However, the focus of the risk assessment of synthetic nanomaterials is currently on insoluble or hardly soluble materials and fibres, which are free structures in the form of particles, rods or tubes that are smaller than a few hundred nanometres in two or three dimensions. At the very least, the handling of these should be subject to immission control approval. Beyond that – to better estimate the relevance of nanomaterials in environmental protection law – the establishment of a reporting obligation for their production and use should be considered. The certificates issued or received should be collected centrally.

Further, for the emissions threshold limit value, the normative definition of boundary standards presupposes a sufficient basis for decision-making and thus scientific findings that are in fact currently lacking (Gantzer, 2004). According to the SRU, decisions will therefore have to remain individual in many areas in the longer term (SRU, 2011). Nevertheless, it would be desirable – as soon as suitable evidence is available – to set limits either for individual or for certain groupable nanomaterials. Therefore, it would make sense to search for a suitable parameter, since mass concentration does not reflect the specific risk potential in an ideal way. The European Parliament is in favour of checking whether emission limit values and environmental quality standards need to be revised so that the surface of the particles is included. However, an orientation on hand of the particle number could also be possible (European Parliament, 2009).

Finally, as far as the burden of proof on the authorities is concerned, in order to assist the competent authorities in pollution control, legal permits for installations from which nanomaterials are released need to be issued. The emission reduction requirement should initially apply not only to substances evidentially hazardous to health but also to those substances for which there is only an initial suspicion (abstract concern in the precautionary principle). In addition, the development of specific guidelines following two different respects is required. Firstly, it should be determined what information the applicant should furnish in order to submit a permit application. Secondly, the authorities should be given guidelines with which the derivation of appropriate limits can be facilitated (NanoKommission, 2011). Finally, when there is still regulatory discretion, differentiation should be made according to a preliminary risk assessment (Scherzberg, 2010).

D.1.02 Soil

The production and industrial use of nanomaterials falls, again, under the remit of the Federal Immission Control Act (BImSchG). Contrary to what the title of the Act suggests, it is not merely about air purity but has rather – for installations subject to licensing – the character of a comprehensive law governing the licensing of industrial installations and thus continues the tradition of trade regulations (Führ, 2007). The focus has been on an integrative approach.

The IED Directive (former IPPC Directive) is responsible for this development, which, together with other aspects of Community law, has determined the legal situation in Germany (Führ, 2007). The following description is therefore largely restricted to the IED Directive.

If certain nanomaterials carry the risk of serious accidents, appropriate thresholds may be imported under the Seveso III Directive (former Seveso II Directive). On the other hand, under the Water Framework Directive nanomaterials could, if necessary, be classified as priority substances and could also be considered in the case of hazards as hazardous waste within the meaning of the EU waste legislation. Consequently, the Parliament pointed out the need for an adaption of waste legislation in its decision (European Commission, 2009c).

Accordingly, should nanomaterials be included in the European List of Wastes⁴⁴ (former EWC), the criteria for acceptance of waste at landfills and the emissions limits would be checked during combustion. In the area of water and air, the emission limit values and environmental quality standards would also be reviewed (Eisenberger et al., 2010).

⁴⁴ Commission Decision 2000/532/EC of 3 May 2000 replacing Decision 94/3/EC establishing a list of wastes pursuant to Article 1(a) of Council Directive 75/442/EEC on waste and Council Decision 94/904/EC establishing a list of hazardous waste (OJ L 226, 6.9.2000, p. 3–24), last amended by Decision of 18 December 2014 (OJ L 370, 30.12.2014, p. 44–86).

EU law also contains plant and environmental regulations that are associated with relevant nanomaterials. The Commission states the importance of individual requirements in its communication on regulatory aspects of nanomaterials (European Commission, 2008b), such as the directive on integrated pollution prevention and control of pollution (IED), and the directive on the control of major-accident hazards involving dangerous substances (Seveso III).

The IED Directive prescribes, in addition to permit requirement, that regulation limits emissions and environmental quality standards are met for the installations covered. Under Community law, largely unregulated systems are outside the scope of the IED Directive. Here, the Seveso III Directive contains substance-specific guidelines for the prevention of operational fault. All of these are, however, not tailored to the specific risk situation of nanomaterials.

Additionally, in the water directives⁴⁵ and selected waste directives,⁴⁶ legislation does not make any explicit reference to nanomaterials. According to the Commission, the currently known risks of nanomaterials can be contained by the existing rules or will be adjusted as needed with ease. Consequently, the control of environmental impacts of nanomaterials in facilities that fall within the scope of the IED Directive could be implemented. If certain nanomaterials carry the risk of serious accidents, appropriate thresholds may be imported under the Seveso III Directive.

The 4th BImSchV outlines which installations are subject to an authorisation under Art. 4 FICA; hereafter it is linked to plants for the production of substances or groups of substances by chemical conversion on an industrial scale, as well as to the further use of such substances, such as surface treatment. In particular, facilities for research, development or testing on a pilot scale are exempted from the authorisation requirement. The concept of installations according to the FICA applies smoothly to plants producing nanomaterials (Führ et al., 2006b).

Furthermore, the catalogue of licenced facilities has not yet been finally formulated (Dederer, 2010). Nanomaterials are not only made by chemical processing (chemical reactions) but also by physical processes such as mechanical zoom (grinding) or physical deposition from the gas phase or explosions, in which no chemical reaction takes place. Therefore, it is not guaranteed that the production of nanomaterials always applies to the meaning of the FICA and, therefore, is not always subject to approval by its systematic principles (SRU, 2011).

⁴⁵ See Directive 2000/60/EC of the European Parliament and of the Council of 23 October 2000 establishing a framework for Community action in the field of water policy (OJ L 327, 22.12.2000, p. 0001–0073); see also Directive 2006/118/EC of the European Parliament and of the Council of 12 December 2006 on the protection of groundwater against pollution and deterioration (OJ L 372, 27.12.2006, p. 19–31).

⁴⁶ See Directive 2006/12/EC of the European Parliament and of the Council of 5 April 2006 on waste (OJ L 114, 27.4.2006, p. 9–21), also Directive 2008/98/EC of the European Parliament and of the Council of 19 November 2008 on waste and repealing certain Directives (OJ L 312, 22.11.2008, p. 3–30) and Council Directive 91/689/EEC of 12 December 1991 on hazardous waste (OJ L 377, 31.12.1991, p. 0020–0027).

Likewise, the use of nanomaterials in itself does not trigger any prior approval. In contrast, were organic solvents to be used for the surface treatment of nanomaterials, they would be subject to approval. The assessment point is then not the nanomaterial but the solvent used. Thus, quantity levels should also apply for and include those. The industrial use of nanomaterials is therefore not subject to approval itself, but requires authorisation permission only if the system uses an organic solvent in the relevant amount (Führ et al., 2006b). As a result, the presence of an authorisation for both the production and use of nanomaterials would be given consistently. Additional limitations of the approval could be for research equipment, development or testing on a pilot scale (see for approval of a production plant for carbon nanotubes in Leverkusen: Parliament of North Rhine-Westphalia (Landtag Nordrhein-Westfalen, 2010)). These gaps in licensing are not justified because for precautionary reasons, more than a legal permit for buildings should be required (SRU, 2011).

If the FICA (Art. 4–21) is applicable, the procedure of the permission process is further prescribed in the 9th BImSchV;⁴⁷ the documents to be submitted have to refer to the sources of emissions and the emissions coming from the plant. If detrimental effects on the environment could be caused, the expected emissions must also be addressed in the application. Since nanomaterials have no likely relatable adverse environmental effects yet, they do not need to be considered in the permission process (SRU, 2011).

The protection principle and the precautionary principle are part of the operator requirements of Art. 5 of the FICA and can prevail as ancillary provisions for the installations approval. The former tries to prevent harmful environmental effects and significant damage, while the latter specifies that appropriate measures following the state of the art must be taken (SRU, 2011).

The IED Directive applies to all installations mentioned in its Annex I. The Annex is arranged – similar to the 4th Federal Immission Control Act (BImSchV) – by industry. Art. 4 and 12 of the IED Directive make clear that both new installations and changes in installations made by operators are covered (Führ et al., 2007b). The IED Directive lays down basic obligations (‘general principles governing the basic obligations of the operator’) in Art. 3, analogously transposed in Art. 5 of the FICA. Installations must be operated in such a way that no ‘significant environmental pollution’ is caused and preventative measures are taken through ‘application of the best available techniques’ (Führ et al., 2007a).

⁴⁷ 9th Ordinance on the Federal Immission Control Act (*9. Bundesimmissionsschutzverordnung – 9. BImSchV* (Ninth Ordinance implementing the Federal Pollution Control Act (Regulation on the Authorisation Procedure) *Neunte Verordnung zur Durchführung des Bundes-Immissionsschutzgesetzes (Verordnung über das Genehmigungsverfahren)* of 29 May 1992 (Federal Law Gazette I p. 1001), last amended by Art. 5 of the Directive of 28 April 2015 (Federal Law Gazette I p. 670).

These demands are to be implemented by competent authorities in the form of ‘conditions of the permit’ in accordance with Art. 9 IED Directive, and emission limit values should be laid down for all relevant pollutants, based on these ‘best available techniques’.⁴⁸ Finally, according to Art. 9 para. 5 IED Directive, the permit should contain suitable emission monitoring requirements.

Art. 10 IED Directive establishes a relationship between permit content and environmental quality standards. Here, a limit value for fine particles, ultrafine particles and very fine dust – as laid down in Community air quality law – is a possibility. However, these are still several times the size of nanoparticles and are therefore not appropriate for coping adequately with the specific risks of nanomaterials. Art. 2 para. 7 of the IED Directive defines an environmental quality standard as ‘the set of requirements which must be fulfilled at a given time by a given environment or a particular part thereof, as set out in community legislation’. Whether such legislation will also include PNEC values in the future, applied according to REACH⁴⁹ within the scope of substance-related risk management, remains to be seen.⁵⁰ After all, it concerns quality values that have been deduced according to a REACH procedure.

Requirements aimed at the ‘control of major-accident hazards involving dangerous substances’ are contained in Directive 2012/18/EU (Seveso III Directive), adopted in Germany in the 12th Federal Immission Control Ordinance (12. BImSchV⁵¹). The directive applies when certain quantitative thresholds in ‘operational areas’ are exceeded and is characterised – in great contrast to the earlier connection with installations – by primary substance-related orientation. Quantitative thresholds are set high (mostly in the four- to six-digit kilogram range).

Besides that, however, they do not cover nanomaterials. This applies both to quantitative thresholds linked to hazard characteristics and to thresholds laid down for individual substances (Führ et al., 2007b).

⁴⁸ Cf. the exchange of information according to Art. 16 as well as the reference documents (‘BREF’) issued on this basis by the Seville Office (European IPPC Bureau); cf. the overview at <http://eippcb.jrc.es/pages/activities.htm>.

⁴⁹ Regulation (EC) No 1907/2006 of the European Parliament and of the Council of 18 December 2006 concerning the Registration, Evaluation, Authorisation and Restriction of Chemicals (REACH), establishing a European Chemicals Agency, amending Directive 1999/45/EC and repealing Council Regulation (EEC) No 793/93 and Commission Regulation (EC) No 1488/94 as well as Council Directive 76/769/EEC and Commission Directives 91/155/EEC, 93/67/EEC, 93/105/EC and 2000/21/EC (EC OJ, 30.12.2006, p. 1–847).

⁵⁰ However, the embodiment of this – weak – demand in the constitutional principle and the resulting inference in decisions of the Federal Constitutional Court on municipal charges for waste and charges for hazardous waste levied by the federal states goes too far; see the detailed comments in (Führ, 1998).

⁵¹ 12th Ordinance on the Federal Immission Control Act (*12. Bundesimmissionsschutzverordnung – 12. BImSchV* (Twelfth Ordinance implementing the Federal Pollution Control Act (Hazardous Incident (Reporting) Ordinance) *Zwölfte Verordnung zur Durchführung des Bundes-Immissionsschutzgesetzes (Störfall-Verordnung)* of 8 June 2005 (Federal Law Gazette I p. 1598), last amended by Art. 79 of the Directive of 31 August 2015 (Federal Law Gazette I p. 1474).

The essence of the directive is the demand for a ‘major action prevention policy’ (Art. 7 Seveso III Directive). This policy has to be drawn up in writing by the operator before the installation is put into operation, properly implemented and made available to the authorities. According to Art. 13 of the IED Directive, competent authorities have to ‘periodically reconsider and, where necessary, update permit conditions’. The reason for this could be the need to revise emission limit values or include new values in the permit, or also new developments in emission reduction technology. Should the regulation have a practical effect, concretisation is necessary not only in emission specifications but also for requirements concerning the latest advances in technology.

Nanomaterials are already being produced and used in plants. On the quantity, however, there are no official details, although the requirements that apply to the construction and operation of the plants have a decisive influence on the protection of the surrounding environment and people (neighbours). The production and use of nanomaterials in plants should be officially controlled (Führ et al., 2006b).

Since the focus of the risk assessment of synthetic nanomaterials is currently on insoluble or hardly soluble nanomaterials, it should at least with them been dealt with underlying subject of approval like in the Art. 4 of the Federal Immission Control Act (BImSchG). There should also be an obligation for the industrial production and use of all other nanomaterials, improving the estimation of the relevance of nanomaterials in relation to pollution control. Issued certificates or received notifications should be collected centrally (SRU, 2011).

For safe use and to ensure that operators take initial safety precautions to prevent accidents or to minimise their effects on humans and the environment as far as possible, the Hazardous Incident Ordinance should be applied in particular to those systems in which nanomaterials are present. Further, this should apply also where an initial suspicion (abstract concern in terms of the precautionary principle) has been identified within such systems and nanomaterials are present in the plant in significant amounts. That would, however, require the determination of appropriate parameters and appropriate thresholds for nanoparticles. However, for the handling of hazardous nanomaterials,^{52, 53} they are not classified in various water hazard classes and as long as such classification is not done, the strictest requirements should apply (Führ et al., 2007b).

⁵² Soil Protection Ordinance (*Bodenschutzverordnung – BBodSchV* (Federal Soil Protection and Contaminated Sites Ordinance) *Bundes-Bodenschutz- und Altlastenverordnung*) of 12 July 1999 (Federal Law Gazette I p. 1554), last amended by Art. 102 of the Directive of 31 August 2015 (Federal Law Gazette I p. 1474).

⁵³ Federal Soil Protection Act (*Bundes-Bodenschutzgesetz – BBodSchG* (Law on protection against harmful soil changes and remediation of contaminated sites) *Gesetz zum Schutz vor schädlichen Bodenveränderungen und zur Sanierung von Altlasten*) of 17 March 1998 (Federal Law Gazette I p. 502), last amended by Art. 101 of the Directive of 31 August 2015 (Federal Law Gazette I p. 1474).

D.1.03 Water

When nanomaterials are manufactured or used industrially, water law requirements on the discharge of substances into water bodies (point sources) have to be observed. However, nanoparticles can also enter waters from diffuse sources, e.g. during the end use or consumption of products. Nanomaterials can enter during manufacturing or processing, and cleaning products or wastewater from households into water bodies (Limbach et al., 2008). The relevant water law instruments can be found in the Water Management Act (WHG),⁵⁴ along with its concretising ordinances, as well as the German Groundwater Ordinance⁵⁵ and the German Waste Water Ordinance.⁵⁶ They are fundamentally based on European law (Reinhardt et al., 2010), in particular the Water Framework Directive 2000/60/EC⁵⁷ (WFD), in conjunction with Directive 2008/105/EC⁵⁸ and the Groundwater Directive 2006/118/EC.⁵⁹ For water conservation, certain activities are linked to the subject of prior administrative decisions at the planning stage, leading to most point sources of contamination being controlled adequately. However, a possible contamination of the waterbody by the use of products containing nanomaterials (eventually ending up as waste (possible diffuse source)) could still happen. Attempts to control this through regulation will be discussed as part of product and waste law in this work.

There are several water law caveats whose principles also apply to nanomaterials. Additionally, the individual provisions include precautionary elements. Thus, certain substances should not be introduced into the groundwater, according to the groundwater directive, while for other substances, permission may only be granted if an adverse entry into the waterbody would be of no concern; in this respect, the precautionary principle also applies (SRU, 2011). This applies also – linked to processes of the state of the art – to the discharge of wastewater.

⁵⁴ Federal Water Resources Act (*Wasserhaushaltsgesetz – WHG* (Act on the Regulation of Water Balance) *Gesetz zur Ordnung des Wasserhaushalts*) of 31 July 2009 (Federal Law Gazette I, 31.7.2009, p. 2585) last amended by Art. 320 of the Directive of 31 August 2015 (Federal Law Gazette I p. 1474).

⁵⁵ Groundwater Ordinance (*Grundwasserverordnung – GrwV* (Regulation on the Protection of Groundwater) *Verordnung zum Schutz des Grundwassers*) of 9 November 2010 (Federal Law Gazette, 11.8.2010, I p. 1513).

⁵⁶ German Waste Water Ordinance (*Abwasserverordnung – AbwV* (Regulation on Requirements for the Discharge of Wastewater into Water) *Verordnung über Anforderungen an das Einleiten von Abwasser in Gewässer*) of 17 June 2004 (Federal Law Gazette I p. 1108, 2625) last amended 2 September 2014 (Federal Law Gazette I p. 1474).

⁵⁷ Directive 2000/60/EC of the European Parliament and of the Council of 23 October 2000 establishing a framework for Community action in the field of water policy (OJ L 327, 22.12.2000, p. 0001–0073).

⁵⁸ Directive 2008/105/EC of the European Parliament and of the Council of 16 December 2008 on environmental quality standards in the field of water policy, amending and subsequently repealing Council Directives 82/176/EEC, 83/513/EEC, 84/156/EEC, 84/491/EEC, 86/280/EEC and amending Directive 2000/60/EC of the European Parliament and of the Council (OJ L 348, 24.12.2008, p. 84–97).

⁵⁹ Directive 2006/118/EC of the European Parliament and of the Council of 12 December 2006 on the protection of groundwater against pollution and deterioration (OJ L 372, 27.12.2006, p. 19–31).

Since nanomaterials are not among the substances whose discharge in groundwater is prohibited, the question of the necessity of a permit is not always entirely clear. Also, for nanomaterials viewed under the Wastewater Ordinance, a definite state of the art has not yet been formulated. Rather, the authorities now are required to formulate requirements independently. This is different only when handling substances hazardous to water; here, the hazard level of a system is presumed to be the highest WHC as long as this is not reliably determined for a substance.

Thus, this systematisation also applies to nanomaterials, but lacks any required assessment of individual nanoparticles. In this respect, precautionary handling in relation to water management is not ensured by the individual reservations of an official decision (SRU, 2011).

The interventions of the state, in addition to the reservations, include the planning and monitoring instruments. However, due to this lack of concreteness, guidelines can only be exercised if the authority itself calls for it (Führ et al., 2007a).

Thus, there is a lack of limits for the discharge of nanomaterials, and the limit values and quality standards for pollutants do not collect any nanospecific characteristics (Führ et al., 2006b). A formulation is needed which enables an evaluation of nanomaterials and limits for particularly problematic nanomaterials in water law and its appendices. The limits should be reduced to the possible lowest technical level.

However, the problem is that without knowledge of risk, no fair values can be determined. Hence, the discharge of particles with unknown hazard potential should be prohibited; they should be collected by the manufacturer before (purposeful) disposal (Führ et al., 2006b).

An introduction of non-conglomerating nanoparticles into water (water as solvent) should be excluded under all circumstances. A specification of the state of the art should be included in the Appendices of the Wastewater Ordinance. Since the authority has to prove what is considered state of the art, appropriate studies must be carried out by the dischargers. This can be overruled by more precise study results, as better scientific exposure assessments become available.

The legislature also holds measures in hand that are sufficiently powerful (authorisation for the discharge of substances and the prohibition of discharging), but is unable to use them on unknown materials (Führ et al., 2006b).

Thus, silver nanoparticles are already being discharged legally into waterbodies (BUND, 2010). Especially for quantitatively high and biologically active particles, the legislature should reconsider its position and apply stronger restrictions on nanomaterials like nanosilver. Thus, discharging could only be allowed under the provision that sufficient research on safety of the introduced particles is present (Führ et al., 2007b).

For regulation concerning installations handling water-hazardous materials,⁶⁰ the requirements for specialised companies are derived either from the potential hazard of the plant (danger existing in the plant using substances hazardous to water), or the hazard level of the system (water hazard class of the materials in the system and the volume or mass). For the latter, it may be that dangerous nanomaterials are dissolved in non-hazardous solvents. Since the mass of nanoparticles can be very small, a low hazard level is usually registered, in spite of the presence of dangerous nanomaterials. Here, the law must take this into account in the future by considering the solvent the materials are dissolved in as part of the sum of the total mass of the substance. If dangerous nanoparticles with a low total weight are dissolved in a non-dangerous solvent, the total mass of solvent and particles should be treated by the field of water law as if the entire resulting mass is a dangerous nanomaterial. This can be completely harmonious with the prevailing legal practice that when the water hazard class is unknown, the highest degree of danger is assumed (Reinhardt et al., 2010). It should therefore also in VwVwS^{61, 62} not be followed the hitherto⁶³ accomplished practice to assess the risk phrases⁶⁴ for the material safety data sheets of nanomaterials following their macro-scale material counterparts. In view of the deficiencies shown, the following changes are proposed (Führ et al., 2007b):

- ∞ For the regulatory approach, water law has so far focused on conventional pollutants and contains no evidence as to how to deal with nanomaterials. Therefore, a decision by the legislature must specifically make it clear in which cases, when mentioning a substance in the various annexes and lists of water law, the nanoscale form is also to be included.
- ∞ For the protection of groundwater, a clarification is needed as to whether the substances listed in the Annexes VII and VIII WFD (Führ et al., 2006b) include the nanoform, for which an abstract concern in terms of the precautionary principle for the water hazard exists.

⁶⁰ Installations Ordinance of water pollutants (*Anlagenverordnung wassergefährdende Stoffe – VAwS* (German Ordinance on Installations Handling Water-Polluting Substances and on Specialised Enterprises) *Verordnung über Anlagen zum Umgang mit wassergefährdenden Stoffen und über Fachbetriebe*) of 31 March 2010 (Federal Law Gazette I p. 377) last amended by Directive 2006/96/EC (OJ L 363, 20.12.2006, p. 81).

⁶¹ Administrative Regulation on the Substances Hazardous to Water (*Allgemeine Verwaltungsvorschrift zum Wasserhaushaltsgesetz über die Einstufung wassergefährdender Stoffe in Wassergefährdungsklassen (Verwaltungsvorschrift wassergefährdende Stoffe – VwVwS)*) of 17 May 1999 (Federal Gazette, 29.5.1999, 98a).

⁶² General Administrative Regulation amending Administrative Regulation on the Substances Hazardous to Water (*Allgemeine Verwaltungsvorschrift zur Änderung der Verwaltungsvorschrift wassergefährdende Stoffe*) of 27 July 2005 (Federal Gazette, 30.7.2005, 142a).

⁶³ Council Directive 67/548/EEC of 27 June 1967 on the approximation of laws, regulations and administrative provisions relating to the classification, packaging and labelling of dangerous substances (OJ 196, 16.8.1967, p. 1–98).

⁶⁴ Regulation (EC) No 1272/2008 of the European Parliament and of the Council of 16 December 2008 on classification, labelling and packaging of substances and mixtures, amending and repealing Directives 67/548/EEC and 1999/45/EC, and amending Regulation (EC) No 1907/2006 (OJ L 353, 31.12.2008, p. 1–1355).

- ∞ If, instead of macro-scale material, the nanomaterial is initiated or used, this should require a separate permission (permission caveat). At the very least, there should be a duty of disclosure, which would allow the authorities to demand a separate permission or adopt subsequent content or ancillary provisions that address the specifics of nanomaterials. This is especially true because there are still no guidelines for dealing with nanomaterials, and it is therefore necessary that the water authorities are aware of the potential industrial dischargers and get an overview of their nature and extent (Führ et al., 2006a). Only in this way can it be ensured that the authorities can intervene in accordance with the precautionary principle at an early stage.
- ∞ If substances hazardous to water are concerned and the hazard class for nanomaterials has not yet been determined with certainty, it should be ensured that nanomaterials are independently classified in respect to the different WHCs. Following the precautionary principle, the highest hazard level should be assumed. In the long term, however, it is desirable that all nanomaterials are classified according to their specific level of hazard in the WHC. However, the extent to which the current hazard classes and categories are sufficient to enable a precaution-oriented handling of nanomaterials must first be reviewed, as their peculiarities might not be able to fit into the current systematisation. In addition, it should be examined whether the basis of the GHS hazard statements need to be amended to include the special properties of nanotechnologies (Führ et al., 2006a).
- ∞ For surveillance, currently, the monitoring of nanomaterials is still a considerable problem. In particular, appropriate parameters for measuring and testing procedures need to be defined. Principally, nanomaterials are included in the list of priority substances according to their hazardous properties (European Commission, 2008b). That those nanomaterials should be listed in the Annexes VII and VIII WFD appears justified (Führ et al., 2006a).
- ∞ Finally, where nanomaterials in wastewater are concerned, in the long run, the discharge of wastewater containing nanomaterials requires a specification following the state of the art. However, it must be checked which parameters for emission thresholds could offer suitable orientation. The authorities should, however – if they are informed that nanomaterials have been introduced via wastewater – specify requirements for wastewater quality (Führ et al., 2006b). In order to assist the competent authorities in the formulation of requirements, the development of appropriate guidelines is required. For their development and application within water law, an orientation for a preliminary risk assessment is recommended; this is further discussed in the following sections of this work that concern wastes and wastewater.

D.1.04 Health and safety in the workplace

Activities involving nanomaterials in the workplace are covered by the German Occupational Health and Safety Act⁶⁵ (*Arbeitsschutzgesetz – ArbSchG*) and, in particular, by the German Hazardous Substances Ordinance⁶⁶ (*Gefahrstoffverordnung – GefStoffV*) and the set of Technical Rules for Hazardous Substances (*Technische Regeln für Gefahrstoffe – TRGS*) governing its implementation in practice. In the case of activities involving biological substances in the workplace, the provisions of the German Ordinance on Biological Agents (*Biostoffverordnung – BioStoffV*⁶⁷) also applies. Central rules include the EU Framework Directive on the introduction of measures to encourage improvements in the safety and health of workers at work 89/391/EEC⁶⁸ as well as the Directive on the protection of the health and safety of workers from the risks related to chemical agents at work 98/24/EC.⁶⁹

On the basis of current scientific knowledge, there is no immediate need to introduce specific provisions at the level of an ordinance in addition to the provisions already in place. However, it is recommended that an open-ended review be carried out to determine whether the provisions of the existing legislation on occupational health and safety, including the Technical Rules, do in fact adequately cover all of nanomaterials' specific requirements (SRU, 2011).

From a technical point of view, nanomaterials that are new, or whose possible effects are hitherto unknown, should only be handled in closed systems (Bello et al., 2008b; Bello et al., 2008a). This applies to the (re-) development process and for dealing with technical measurement or production. Although complete ignorance is common at the early research stage, the legislature should not tolerate an absolute lack of knowledge about a newly created substance in later stages of development (Working Group 3 of the NanoKommission, 2010).

⁶⁵ Occupational Health and Safety Act (*Arbeitsschutzgesetz – ArbSchG* (Act on the implementation of occupational safety measures for improving the safety and health of employees at work) *Gesetz über die Durchführung von Maßnahmen des Arbeitsschutzes zur Verbesserung der Sicherheit und des Gesundheitsschutzes der Beschäftigten bei der Arbeit*) of 7 August 1996 (Federal Law Gazette I p. 1246) last amended by Art. 427 of the Directive of 31 August 2015 (Federal Law Gazette I p. 1474).

⁶⁶ Hazardous Substances Ordinance (*Gefahrstoffverordnung – GefStoffV* (Ordinance on Protection against Hazardous Substances) *Verordnung zum Schutz vor Gefahrstoffen*) of 26 November 2010 (Federal Law Gazette I p. 164–1644), last amended by Art. 2 of the Directive of 3 February 2015 (Federal Law Gazette I p. 49).

⁶⁷ Ordinance on Biological Agents (*Biostoffverordnung – BioStoffV* (Regulation on safety and health at work with biological materials) *Verordnung über Sicherheit und Gesundheitsschutz bei Tätigkeiten mit Biologischen Arbeitsstoffen*) of 15 July 2013 (Federal Law Gazette I p. 2514).

⁶⁸ Council Directive 89/391/EEC of 12 June 1989 on the introduction of measures to encourage improvements in the safety and health of workers at work (OJ L 183 p. 0001–0008).

⁶⁹ 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 (fourteenth individual Directive within the meaning of Article 16 para. 1 of Directive 89/391/EEC) (OJ L 131, 5.5.1998, p. 11–23).

Furthermore, in the following scale-up steps, this is no longer acceptable. The developer or manufacturer should provide sufficient knowledge of risk. Otherwise, the developer or manufacturer should at least handle further production with the highest possible security level to adequately protect employees from possible unknown risks and to comply with the information disclosure obligation (Art. 35 REACH). However, as long as nanomaterials have the same CAS Registry Number (CASRN) as the macro substances, there is no legal obligation to conduct substance-specific studies, except for fullerenes, as they are not a EINECS material and have been given their own CASRN. One possibility would be for the legislature to create a CASRN for the category ‘unknown nanomaterial’ and prescribe generic and specific tests that then contribute to the necessary knowledge of nanospecific hazards. If the material is no longer unknown, it can be treated independently. Here, the legislature can decide either to assign a new CASRN or to assign the material to the CAS number of the bulk material (Führ et al., 2006b).

Extensive nano-regulation within the REACH Regulation is a very promising possibility. A large part of the regulation is already fit for this purpose. In addition, recording nanomaterials in the TRGS seems to be useful. A characterisation of nanomaterials also seems very important, because risk assessments can be made only if the manufacturer or processor also knows that a nanomaterial being processed. If this information is missing, a nanospecific risk analysis is impossible. Therefore, it is recommended to always require a transfer of information, even if nanomaterials are knowingly generated or passed on (SRU, 2011).

Furthermore, the Hazardous Substance Ordinance should list nanoparticles that are airborne under its Annex for ‘particulate hazardous substances’; this would lead to preventive measures for health and safety. Likewise, the TRGS cover activities involving nanomaterials, although they need to contain special rules on nanomaterials. Such a TRGS was established by the Federal Institute for Occupational Safety and Health (BAuA) and the Council of Chemical Associations (VCI) (BAuA and VCI, 2007). In addition, unknown substances should be treated with the greatest possible care, following TRGS 400: ‘In the absence of relevant test data, the employers must assume that hazardous properties are present for the purpose of their risk assessment’.

In addition, the principle of minimising exposure always applies as a basic requirement under the Hazardous Substances Ordinance; an activity involving hazardous substances may only be commenced after a risk assessment has been conducted, as this is the bedrock of occupational health and safety and the basis for planning protective measures. The NanoKommission supports current efforts by the Committee on Hazardous Substances to initiate a Working Group review of any needs to be met in terms of Technical Rules, Occupational Health and Safety Guidance and, if appropriate, rules at the ordinance level.

The same goes for the TLV Commission's efforts to evaluate toxicological test data on nanomaterials. The NanoKommission supports efforts to review the introduction of limits for nanodusts and establish what those limits should be. In terms of the precautionary principle, it would be appropriate to put in place transitional provisions for cases where no improvement is foreseeable in terms of available information (Working Group 3 of the NanoKommission, 2010).

In the context of health and safety in the workplace, there are many difficulties due to the fact that specific exposure data are lacking or that procedures for testing nanomaterials are still in their infancy. In both of these respects, there is a perceived need for action (EEA, 2001).

Ultimately, the primary goal must be to establish a correlation between exposure levels and adverse health effects, as this is crucial for establishing substance-specific limits for nanodust (Working Group 3 of the NanoKommission, 2010). The requirement is therefore for substance-specific, individual marginal levels or benchmarks for nanotechnological dusts and particulates in the workplace. The limit values must already be known in technical scale before use. Otherwise, they should be dealt with – as has already been described – only with the highest degree of care, as applied under the precautionary principle (EEA, 2001).

Working with the greatest possible caution would give maximum protection because of the exaggerated caution against all possible dangers. However, this could go too far and potentially impair technical research. Therefore, for the development of new materials, it is sufficient to note that only commonly predictable hazards need to be controlled. In the interests of health and safety in the workplace, it must also be considered whether there is a need for surveillance bodies and occupational health and safety organisations to obtain information to identify companies working with unbound nanomaterials (i.e. not contained or bound within a concrete matrix (Working Group 3 of the NanoKommission, 2010)).

Debate is currently under way in the German Government's Committee on Hazardous Substances (*Ausschuss für Gefahrstoffe* – AGS) and in the German Research Foundation's Senate Commission for the Investigation of Health Hazards of Chemical Compounds in the Work Area (*MAK-Kommission*) on setting a general, non-substance-specific limit for nanodusts.

Setting a limit of this sort would represent another regulatory instrument in the context of the Hazardous Substances Ordinance, similar to the general limits already in place for inhalable dust (10 mg/m³) and alveolar dust (3 mg/m³). Framework factors affecting scientific identification of a general assessment criterion would need to be tested and laid down on the basis of expert consensus within the relevant circles of the AGS. In the longer term, it may become necessary to set limits specifically for nanodusts (Working Group 3 of the NanoKommission, 2010).

Another important source of relevant information in this context are the legislative provisions relating to the EU internal market, which concern occupational health and safety. In this regard, there is a perceived need for adjustments to existing provisions. Efforts must be made to promote the generation of nanospecific test data. The inclusion of a clear and explicit clause in REACH stating that the testing of a substance containing a nanomaterial must be undertaken if the substance is placed on the market (or used) as a nanomaterial. This is particularly relevant for long-term studies on inhaled substances, which play a special role in occupational health and safety (Oberdörster, 1996; Oberdörster et al., 2005; Donaldson et al., 2003; Borm, 2002; Donaldson et al., 2001; Dreher, 2004; Kreyling et al., 2004). In addition, a provision should be introduced requiring Material Safety Data Sheets (MSDS) prepared in accordance with REACH to state explicitly if a nanomaterial is present. Employers need this information on the guidance documents (MSDS) to decide whether to use and how to handle nanomaterials in the workplace.

As outlined above, from the point of view of occupational health and safety, priority must be given to generating nanospecific test data and other information on substances. Public funding for research could be channelled through the Federal Ministry of Education and Research (BMBF) research support system, but also through other government agencies' research programmes. In accordance with the 'polluter pays' principle, however, the business sector carries the primary responsibility for promoting research in this field, as this is laid down explicitly in the provisions of the EU internal market. Amendments to this legislation would also require actions at EU level (Working Group 3 of the NanoKommission, 2010). As more information becomes available, provisions in the narrower field of occupational health and safety legislation must be subject to continuous review in order to address potential adjustment requirements. Thanks to the structure of the Hazardous Substances Ordinance and the possibility of developing and using Technical Rules, amendments can be put in place swiftly.

The topic of nanomaterials is currently under discussion in a working group of the Committee on Hazardous Substances. The Working Group has been mandated to first of all gather information and assess whether there is a need for a nanospecific Technical Rule relating to Hazardous Substances (a 'Protective Measures TRGS'). With regard to a general limit for nanodusts, the available scientific data must be reviewed with a view to establishing whether setting such a limit is feasible or advisable. In this context, the Federal Institute for Occupational Safety and Health (BAuA) could undertake vital preliminary work for Sub-Committee 3 of the Committee on Hazardous Substances, the body to which the task of making an expert assessment and finally making recommendations on such a limit for (hazardous) nanomaterials would ultimately fall (Working Group 3 of the NanoKommission, 2010).

Announcement 527⁷⁰ on Hazardous Substances by BAuA reflects the state of the art, the state of occupational health and occupational hygiene as well as other sound work and scientific knowledge relating to activities involving hazardous substances, including the classification and labelling of nanomaterials. The objective of the announcement is to give recommendations for the protection of the safety and health of employees in the workplace during activities involving substances, mixtures or articles consisting of or containing manufactured nanomaterials. The basis for the announcement is the EC recommendation on the definition of the term nanomaterial. Following this, a substance or a mixture consisting of or containing manufactured nanomaterials shall not be generally regarded as a dangerous substance or a hazardous substance as defined in the Hazardous Substances Ordinance. The risk assessment of manufactured nanomaterials requires a differentiated consideration based on the properties of the respective manufactured nanomaterial and the activities performed. Currently, uncertainties persist in characterising the associated risk, and the insufficient possibilities for determining exposure may lead to a lack of clarity in assessing the risk and differentiating between the occupational safety and health measures to be derived from such a risk (BAuA, 2013).

The announcement complements the Technical Rules for Hazardous Substances with regard to the risks caused by manufactured nanomaterials, and in particular the Technical Rule for Hazardous Substances (TRGS) 400 on the ‘Risk Assessment for Activities involving Hazardous Substances’ and the TRGS 402 on the ‘Identification and Assessment of the Risks from Activities involving Hazardous Substances: Inhalation Exposure’. The character of the announcement is, however, that of a conceptual guidance, and it contains more specific guidelines for action only where necessary and possible (BAuA, 2013).

The scope of its assessment includes all workplaces along the value chain where activities are performed with manufactured nanomaterials. They include research and development, production, industrial and manual processing and treatment, as well as disposal, and shall also cover activities such as cleaning, servicing, and maintenance and repair work beyond other criteria mentioned in any proposal for an assessment criterion (BAuA, 2015; BAuA, 2013).

In the context of risk assessment, all exposure routes shall be taken into account. For inhalation exposure, it is necessary to assess the exposure effects both with regard to the particle fraction and to liquid aerosols consisting of nanoparticles or containing nanomaterials, and consisting of or containing non-nanoscale aggregates or agglomerates of nanoparticles (BAuA, 2013).

⁷⁰ Announcements on Hazardous Substances – Manufactured Nanomaterials (Announcement 527) of May 2013 (Joint Ministerial Gazette 2013 (No. 25) pp. 498–511).

Although nanomaterials are covered by this and also current legislation on occupational health and safety, a review would be beneficial to determine whether existing provisions are sufficient and reflect the current state of technology, and whether they provide adequate protection for employees in the workplace from a health and safety perspective. Particular attention needs to be paid in this context to processing and handling of products/articles. Even in applications that are widely used, the current state of technology will first of all need to be established and debated.

Due to the outlined gaps in the legal regulation of the use of nanomaterials, defects can also arise in the application of labour protection regulations in the implementation of the precautionary principle (Köck et al., 2002). Currently, no nanospecific company-related risk assessment is possible, due to an information gap between purchaser and manufacturer. Also, the employer itself is not committed to a full update of its risk knowledge or a nanospecific risk assessment. In particular, it is currently not explicitly demanded as part of the evaluation to resort to ‘readily accessible information’; that is, current information available in popular media and published scientific studies. This can, however, only apply as long as such risk studies indicate no increased potential risk. If there is any doubt, protection measures are required.

In the need for manufacturing reform, the information currently available falls mainly under the remit of REACH. The basis of the manufacturer’s recommended dose is the perceived risk assessment of the substance and the likely exposure of workers, consumers and the environment. In any case, the occupational health and safety regulations are more specific provisions to be based on the extent of worker exposure. On the level of the EU, there are so far no useful initiatives to give guidance. Instead, an increase in legal certainty through the formulation of an independent Technical Rule Nano would be achievable. In addition, specific individual policies could be adopted. There are currently many gaps in our knowledge of nanoparticles, meaning that there are important uncertainties surrounding the toxicological and physico-chemical hazards, the appropriate dose/exposure metric(s), the means of measuring exposures, the risks to health and the effectiveness of control measures (Hansen, 2009).

D.1.05 Summary

The legal framework is designed, as a rule, to provide R&D with the greatest possible scope. From that perspective, R&D activities are the subject of legal regulation only in exceptional circumstances, as in the area of genetic engineering. In R&D, regulations in legislation on water and waste also have to be observed, but there are no peculiarities from a legal point of view regarding nanomaterials. On the other hand, it could also be difficult to register (immission) inputs of nanomaterials from research and development (Führ et al., 2007a)

The most important instrument of pollution control law is the system of authorisation of plants and equipment through which compliance with ambient air quality requirements may be imposed and for which compliance is ensured and monitored by mandatory measurements. In addition, emission limits, alarm thresholds and margins of tolerance trigger measures for certain areas when exceeded. With regard to the precaution-oriented handling of nanomaterials, it should be pointed out that the emission control regulations permit does not apply per se for all of production or processing of nanomaterials, especially when produced on a pilot scale – then, only a building permit is required (Pache, 2009).

Furthermore, the competent authorities' lack of expertise limits the overview of where nanomaterials are manufactured or processed, and thus is not justified (SRU, 2011). A register of facilities that deal with nanotechnologies would be desirable. Nanotechnological companies should subject themselves to the duty of ensuring that emissions do not occur too densely and then accumulate. Further, a mixture of different nanoemissions (mutually increasing under some conditions) should be pre-identified and avoided (Pache, 2009).

An additional problem is that there are no current limits for nanomaterials themselves. Moreover, there is legal uncertainty in that the applicability of the limits for the macro-scale material on the nanoscale material is unclear. This is not adequate, because it is short-sighted to use the values for the macro-scale material for nanoscale counterparts. Even for nanomaterials – if they are classified as hazardous to health – the emissions minimisation principle applies to that very classification. However, in many nanomaterials this is not initially possible (Pache, 2009).

With regard to limits, there are also more fundamental problems: so far, parameters which are suitable for the establishment of limits for nanomaterials have not been recognised, nor are there appropriate measurement techniques for emissions. All this provides authorities with enormous problems. They must set the standard of review and also have the burden of proving adequacy when determining the limits. For precautionary reasons, this situation is not justifiable and requires correction (SRU, 2011). There is an urgent need for appropriate limits for nanomaterials, which would need to be evaluated even in case-by-case decisions (Pache, 2009).

As a partial solution, it is recommended that for the individual nanomaterials with gaps in knowledge on their risk profile, the largest possible generic or potential risk – with appropriate protective measures – should be assumed. This should remain in effect until the operators are able to prove otherwise, or general research results are available that allow a realistic assessment (Pache, 2009). As a support to the authorities, a generous standard particle could be developed or defined which could be tested by way of example and provide a certain level of protection until clear and specific research results for single specific particles are available.

D.2. Processing and placing on the market

Unlike the previous section, no overarching law is discussed in this section. However, the following considerations concentrate on elements of chemicals law defined as regulations, such as Art. 7, 9 and 9a of the German Chemicals Act, which, by means of special mechanisms (for instance, specific test specifications), aim for systematic identification of substance-related risks. The reason for this is the intention of the legislator to register substances at an early stage, directly after production (Bergeson, 2013). Following this, ‘derived chemicals law’ is distinguished from ‘primary chemicals law’ (directed at data collection) by the fact that, based on data from primary chemicals law, it includes specifications for identifying and – through appropriate action – ‘preventing’ dangers in subsequent individual use and controlling risks (as per the wording in the REACH Regulation). In future, specifications of substances according to the REACH Regulation will have to be observed ever more closely (Führ et al., 2007b).

Registration as a new substance was possible under Directive 67/548/EEC, whilst existing substances were controlled under Regulation 793/93/EEC. The legal treatment of nanocompounds both under existing-substance and new-substance law postulates a systematic evaluation of the risks for human health and the environment emanating from these substances only when certain quantitative thresholds have been reached. The question arises of whether this standard is adequate, considering the very small volume placed on the market; the introduction of nanospecific quantitative thresholds needs to be considered.⁷¹ Furthermore, the criteria according to which a substance is assigned to the existing-substance or new-substance regime need to be clarified. To ensure the safety of products (following Regulation (EC) 765/2008),⁷² product law does not approach alternative or complementary instrumentations. These will be presented in the following, as they probably are fit for a large proportion of nanoproducts already used or could be considered for future nanoproducts (SRU, 2011).

Physically, the distribution of nanomaterials from the place of manufacture or from transitional storage to fixed-site warehouse or consumer locations can take place in mobile enclosures by road or rail, by sea or air. Safety demands on transport technology and secure enclosure are laid down in the European Convention on the International Transport of Dangerous Goods.⁷³

⁷¹ See the comments on regulative options within the scope of the REACH Regulation.

⁷² Regulation (EC) No 765/2008 of the European Parliament and of the Council of 9 July 2008 setting out the requirements for accreditation and market surveillance relating to the marketing of products and repealing Regulation (EEC) No. 339/93 of the Council (OJ L 218, 13.8.2008, p. 30–47).

⁷³ European Agreement concerning the International Carriage of Dangerous Goods by Road (ADR) applicable as from 1 January 2015; 2015 edition (ECE/TRANS/242, Vol. I and II), and corrigenda.

D.2.01 Equipment and Product Safety Act

The Product Safety Act (ProdSG)⁷⁴ (former GPSG)⁷⁵ serves to implement the so-called new conception of product safety into German law and, in addition to the General Product Safety Directive 2001/95/EC,⁷⁶ the new approach serves to harmonise the various directives in German law (Kapoor et al., 2002). The Toy Safety Directive 2009/48/EC⁷⁷ (as a complementation to the new concept) is also concerned with this. It is characteristic of the new regulatory approach that the European directives and the transposition of those laws only formulate basic requirements and objectives for specific areas. The fulfilment of these requirements will be achieved by European standards, in which their adherence to the requirements of the Directive or the law is assumed. Technical equipment and consumer products come under the scope of the ProdSG, unless other laws contain provisions at least equivalent (SRU, 2011). The law is aimed at ensuring safety and health; the protection of the environment may partly be included but is not considered to be a primary goal (Klindt, 2001).

After the so-called new design, the instrument to ensure safe products is the responsibility of the product manufacturer. Therefore, the producers and distributors pursuant to Art. 3 para. 1 ProdSG must comply with the safety provisions of the binding regulations that implement the harmonisation of policies on the basis of Art. 8 para. 1 ProdSG. Following this requirement, they must ensure that health and safety are not endangered but, beyond this, that risk provision must also be ensured (SRU, 2011).

Thus, while it is assumed (Wilrich, 2004) that the ProdSG is an expression of the precautionary principle, this is only because its goal is the prevention of unsafe products appearing on the market and not because of the requirements made on safety. The ProdSG is therefore more likely to be assigned to emergency law (Geiß et al., 2005; Hennig, 2008) because producers and distributors have to comply with the requirements of certain safety and health standards to presume compliance. The latter were developed following specification of the European Commission security objective by private standards organisations (Herrmann et al., 2010).

⁷⁴ Product Safety Act (*Produktsicherheitsgesetz – ProdSG* (Act on the provision of products on the market) *Gesetz über die Bereitstellung von Produkten auf dem Markt*) of 8 November 2011 (Federal Law Gazette I p. 2178, 2179; 2012 I p. 131), last amended by Art. 435 of the Directive of 3 August 2015 (Federal Law Gazette I p. 1474).

⁷⁵ Former Equipment and Product Safety Act (*Geräte- und Produktsicherheitsgesetz – GPSG* (Act on Technical Equipment and Consumer Products) *Gesetz über technische Arbeitsmittel und Verbraucherprodukte*) of 6 January 2004 (Federal Law Gazette I p. 2–219) repealed on 8 November 2011 (Federal Law Gazette I p. 2178).

⁷⁶ Directive 2001/95/EC of the European Parliament and of the Council of 3 December 2001 on general product safety (OJ L 11, 15.1.2002, p. 4–17).

⁷⁷ Directive 2009/48/EC of the European Parliament and of the Council of 18 June 2009 on the safety of toys (OJ L 170, 30.6.2009, p. 1–37).

The explicit statement of the presumption in ProdSG is an expression of the new conception. For those products for which no regulation exists, such as simple furniture and textiles, sports and leisure products, craft equipment, etc. (Klindt, 2007), it must still be ensured that health and safety are not endangered, according to Art. 3 para. 2 ProdSG.

This is also typical of the new approach's presumption. In compliance with standards or other technical specifications of the Committee on Technical Work Equipment and Consumer Products (*Ausschuss für technische Arbeitsmittel und Verbraucherprodukte – AtAV*), it is also presumed that safety and health requirements are conformed to. However, so far, there are no such standards for nanotechnological products. Both for the harmonised area of Art. 3 para. 1 ProdSG (there are, for example, harmonisation directives for toys or aerosol packaging) as well as for the non-harmonised area of Art. 3 para. 2 ProdSG, manufacturers are responsible for ensuring the specified security levels. Contrarily, there is no requirement for standard-compliant production (Wiesendahl, 2007; Kapoor et al., 2008). However, it is assumed in such cases that the requirements have been fulfilled. According to Art. 3 ProdSG, the legal responsibility to bring compliant products onto the market always rests with the product manufacturer.

A preventive prohibition with reservation of authorisation – for example, a conditional approval for the use of certain substances in certain product categories – is not envisaged (Wilrich, 2004). The responsibility for the product is not restricted to the obligation to only place safe products on the market, but rather, according to ProdSG Art. 6 para. 1 no. 1 c, also applies in measures aimed at reducing the impact of product hazards – that is, harm reduction (Wilrich, 2004).

While the European Commission has already granted mandates to the European standardisation bodies concerning standardisation with respect to nanosciences, nanotechnologies and nanomaterials (European Commission, 2007; European Commission, 2010), there is, however, no comprehensive review of the standards with regard to the guidelines of the aforementioned new concept. Accordingly, adjustment of the relevant existing standards has not been initiated, and no new standards for nanoproducts have been developed. Essentially, there is also still the question of how voluntary standards could offer sufficient security for nanoproducts (Frater et al., 2006). This is especially true because the private standards organisations have a certain way of interpreting these standards, and an orientation based more on the state of the art than the height of the level of protection (Goebelbecker et al., 2014; SRU, 2004).

In addition to the vertical (product-specific) product safety legislation mentioned below, the EU also has horizontal (hazard-specific) product safety regulations. Central to this is the general product safety regulation that includes different products, any one of which may be hazardous.

It basically applies to products for which no separate legal framework is provided. However, an extension to risks arising from nanoproducts is not currently being negotiated (Eisenberger et al., 2010). Therefore, to ensure the health and safety of products, the ProdSG takes a unique path. The guarantee of safety and health is left primarily as the responsibility of product manufacturers who comply with prescribed safety targets and are in this case guided by standards. Additional intervention options for authorities other than the obligation to register, restrict and prohibit the use of certain substances are not provided (SRU, 2011). This is particularly problematic for the reason that the standards are not yet adapted to nanospecific characteristics and specialities and that there are no standards for dealing with nanoproducts. Therefore, liability can be assumed until a comprehensive review and adjustment has been made.

Since the ProdSG also aims only at the prevention of threats (Klindt, 2007), there is a deficit of coverage, so that preventive-oriented handling of nanomaterials through the instruments of ProdSG cannot be guaranteed. Also, in the context of market surveillance, these deficits cannot be compensated for (SRU, 2011). In addition to the standard problems for nanoproducts, there exists the effect of presumption of CE marking, which makes it difficult for the authorities to take action regarding market surveillance. Consumer information is ensured by information obligations and also partly by the safety signs. However, there is no obligation to declare nanoscale components and no requirement to provide specific information to the user on the use of nanomaterials. In the absence of a nanoproduct register, such information is strikingly absent for consumers. The dissemination of information in the supply chain through the instrument of the existing traceability and labelling requirements is in this regard currently insufficient in relation to nanomaterials, because information about nanoscale ingredients does not need to be given. A preventive-oriented handling of nanomaterials cannot be assured (SRU, 2011).

To conclude, the instruments of liability law and the ProdSG are not enough to ensure a state-controlled precaution-oriented handling of nanomaterials. These deficits are not compensated for by the fact that the instruments of chemicals law may also partly apply to nanoproducts. Therefore, a basis for authorisation should be made in order to allow public policies to express an abstract concern for individual products, certain product groups or categories of use that are possible or already in existence. What measures are appropriate should be determined in detail on the basis of scientific criteria developed for a preliminary risk assessment and using a scientifically developed model for identifying appropriate state precautionary measures. Those provision-oriented measures can be taken on this basis by the authorities. However, they should not lead to the idea that product liability and the new approach for nanomaterials no longer apply; rather, they should complement each other (SRU, 2011).

Finally, for nanospecific standards, the new concept of standardisation makes an important contribution to ensuring safe products. Even if the approach for ensuring precautionary-based handling of nanomaterials has systemic gaps that cannot be closed, the European Commission should ensure that the standardisation bodies deal comprehensively with any existing features of nanomaterials. The existing standards should then be adjusted for nanoproducts, or specific new standards should be developed (SRU, 2011).

The rules for the liability for nanoproducts are especially important in areas where the safety of substances and products is not assured by admission procedures. Here, liability can be facilitated by a breach of generally accepted standards for the responsible use of nanomaterials. In establishing liability, causality comes into account, as well as a presumption of fault, given that the use of the product was detected. This would facilitate liability and would create an incentive for producers to implement their product responsibility (SRU, 2011).

If the safety of the environment or health is concerned, individual products, certain product groups and categories of uses should, if there is an abstract concern, be restricted, listed or licensed as necessary. There are causes for concern, for example, in the use of nanomaterials in consumer sprays, for products containing silver nanoparticles, in the manufacture and processing of nanomaterials with fibre-like, persistent structures and in the open use of nanoscale iron oxide (SRU, 2011). To protect the environment, the use of nanoscale silver in textiles should be made subject to authorisation. An authorisation may, for instance, be granted if the fabrics are designed for people with skin diseases or for use in hospitals (BUND, 2010).

In a wide range of product legislation, no official post-market surveillance takes place. Here it is particularly important to strengthen the role of the supervisory authorities. The problems here are in two areas. Firstly, the monitoring is based mainly on plant inspections and analysis of products. Since the analysis of nanomaterials is not yet very well developed, the monitoring must largely rely on operational controls. In this respect, however, it is problematic that the authorities have insufficient information on the use of nanomaterials in products. As a consequence, the supervisory authorities may take action only if the hazard is obviously present (SRU, 2011).

Further, to facilitate a nanoproduct register, which would provide an overview of the nanoproducts available on the market, and to intervene with targeted nanoproducts, the introduction of a reporting requirement for products containing nanomaterials is specifically recommended. This should result in a partial public product register (European Parliament, 2009). Such a product register should be located at EU level in order to increase its geographical reach and ensure that the negative effect on trade is as low as possible (SRU, 2011).

The regulation of products containing nanomaterials should consider traceability as key. However, an overlap between other reporting requirements and the traceability system should be avoided. Nanomaterials should, for precautionary reasons, be more widely defined within the scope of the reporting requirement. With respect to particle size, nanomaterials in a range up to 300 nm should be included, and agglomerates and aggregates of the primary particles should be covered with no size limit (Herrmann et al., 2010).

For the identification of nanoscale ingredients in the areas where, according to the current legal situation, the ingredients must be stated anyway, the label should have an addendum⁷⁸ referring to the nanoscale ingredients. In addition, the label should identify the nanoscale ingredients and their relevant effects (e.g. antibacterial effects) as well as stating which nanoscale ingredients are released. If certain risks are connected to the use of nanomaterials, consumers should be alerted to this, stating the instructions for use (SRU, 2011).

Finally, for information on the effects and risk profile, simple labelling of nanoscale ingredients is criticised because consumers might not be able to do an assessment of the risks associated with the nanomaterial; this is due to the fact that the potential risks depend on various factors (e.g. size or surface treatment) that cannot be mapped in an easy way. Therefore, further voluntary, useful product and material information should be offered. Manufacturers and dealers should actively participate in the provision of such information (SRU, 2011).

D.2.02 Chemicals legislation

Those placing nanomaterials on the market have to comply with the provisions of chemicals law, as long as chemicals law is applicable to the particular case. The following comments define ‘primary chemicals law’ as, for example, Art. 7, 9 and 9a of the German Chemicals Act,⁷⁹ which, by means of special mechanisms (for instance, specific testing specifications),⁸⁰ aim to systematically identify substance-related risks, with the possibility of regulating special stronger substances within the Chemicals Prohibition Ordinance.⁸¹

⁷⁸ An addendum is an addition required to be made to a document by its author subsequent to its publication.

⁷⁹ Chemicals Act (*Chemikaliengesetz – ChemG* (Act for Protection against Hazardous Substances) *Gesetz zum Schutz vor gefährlichen Stoffen*) of 28 August 2013 (Federal Law Gazette I p. 3498, 3991) last amended by Art. 431 of the Directive of 31 August 2015 (Federal Law Gazette I p. 1474).

⁸⁰ The quoted standards of the German Chemicals Act result from implementation of Art. 7 para. 1 in connection with Annex VII and VIII of the former Directive 67/548/EEC.

⁸¹ Chemicals Prohibition Ordinance (*Chemikalien-Verbotsverordnung – ChemVerbotsV* (Regulation on bans and restrictions on the marketing of dangerous substances, preparations and articles under the Chemicals Act) *Verordnung über Verbote und Beschränkungen des Inverkehrbringens gefährlicher Stoffe, Zubereitungen und Erzeugnisse nach dem Chemikaliengesetz*) of 13 June 2003 (Federal Law Gazette I p. 867) last amended 24 February 2012 (Federal Law Gazette I p. 212).

The reason for this is the intention of the legislator to register substances at an early stage, directly after production (Rehbinder et al., 1985). This includes information specifications for identifying and – through appropriate action – preventing dangers in subsequent individual use (Art. 8 GefStoffV) and controlling risks. Specifications in REACH will have to be observed as well as related legislation.^{82, 83, 84, 85, 86, 87}

Registration as a new substance is a possibility (CLP Regulation (EC) No 1272/2008; former Directive 67/548/EEC). As opposed to this, existing substances were dealt with in Regulation 793/93/EEC⁸⁸ (now REACH). Whether a substance in the nanoform falls under the legal regime for existing or new substances depends on whether the that substance is listed in the EINECS register.⁸⁹ According to the latest formulation in the Manual of Decisions⁹⁰ ‘substances in nanoform that are in EINECS (e.g. titanium dioxide) shall be regarded as existing substances’. One substance that would have to be treated as an existing substance is carbon, which is listed in EINECS as ‘Symbol C, CAS-No. 7440-44-0, EINECS No. 231-153-3’, even when manufactured or marketed in the nanoform (nano powder).⁹¹ Substances belonging to the carbon nanotubes include synthetic graphite, having the layered structure characteristic of the existing substance graphite (CAS 7782-42-5), and accordingly have to be treated as the existing substance (Kitzinger, 2006). This is in contrast to, for example, substances not in EINECS, such as carbon allotropes or fullerenes such as C-60 or C-70 compounds (European Commission, 1999).

⁸² 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 (fourteenth individual Directive within the meaning of the Art. 16 para. 1 of Directive 89/391/EEC (OJ L 131, 5.5.1998, p. 11–23).

⁸³ Directive 2004/9/EC of the European Parliament and of the Council of 11 February 2004 on the inspection and verification of good laboratory practice (GLP) (OJ L 50, 20.2.2004, p. 28–43).

⁸⁴ Directive 2004/10/EC of the European Parliament and of the Council of 11 February 2004 on the harmonisation of laws, regulations and administrative provisions relating to the application of the principles of good laboratory practice and the verification of their applications for tests on chemical substances (OJ L 50, 20.2.2004, p. 44–59).

⁸⁵ Now Regulation (EC) No 1272/2008.

⁸⁶ Former Directive 1999/45/EC of the European Parliament and of the Council of 31 May 1999 concerning the approximation of the laws, regulations and administrative provisions of the Member States relating to the classification, packaging and labelling of dangerous preparations (OJ L 200, 30.7.1999, p. 1–68).

⁸⁷ Former Directive 67/548/EEC.

⁸⁸ Regulation 793/93/EEC of 23 March 1993 on the evaluation and control of the environmental risks of existing chemical substances (OJ L 84, 5.4.1993, p. 1–75), repealed on 18.12.2006 (Federal Gazette L 396 p. 1).

⁸⁹ The existence of a substance in this register results, in accordance with Article 2 (e) of the regulation on existing substances, in its treatment as an existing substance, non-existence in the register to its treatment as a new substance.

⁹⁰ Manual of Decisions for implementation of the 6th and 7th amendments to Directive 67/548/EEC of 3.7.2006, (EUR 22311, Section 5.1.3, p. 64). ‘Substances in nanoform which are in EINECS (e. g. titanium dioxide) shall be regarded as existing substances. Substances in a nanoform which are not in EINECS (e.g. carbon allotropes other than those listed in EINECS) shall be regarded as new substances’.

⁹¹ For instance, by Sigma-Aldrich under the designation, catalogue number 633100, ‘Carbon nanopowder: Amorphous materials formed by laser techniques’; source: www.sigma-aldrich.com, 4.6.2006.

In the following section, current demands on both variants are explained and substance-specific information relevant to the assessment of risk is then described using the example of specific substances that would have to be notified by manufacturers under both legal regimes (Führ et al., 2007b). However, the legal characterisation of nanomaterials is controversial (Führ et al., 2006b) as they can be enrolled – as shown – as a new substance (Directive 67/548/EEC⁹²) or fall under the Existing Substances Regulation No 793/93. The question is whether nanomaterials constitute a separate ‘material’ in the legal sense. Nanomaterials have special properties because of their small particle size and thus – in this aspect – occur exclusively. Information should be available on substances that are already produced specifically and exclusively in this particular particle size (for example, carbon nanotubes (CNTs) and fullerenes) and how much and where they are used, in the context of recent research.

From the material legal point of view, it should be made clear that nanomaterials represent a new form, equipped with new functionality, that is different to the non-nanoscale form, even if they are of the same appearance and represent identical fabric from the chemical and molecular structural view of the materials. Cases of this kind are characterised by a substance having been used in non-nano format for some time, with its appearance in nanoscale being realised and brought into commercial use only recently. Such new applications of an already long familiar substance are likely; for example, substance law mechanisms already provide for titanium dioxide (TiO₂) in the order of 60 nm in sunscreens.⁹³ For the latter variant, materials law must present measures with which the possible different manifestations of a substance and resulting different risks (as in the case of titanium dioxide) can be handled adequately (Führ, 2009).

The above-mentioned assignment of substances in the nanoform to existing and new substances is based on information also contained in the Manual of Decisions (European Commission, 1999). This assumes that the occurrence of a chemical in the nanoscale form is not enough for it to be considered to be a new substance because, irrespective of the particle size, a single substance is involved (for example, titanium dioxide in both the nanoscale form and another form is to be treated as an existing substance). This does not correspond with the definition of a substance in prevailing chemicals law (Kitzinger, 2006).

Substances are initially distinguished with regard to their natural occurrence as elements or molecules, and then as substances that are manufactured (Kitzinger, 2006). The regulatory object of prevailing chemicals law is ‘the substance’.

⁹² Council Directive 67/548/EEC of 27 June 1967 on the approximation of laws, regulations and administrative provisions relating the classification, packaging and labelling of dangerous substances (OJ 196, 16.8.1967, p. 1–98).

⁹³ TiO₂ particles of this size are UV absorbers (e.g. Nohynek 2006, Eusolex®; Tinosorb or TEGO SUN Z 500/800).

A substance is defined in Art. 3 para. 1 of the German Chemicals Act and in Art. 2 para. 1a of Directive 67/548/EEC as a ‘chemical element or substance in the natural state or obtained by any manufacturing process, including any additive necessary to preserve its stability and any impurity deriving from the process used, but excluding any solvent, which may be separated without affecting the stability of the substance or changing its composition’.

This leads to the question of whether the occurrence of an individual substance in the nanoscale form independently satisfies the definition of a substance, because this is not to be found in the definition itself. Beyond the criteria mentioned in the above definition, substances have always been distinguished primarily based on their chemical and physical properties, which are characteristic and invariable for a substance (Rehbinder et al., 1985). This means that if different properties can be observed then different substances are involved. Until now, it was generally assumed that the properties of a substance are independent of the size and form.

On the basis of this assumption, it was irrelevant for the definition of a substance whether a chemical existed in the nanoscale configuration or in some other form. However, as soon as different manifestations involve special properties (as in the example of titanium dioxide with the property of ecotoxicology, which was observed at the nanoscale but in no other manifestation), from the point of view of chemical law two different substances must exist because their different risks call for appropriately varied treatment (SRU, 2011).

For the legal treatment of nanomaterials, a systematic evaluation of the risks for human health and the environment emanating from these substances is only demanded when certain quantitative thresholds have been reached. This is the case both under existing and new substance law. Even though this threshold is much lower in new substance law (10 kilograms) than in existing-substance law (1000 kilograms), it is questionable whether this standard is adequate, because of the very small volume placed on the market and being produced (limits are based on production volumes). Here, the introduction of nanospecific quantitative thresholds need to be considered (SRU, 2011) – see the comments on regulative options within the scope of REACH in the following section.

Furthermore, the criteria according to which a substance is assigned to the existing-substance or new-substance regime need to be clarified⁹⁴ (Führ et al., 2007b).

⁹⁴ Examples nanopowder and carbon-nanotubes: A to be treated as an existing substance is carbon, listed in EINECS as symbols C, CAS-No. 7440-44-0, EINECS 231-153-3. If this substance would now be produced/ distributed in the nanoscale, for example, the so-called nanopowder, it would not be treated as new substance. In contrast, for example, those produced nanoscale carbon compounds that are not listed in EINECS, such as fullerenes as C-60 or C-70 compounds. Opposing (Kitzinger, 2006): carbon nanotubes are synthetic graphites and have the graphite (CAS 7782-42-5) characteristic layered structure; assigned to the existing substance graphite.

D.2.03 REACH

Since 2007, chemicals in Europe have been subject to the EU Regulation REACH,⁹⁵ which is directly applicable in the EU member states according to Art. 2 TFEU (Rehbinder, 2007). This framework regulation involves the manufacture, marketing and use of substances in preparations and articles. In accordance with the precautionary principle, it is intended to ensure that only substances that do not adversely affect human health or the environment are manufactured, marketed, imported or used (Ingerowski, 2009). In the scope of REACH, the risks of manufactured and marketed substances are primarily to be determined – following the Test Method Regulation (TMR)⁹⁶ – by manufacturers or importers and processors. In addition, the industry is required to provide the user with a safe means of disposal of the substance (by classification and labelling systems as well as safety data sheets (Köck, 2009)).

Essentially, all substances, preparations and products that are manufactured and marketed in volumes above one tonne per year are subject to registration. Existing substances are included in the directory and, according to Art. 3 para. 20 REACH, are listed separately to so-called phase-in substances, which undergo a transitional period in the registry; these substances must be registered by 2018. For all other substances, for which no exceptions have been established, the registration requirements have existed since 2008 (SRU, 2011).

Registration under REACH allows the creation and collection of risk information. However, for the registration of a substance, neither its shape nor size is of relevance. This means that the nanoforms of substances are not considered separately (Kayser, 2009); nevertheless, it is not ensured that for their registration all relevant information requirements are passed on. Consequently, a majority of the substances in question (e.g. nanosilver) do not need to be registered independently (SRU, 2011).

However, when a substance that has been registered in its macroscopic form then needs to be manufactured in nanoform, the corresponding information in the directory for registered substances must be updated (European Commission, 2008c).

⁹⁵ Regulation (EC) No 1907/2006 of the European Parliament and of the Council of 18 December 2006 concerning the Registration, Evaluation, Authorisation and Restriction of Chemicals (REACH), establishing a European Chemicals Agency amending Directive 1999/45/EC and repealing Council Regulation (EEC) No. 793/93 and Commission Regulation (EC) No. 1488/94 as well as Council Directive 76/769/EEC and Commission Directives 91/155/EEC, 93/67/EEC, 93/105/EC and 2000/21/EC (OJ L 396, 30.12.2006, p. 1–849) last amended by Regulation (EC) No. 1272/2008 of the European Parliament and of the Council of 16 December 2008 on classification, labelling and packaging of substances and mixtures, amending and repealing Directives 67/548/EEC and 1999/45/EC last amended of the Directive of 29 May 2007 (OJ L 136 p. 3–280).

⁹⁶ Council Regulation (EC) No 440/2008 of 30 May 2008 laying down test methods pursuant to Regulation EC No 1907/2006 of the European Parliament and of the Council on the Registration, Evaluation, Authorisation and Restriction of Chemicals REACH (OJ L 142, 31.5.2008, p. 1–739).

As a result, it can be stated that REACH contains a number of positive elements for a preventive risk decision process (Bowman et al., 2007; Rucireto, 2011; Rudén et al., 2010). However, the REACH Regulation is, as an approach, largely preventive-oriented and transparent with regard to the regulation of chemicals – and thus also of nanomaterials (SRU, 2011).

The REACH Regulation states, for example, that a great deal of process information is published on the Internet. In addition, REACH gives consumers new rights to information (material databases, information rights against ECHA and merchants) and has institutionalised the participation of the relevant European and national stakeholders, as well as external stakeholders, in key decision-making procedures. Transparency, however, is limited by the fact that information is not processed in a consumer-friendly way and is published only partially in order to safeguard confidential business information (Ingerowski, 2009).

However, with the principle ‘no data, no market’ (Art. 5 REACH), there will be a significant shift in the burden of proof back to the material manufacturer. However, this does not take place in the main substantive REACH instruments – the restriction and the authorisation requirement – rather, the authorities still carry the burden of proof regarding the dangerousness of a substance. Above all, however, the appropriate criteria (‘unacceptable risk’ for restrictions and ‘very high concern’ or ‘probable serious effects’ from the permit requirement) are structured in such a way that scientific evidence for a specific risk (in the legal sense) is required; an abstract concern within the meaning of the precautionary principle is not enough (SRU, 2011). Overall, REACH is therefore heavily based on the scientific evaluation of known risks and offers little in the way of a starting point for the regulation of substances for which hazards are merely possible, but not proven. This is not just a nanospecific problem but applies to all chemicals. However, due to the uncertainty around nanomaterials, it has special relevance to them (Führ et al., 2007a).

Matters relating to the risks posed by nanomaterials (authorisation, restriction, classification) are decided not only in specific regulatory instruments but also in upstream, more opaque decisions. It is critical to assess whether a nanomaterial is registered separately or within the macro substance, and this decision is often taken without specific instructions and largely autonomously from manufacturers. A lack of commitment to submitting a separate file for nanomaterials gives manufacturers the ability to sometimes partly circumvent the disclosure requirements. The dossier evaluation of nanomaterials and their possible inclusion in the action plan are areas in which there are large margins not yet adequately constrained by criteria (SRU, 2011).

A trade-off between benefit and risk only takes place in the approval process and so possible restrictions will only be made for substances that have been found to be of specific concern by the risk assessment (SRU, 2011).

REACH, therefore, does not constitute an instrument that allows a risk/benefit assessment for substances and applications that cannot yet be fully assessed, which applies to nanomaterials. Since such a balancing exercise regarding specific uses is beneficial only in relation, however, it is also questionable whether this can be done by REACH, with its comparatively limited information about products and uses (SRU, 2011). It is necessary to amend the REACH Regulation and the ECHA Guidance documents to include nanospecific provisions and information requirements. A key part of this will be amending the regulation to include a definition of nanomaterials. For substances on the nanoscale, the requirements relating to provision of information under REACH should be expanded to include nanospecific information.

Requirements concerning the data to be provided when registering substances under REACH are tied to the annual volume of a substance manufactured or imported by the registrant. In the case of nanomaterials, even the use of the smallest amounts can give reason for concern. For this reason, the volume (tonnage) threshold concept currently in use must be adapted if it is to be applied to nanomaterials. Nanospecific chemical safety assessment and the production of a chemical safety report should therefore be compulsory at a lower volume threshold than 10 tonnes per year. Scientists and organisations have called for the volume threshold to be set at less than one tonne per year (Working Group 3 of the NanoKommission, 2010).

The conditions set out in Art. 39 REACH on the application of downstream user obligations in accordance with Art. 37 and 38 REACH mean that in cases where the bulk material does not have to be classified as hazardous, but the nanomaterial might possess hazardous properties within the meaning of the CLP Regulation, these obligations do not apply. Even where downstream users have an obligation to produce an MSDS, there is an additional deficiency in that there are no standard requirements regarding the data to be provided. As information on the bulk form of a substance is not necessarily transferable to the nanomaterial, the need to require separate data is all the greater. Overall, in cases where the downstream user produces a nanomaterial from the bulk material and is not considered the manufacturer, the information required under Art. 37 and 38 REACH is less extensive than that required for registration.

Also, the long transitional deadlines for registration of phase-in substances laid down in Art. 23 REACH should not apply to substances on the nanoscale. This would not be compatible with the precautionary principle. In order to ensure continuity of manufacturing, importation and marketing, however, a deadline should be set by which all substances in the nanoscale already on the market must be registered. In principle, REACH allows for the regulation of substances and therefore also of nanomaterials (Working Group 3 of the NanoKommission, 2010).

The requirements of registering and updating the legal framework for self-responsible risk identification by the industry as a requirement of REACH's substance evaluation (ECHA, 2007) also aim to provide authorities with the power to conduct their own risk assessment, whereby they may require the submission of additional information and data by the industry. To minimise the risks posed by substances (in the legal sense), the instruments of approval of title and restriction serve both the registration and the restriction. When focusing on the handling of substances, their regulation in other areas – such as in environmental law and partly also in the product law – cannot be adequately provided for. When passing on information used in addition to the information requirements – in particular the obligation to prepare and disclose safety data sheets – labelling requirements according to the CLP Regulation should be included. As such, the instruments for a precaution-oriented handling of nanomaterials are present (SRU, 2011).

The exact analysis shows, however, that such instruments are not currently provided because of the aforementioned REACH deficits. Nanospecific regulatory gaps are found predominantly in the context of registration, such as the exclusion of the effects of nanomaterials, which are not treated as separate substances despite their improved properties, although there are some exceptions. Further, for nanomaterials, no registration dossier must be submitted and the data to be provided does not have to refer to the nano-properties. In addition, the data requirements and the test methods used to determine them are not sufficiently fitting to the specifics of nanomaterials, meaning that their special qualities are not identified and registered (SRU, 2011).

Added to that is the problem of the threshold amount within the registry. Nanomaterials usually have a higher reactivity per unit mass than conventional materials, but do not have to be registered, despite their lower mass, until they reach the same volume thresholds. Here, quantity thresholds are crucial not only for the scope of the requested data but also for the question of whether a Chemical Safety Report is included in the registration dossier. Thus, they have vast influence on the content of the registration dossier. These nanospecific regulatory gaps mean the registry cannot guarantee an adequate risk assessment. It is problematic that the loopholes in the registration process affect all other stages of the process within REACH (SRU, 2011).

Where the base is missing, other instruments cannot build upon. Deficits are found where obligations of the industry or interventions by the authorities on dangerous properties or PBT and vPvB (Annex XIII REACH) characteristics of substances exist. This is problematic because the findings still do not permit definitive conclusions about the presence of these properties, and an abstract concern has no corresponding classification. This affects the obligation of the registrants to prepare a chemical safety report that only needs to include an exposure assessment and risk characterisation if a dangerous or a PBT or vPvB substance is present (SRU, 2011).

Under similar conditions, a material is initially included in the candidate list (Art. 59 para. 10) and later in Annex XIV of REACH and is thus subject to approval. This has implications for the extent of regulatory risk management, as this can only be enforced when there is a present danger. In addition, the authority carries the burden of proof for the nanospecific regulatory gaps in registration. As long as there is no defined necessity that data are generated, the authorities themselves need to demonstrate that a nanomaterial is dangerous or has the properties of PBT or vPvB. This does not conform to the precautionary principle and its immanent presumption of dangerousness. A preventive-oriented risk management of nanomaterials therefore cannot be assured, and the deficits have an impact not only on risk management but also on the communication of risk, particularly within the supply chain (Führ et al., 2006b).

Material safety data sheets are currently created and passed on through the supply chain only for substances with hazardous properties or PBT and vPvB. In regard to the content of MSDS, the nanospecific regulatory gaps during the registration process have the impact that if the relevant information is not identified in the registry it cannot be included in the MSDS. As a result, neither nanospecific regulatory gaps nor deficits can be identified in the design of instruments, which reinforces their effects on a precaution-oriented handling of nanomaterials (SRU, 2011).

As nanomaterials present special problems (e.g. high reactivity and mobility due to small size) that could not be sufficiently addressed by equality with macro-scale materials, there are also independent starting points in the REACH Regulation to ensure that nanomaterials are considered as separate substances to their macro-scale counterparts and thus subject to REACH instruments. These may also be focal points for special obligations, as some parties propose the inclusion of a suitable definition of nanomaterials in Art. 3. The definition should clarify the term ‘nanomaterials’, which should be treated within the scope of REACH principles as independent substances (legal fiction), unless otherwise arranged (SRU, 2011).

Principally, it is necessary that the definition be based on simple parameters and broad precautionary reasons with regard to the size limit. The size specification limit below which particles must fall should be determined. The 1% threshold proposed by the European Commission could be adopted based on the number of particles (European Commission, 2010). Moreover, the use of clear criteria on which substances the definition is not intended to refer to (e.g. agglomerates and aggregates) needs to be included. However, nanomaterials are not always subject to the same definition requirements. The focus of the risk assessment is currently on nanomaterials in the size range up to 100 nm. However, for precautionary reasons, larger materials (up to 300 nm) can also justifiably be observed.

Taking into account that nanomaterials of the same chemical composition can, as a function of size and surface treatment, have different characteristics, it is actually necessary to differentiate further. However, when no individual case can practically be made, analogy should be possible. For this purpose, it may be necessary to divide nanomaterials into different groups. This is to ensure that not only can nanomaterials be considered independently from their macro-scale counterparts but they can also be differentiated from each other (Hansen, 2009).

Nanomaterials that belong to a group could be treated as separate substances unless otherwise arranged. Moreover, a clause should be included that allows the definition to be adapted to current technical and scientific developments. In addition to its own file containing the default data, the registration should also include an advanced base data set. This would include a simplified basic data set goal for the special preliminary risk assessment according to the criteria that allow characterisation and exposure assessment (SRU, 2011).

In order to ensure that manufacturers know how to care for nanomaterials, relevant information can be passed on to the ECHA, where the registration requirement must be adjusted. In this regard, it must be explicitly included in the text of the regulation that nanomaterials should be registered regardless of macro-scale counterparts with their own dossier (Pronk et al., 2009).

This is justified because nanomaterials may have altered properties and therefore could be hazardous; the precautionary principle dictates a separate risk assessment. Also, for reasons of transparency, independent registration appears to be justified. In addition, it must also be ensured that the conditions applicable to phase-in substances do not apply to transitional periods and are formulated with a number of exceptions for nanomaterials. This is accomplished when nanomaterials are treated as separate substances under REACH; however, an explicit arrangement in the regulation text is required (Pronk et al., 2009; RCEP, 2008).

For industrially manufactured nanomaterials, ECHA should hold the simplified basic data that is available, independent of any quantity thresholds. This is intended to ensure that, for nanomaterials bigger than 100 nm, at least the physico-chemical data are presented for characterisation. If information should be obtained on the use of the material, the acquisition of additional data according to the type of use (e.g. consumer-oriented uses) should be required. An extended basic data set could also be provided by the manufacturer and should include references to the specific characteristics of nanomaterials. It would, for example, provide information about the size distribution, solubility, bio-persistence, toxicokinetics, and acute and chronic toxicity of nanomaterials (Pronk et al., 2009). The goal of the basic data set is to expand the knowledge base on nanomaterials as soon as possible (European Parliament, 2009).

In addition, the findings from the extended basic data set should put the registrant in the position of being able to carry out a preliminary risk assessment. For the exposure and risk assessment, the comprehensive chemical safety assessment needs to be performed for all nanomaterials that give rise to an abstract concern in conjunction with the meaning of Art. 14 para. 4 of Annex I of the REACH Regulation. Therefore, it is recommended that a preliminary risk assessment on the basis of the developed material-related criteria be required. The registrant of the nanomaterials should perform a comprehensive chemical safety assessment and submit a chemical safety report to ECHA (European Parliament, 2009; Pronk et al., 2009; Scherzberg, 2010). Principally, no nanomaterials should – without product registration – be placed on the market without exposure assessment (European Parliament, 2009).

In particular, long-term effects may show up in some cases if substances have already been used. For the purpose of continuous risk assessment, in addition to registration, the updating requirement should therefore also be strengthened in terms of market monitoring obligations. The registrant should be required to obtain and evaluate additional information and data, not only because of new scientific knowledge but also due to observation of the market. This requires good communication in the supply chain, not only from manufacturer to dealer but also in the opposite direction (SRU, 2011).

The Working Group has identified the following deficiencies, listed here as a final overview and conclusion of this chapter (Working Group 3 of the NanoKommission, 2010):

- ∞ When registering a substance, there is currently no explicit requirement to carry out nanospecific tests or provide data on whether a substance is on the nanoscale. Indeed, the provisions appear inadequate in terms of ensuring consistent identification of nanoscale substances and their uses. To rectify this, the meaning of nanomaterials under REACH should first of all be defined (Führ, 2009).
- ∞ Test procedures need to be clarified in more detail at OECD level with a view to meeting the requirements on provision of information and complying with risk identification procedures.
- ∞ There is currently no evidence base for assessing whether or not the data on nanomaterials in registration dossiers already submitted are meaningful. It is also unclear how substances in the nanoscale are covered in the registration of the bulk form of materials and what nanospecific data are being submitted in this regard (Hansen, 2009).
- ∞ Moreover, in the case of nanomaterials, it is possible to take advantage of transitional registration deadlines for phase-in substances, despite the fact that in some instances these may be new forms of a substance about which, in contrast to the bulk form, no empirical knowledge exists. This presents problems in terms of the precautionary principle.

- ∞ If the nanoscale form of a substance is not deemed to be a different substance from its bulk counterpart, consideration needs to be given to how to deal with situations where a downstream user produces a nanoform of the material from the bulk material, but the manufacturer of the bulk material has not included the nanoform in his registration dossier. One possibility might be to amend the provisions limiting the obligations of downstream users compared to those of registrants set out in Art. 37 ff. in conjunction with Annex VII of REACH in the case of nanomaterials (Working Group 3 of the NanoKommission, 2010).
- ∞ The tonnage bands under REACH should also be reviewed; these currently provide for a general registration obligation (for volumes of more than 1 tonne per registrant per year) but also set out specific requirements for data provision in each band (Führ et al., 2006a).
- ∞ The limit of 0.1 per cent by weight for ‘substances in articles’ appears inappropriate as nanomaterials can exert specific effects at even smaller concentrations (Führ et al., 2006b).
- ∞ As a matter of principle, Annexes IV and V (Exemptions from the obligation to register) should not include substances in the nanoform.⁹⁷

D.2.04 Classification, Labelling and Packaging (CLP Regulation)

The CLP Regulation⁹⁸ (Classification, Labelling and Packaging of Substances) applies, according to Art. 1 of the regulation, to the classification, labelling, and packaging of substances, mixtures and certain specific articles, and thus, in principle, also to nanomaterials (European Commission, 2009d). However, cosmetic products, foods and food additives, which are intended for consumption in the form of finished products, are excluded from the scope. In addition, waste is also not considered a substance, mixture or article (SRU, 2011).

The CLP Regulation complements the REACH system in the control of substances. The classification, labelling, packaging and reporting of hazardous substances and mixtures does not explicitly address nanomaterials under the regulation; however, the therein-regulated obligations still apply for them in general. This is because substances in all the probable forms in which they are marketed and used must be reviewed, evaluated, and thus classified. Consequently, there is no lack of reference for nanomaterials, at least in the classification. What are missing are mainly some guidelines for the designation or labelling of nanomaterials. In addition, the obligations under the CLP Regulation largely fail due to lack of information on health and environmental hazards, in particular of nanomaterials (Führ et al., 2007a).

⁹⁷ Carbon and graphite have already been removed from Annex IV because it can occur in nanoscale form.

⁹⁸ Regulation (EC) No 1272/2008 of the European Parliament and of the Council of 16 December 2008 on classification, labelling and packaging of substances and mixtures, amending and repealing Directives 67/548/EEC and 1999/45/EC, and amending Regulation (EC) No 1907/2006 (OJ L 353, 31.12.2008, 1–1355).

This is due to the fact that if nanospecific information is not already available, or will be determined during the registration under the REACH Regulation, there is according to the complementing CLP Regulation no comprehensive requirement for acquiring new information. Although available information must be collected, new tests must be carried out only in terms of physical hazards. To that extent, therefore, the deficits under the REACH Regulation transfer their ineffectiveness onto the CLP Regulation. For nanomaterials for which the CLP Regulation might have its own scope – i.e. those below the requirements for the REACH threshold quantity – similar problems exist with respect to the test methods and information requirements, and also with regard to the classification criteria, during the registration process. There is a lack of adaption to nanospecific characteristics. It should further be noted that the CLP Regulation contains no tools for dealing with the general lack of knowledge about specific risks, although the allocation to the various categories contain some elements to control hazards (e.g. safety margin and the classification for concern). Principally, substance law, with its instruments, has good ways to deal with the risks posed by nanomaterials, while risk assessment is used primarily for the registration and updating requirement (SRU, 2011).

Classification, labelling and packaging in accordance with the CLP Regulation could be added in addition to substance-related risk management measures, authorisation and restriction according to the REACH Regulation. In detail, however, nanospecific problems and deficiencies in the implementation of the precautionary principle do exist, and a preventive-oriented handling of nanomaterials in substances legislation currently cannot be fully assured. However, since the instruments generally appear suitable to ensure a precaution-oriented regulation of nanomaterials, the introduction of instruments for special materials like nanomaterials through a separate law is not required (Führ et al., 2006a; RCEP, 2008).

The instrument of classification aims to assign materials based on an assessment of their properties, hazard classes and hazard categories. The importance of classification is that it is a trigger for special regulations, emission limits, prohibitions or other requirements, in particular in environmental law (Franco et al., 2007). Principally, it is the responsibility of the manufacturer, importer or downstream user to classify the substances and mixtures according to the danger they pose.⁹⁹ Certain substances, however, are subject to EU-wide harmonised classification.

The hazard category provides information about the potential danger, i.e. the strength of danger. Thus, for water hazardous substances, there are four possible categories, with the lowest not being a cause for concern (Annex I, Part 4 of the CLP Regulation).

⁹⁹ Substances that cause sensitisation by skin contact and CMRs.

These obligations also apply in principle to nanomaterials, as information and assessment of a substance have to relate to the form in which it is likely to be marketed and used (Art. 5 para. 1, Art. 8 para. 6 and Art. 9 para. 5 of the CLP Regulation); for the specific use of nanomaterials, in particular the role particle size plays, these requirements apply separately (European Commission, 2009d; ECHA, 2009).

Accordingly, the various physical forms of a substance may differ in their classification. However, the classification criteria themselves do not hold nanospecific characteristics. The hazardous properties of nanomaterials due to the lack of recognised test methods cannot currently be sufficiently established and evaluated. Also, there are problems insofar as the determination of health and environmental hazards are, according to the CLP Regulation, only based on available information on physical hazards. Classifications in this regard are therefore unlikely as long as the corresponding data has not been determined to fulfil the registration requirement in REACH. To this extent, in spite of the obligations under the CLP Regulation, the gaps in the registration cannot be closed. Rather, these gaps affect the CLP Regulation.

This is problematic, as many legal obligations both in substance law (e.g. REACH: creation of a chemical safety report, establishment of a registration of title, preparation and dissemination of the safety data sheet) and environmental law (e.g. limits under the Federal Immissions Control Act) build on the classification in the CLP Regulation. A further problem is that the classification is not suitable as a starting point for precautionary measures, although the assignment to the different risk categories can be regarded as precautionary elements (e.g. safety margin, or the classification for concern). The classification is not, however, an instrument for dealing with structural ignorance, as in the case of nanotechnologies (SRU, 2011).

The provisions for harmonised classification are subject to Art. 36 of the CLP Regulation, wherein substances can be considered (on the basis of human evidence or positive results from an appropriate animal test) as known or presumed to cause heritable genetic mutations, be carcinogenic or be toxic to reproduction; those substances for which there is at least a suspicion can also be included. Harmonised classification – regardless of the described hazardous characteristics – is possible, because the method under Art. 37 is relevant (SRU, 2011).

Thereafter, both the competent national authorities as well as manufacturers, importers and downstream users can submit a proposal for harmonised classification and labelling to the ECHA. For this proposal, a risk assessment position is noted; the parties concerned have the opportunity to give remarks. Following this, the ECHA sends the opinion and comments to the European Commission. Following its decision on harmonised classification and labelling, manufacturers, importers and users are then bound to this classification (SRU, 2011).

The labelling requirement under Art. 17 of the CLP Regulation is for information on the completed classification of substances or mixtures and the resulting consequences and contains, for example, identification of the substance, classification-relevant hazard pictograms, signal words, and the hazard and precautionary statements. For the identification of the substance, the name, the identification number, the CAS number and the defined name according to the nomenclature of the International Union of Pure and Applied Chemistry (IUPAC nomenclature) have to be used. If some nanomaterials are marked as hazardous in the future according to the CLP Regulation, they can be distinguished from their macro-scale counterparts according to current designation guidelines in most cases. Although fullerenes and carbon nanotubes have their own CAS number, for the majority of nanomaterials there is no corresponding solution. Therefore, one can see no reference to the nanoscale in the name, which has an effect on the labelling. Also, a nanospecific labelling requirement (such as a special note or pictogram) is not provided. Furthermore, a labelling requirement for risks due to large uncertainty in the knowledge of potential study endpoints is also not provided, accordingly, any messages due to still existing uncertainties in the risk assessment (SRU, 2011).

The packaging of dangerous substances or mixtures must meet certain requirements under Art. 35 of the CLP Regulation. Packaging must be such that its contents cannot escape and it should be able to withstand all stresses and strains normally encountered during handling. These requirements also apply to nanomaterials if they have been classified as dangerous (SRU, 2011).

According to Art. 40 of the CLP Regulation, manufacturers and importers are obliged to report hazardous substances and materials. The reporting requirement is not subject to the passing of quantity thresholds and specifically includes the identity of the applicant, the identity and classification of the substance as well as the labelling elements for the substance. In the case of the classification of a substance, it must also be specified whether it was made due to lacking, inconclusive, or conclusive but not sufficient information. This requirement exists in some, but not all, hazard classes because if substances are registered under the REACH Regulation, communication is thereby established so that the reporting requirement under the CLP Regulation ultimately applies only to hazardous substances produced in an amount of less than 1 tonne per year per manufacturer or importer. Therefore, a classification and labelling inventory has been created (Project of Emerging Nanotechnologies, 2007) in which the reported information is included on the basis of the information required under the CLP Regulation or the registration requirement notified under the REACH Regulation and maintains the ECHA pursuant to Art. 42 of the CLP Regulation. The information that is publicly available there is stipulated by Art. 119 of the REACH Regulation (SRU, 2011).

Additionally, hazardous substances in nanoform must – unless they are registered under the REACH Regulation – be reported to the ECHA. However, a reporting requirement should still be established on the definition of the substance and not on the marketed name. Otherwise, no differentiation between nanomaterials and their macro-scale counterparts can be made. It is therefore indistinguishable how, with the potentially different classifications of a substance as a function of particle size, it is to deal with the substance. It is also imprecise how the nanoscale is established by the classification and labelling inventory transparency, since only the identity of the substance – as it is determined in accordance with Annex VI Section 2 of the REACH Regulation – must be reported. Ultimately, therefore, there is a need for clarification regarding the notification procedure for dangerous substances in nanoform. Even though nanomaterials should actually be classified by competent persons, it cannot be assumed that transparency regarding nanomaterials and their harmfulness can be created by the reporting requirement of Art. 40 of the CLP Regulation (SRU, 2011).

D.2.05 Hazardous Substances Ordinance (GefStoffV)

The rules of the Hazardous Substances Ordinance¹⁰⁰ cannot compensate for the aforementioned deficits of the REACH and CLP Regulation. The reason for this is, firstly, that the regulation objective here is labour protection (Art. 1 GefStoffV) and – contrary to what the wording in Art. 1 para. 1 sent. 2 GefStoffV might suggest (‘to protect the environment from substance-related harm’) – it is only secondarily, and very selectively, concerned with environmental protection (LASI, 2005; Schäfer, 2005).

One example is Art. 8 para. 6 and 7 GefStoffV, which specifically refers to possible harm to the environment caused by the storage of hazardous substances.¹⁰¹ The Hazardous Substances Ordinance therefore covers the protection of the environment in part, as REACH also intends to do. However, it is not able to fill in the gaps because it is ‘derived substances law’; it lacks a systematic and comprehensive commitment within the meaning of ‘primary chemicals law’ and so doesn’t analyse nanomaterials in relation to dangers for humans or the environment (SRU, 2011). The Hazardous Substances Ordinance builds instead on the results of primary chemicals law and therefore contains no material-specific test programme (Führ, 2009).

¹⁰⁰ Hazardous Substances Ordinance (*Gefahrstoffverordnung – GefStoffV* (Ordinance on protection against hazardous substances) *Verordnung zum Schutz vor Gefahrstoffen*) of 26 November 2010 (Federal Law Gazette I p. 1622), last amended by Art. 2 of the Directive 3 February 2015 (Federal Law Gazette I p. 49).

¹⁰¹ See also the decision of the Federal amendment (under A1) on the revision of Art. 1 GefStoffV (German parliament printed matter 413/04, 1).

The persistence of the obligations under Art. 7 ff. GefStoffV to pass on information and assess risks accordingly, as mentioned, results from the power given by Art. 19 para. 1 sent. 1 of the Chemicals Act (measures for the protection of employees) and Art. 3, 5 ArbSchG.¹⁰² If data is not available or accessible through the duties of ‘derived substances legislation’, it doesn’t lead to protection in terms of occupational safety either (Führ, 2009).

Therefore, the resulting protection obligations exist for the benefit of employees (and employee-related persons) and thus represent only a small and also very specific portion of the population. Thus, they are not suitable for the regulatory situation because they do not have the comprehensiveness intended by the material law, according to Art. 1 of the Chemicals Act, to ensure that humans and the environment in general are protected against the harmful effects of dangerous substances, and (especially) to avert and prevent the occurrence of such substances (Führ et al., 2007a).

The requirements of Art. 5 GefStoffV (Classification and Labelling) and Art. 6 (MSDS) are based on authorisations following Art. 14 of the Chemicals Act, and thus – although not exclusively – concern the relationship between employers and employees, it also lacks, as well as the obligations imposed by Art. 7 ff., of a fundamental prerequisite to close the identified gaps. There is a lack of commitment in the original substance law to control substances in the nanoscale systematically and comprehensively with regard to possible outbound dangers for humans and the environment. The absence of this obligation cannot be compensated for on the basis of primary chemicals law. This is evident, for example, in the context of Art. 5 para. 1 sent. 4 GefStoffV, according to which the manufacturer or importer of a substance shall consider all of the hazardous properties in the classification, including:

- ∞ The results of the tests described in Art. 7, 9 and 9a of the Chemicals Act;
- ∞ Harmful findings by a body of scientific knowledge (Art. 4 of the GefStoffV);
- ∞ Findings obtained in an approval process.

The application of the provisions of the Hazardous Substances Ordinance therefore requires knowledge of the substance and material properties on a fact-based assignment to a category of danger, initially on the basis of the primary chemicals law – such as Art. 7, 9 and 9a of the Chemicals Act – or must be obtained or be available through a ‘body of scientific knowledge’ for this particular case (Führ et al., 2006a).

¹⁰² Occupational Health and Safety Act (*Arbeitsschutzgesetz – ArbSchG* (Act on the implementation of occupational safety measures for improving the safety and health of employees at work) *Gesetz über die Durchführung von Maßnahmen des Arbeitsschutzes zur Verbesserung der Sicherheit und des Gesundheitsschutzes der Beschäftigten bei der Arbeit*) of 7 August 1996 (Federal Law Gazette I p. 1246) last amended by Art. 427 of the Directive of 31 August 2015 (Federal Law Gazette I p. 1474).

At this point, returning to the beginning of this chapter, a distinction is drawn: the application of primary chemicals law ensures that the data that are necessary to initially implement the provisions of the Hazardous Substances Ordinance are obtained; they can then be referred to secondary or derived substances legislation (Führ et al., 2006a).

As already noted, systematic collection of the material properties of nanomaterials cannot currently be guaranteed by the existing original material law. The Hazardous Substances Ordinance compensates partially for the weaknesses of primary chemicals law through the independent duties and obligations it places on the employer; however, in addition to the data of the producer, other ‘readily accessible sources’ need to be used (Art. 7 para. 2), especially in the area of waste materials (Führ et al., 2006a).

Although the regulations with regard to classification and labelling (Art. 5), safety (Art. 6), and information gathering and risk assessment (Art. 7 ff.) are independent of quantity, they draw on the insights of primary substance law, which for its part contains quantity thresholds and does not specifically address materials on the nanoscale. The duties of the protective actions (Art. 7 ff.) are aimed at the ‘employer’ and are largely limited to the ‘assessment of working conditions’ and to ‘risks to the health and safety of workers.’ Adequate compensation with respect to the identified deficiencies in environmental law (particularly original substance law) is not provided.

The ascertainment of the properties of a substance in the nanoscale form and, in so far as dangerous properties are concerned, their transference into appropriate risk information and measures for the control of substance-related risks, is necessary. This protection would have to cover not only employees but all those who could be subject to their effects, as well as all environmental media. A more precise examination of the regulatory approach and individual provisions makes clear, however, that these functions are not covered (Führ et al., 2007b).

To sum up, the following can be stated: regulations with regard to classification and labelling (Art. 5 GefStoffV), safety data sheets (Art. 6), as well as the ascertainment of information and assessment of danger (Art. 7 ff.) apply irrespective of quantity. They fall back, however, on the insights of primary chemicals law, which recognises quantitative thresholds and does not so far address substances in the nanoscale form (Führ et al., 2007b).

Requirements with respect to protective measures (Art. 7 ff.) are directed at the employer and are largely restricted to the ‘assessment of working conditions’ or ‘dangers to the health and safety of employees’ (SRU, 2011). The Hazardous Substances Regulation does not contain a problem-adequate compensation effect with respect to the identified deficiencies in environmental law (in particular in original substances law) (Führ et al., 2007b).

D.2.06 Restriction of Hazardous Substances (RoHS Directive)

To address potential risks from certain hazardous substances repeatedly embedded in electrical and electronic equipment, the EU adopted Directive 2002/95/EC on the Restriction of the use of Hazardous Substances in electrical and electronic equipment¹⁰³ (RoHS), which is closely related to EU Directive 2012/19/EU on Waste Electrical and Electronic Equipment (WEEE)¹⁰⁴.

The RoHS Directive places restrictions on the use of certain hazardous substances, particularly heavy metals and certain flame retardants. This came into force on 1 July 2006; however, there have been a number of amendments proposed by the EU Parliament Committee on the environment, public health and food safety that particularly deal with nanomaterials. The recast published on 1 July 2011 includes notification procedures for the use of nanomaterials ('substances of very small size or with very small internal or surface structure'), together with a standard for the identification and detection of them, including harmonised labelling in EEE (electrical and electronic equipment). However, proposed restrictions of long multi-walled carbon nanotubes (MWCNTs) that are asbestos-like (Han et al., 2008), and nano silver, with the recommendation for immediate labelling and a possible ban in EEE, were not adopted (Nanotechnology Industries Association, 2013).

In Germany, the ElektroG¹⁰⁵ is used as a transposition of the RoHS Directive, as well as of the WEEE Directive, with the addition of the ElektroStoffV.¹⁰⁶ Beyond identification, collection, treatment and recycling obligations, the ElektroG formulates material bans. According to these, certain heavy metals and brominated flame retardants – following the RoHS Directive – in new electrical and electronic equipment may only be included up to a weight percentage of 0.1 and cadmium of 0.01 per homogeneous material (Art. 5). However, based on the RoHS and WEEE Directives, nanomaterials are not banned as hazardous, and there is no obligation to provide information for re-use or treatment, as the necessary data is missing (Frater et al., 2006).

¹⁰³ Directive 2002/95/EC of the European Parliament and of the Council of 18 December 2002 on the restriction of the use of certain hazardous substances in electrical and electronic equipment (OJ L 37, 13.2.2003, p. 24–39).

¹⁰⁴ Directive 2012/19/EU of the European Parliament and of the Council of 4 July 2012 on waste electrical and electronic equipment (WEEE) (OJ L 197, 24.7.2012, p. 38–71). Former: Directive 2002/96/EC of the European Parliament and of the Council on waste electrical and electronic equipment (WEEE) (OJ L 37, 13.2.2003, p. 24–39).

¹⁰⁵ German Electrical and Electronic Equipment Act (*Elektro- und Elektronikgesetz – ElektroG* (Act Governing the Sale, the Return and Environmentally Sound Disposal of Electrical and Electronic Equipment) *Gesetz über das Inverkehrbringen, die Rücknahme und die umweltverträgliche Entsorgung von Elektro- und Elektronikgeräten*) of 20 October 2015 (Federal Law Gazette I p. 1739), last amended by Art. 3 of the Directive of 20 October 2015 (Federal Law Gazette I p. 1739).

¹⁰⁶ EEE-Substances Ordinance (*Elektro- und Elektronikgeräte-Stoff-Verordnung – ElektroStoffV* (Regulation on the Restriction of Hazardous Substances in electrical and electronic equipment) *Verordnung zur Beschränkung der Verwendung gefährlicher Stoffe in Elektro- und Elektronikgeräten*) of 19 April 2013 (Federal Law Gazette I p. 1111), last amended by Art. 1 of the Directive of 28 November 2014 (Federal Law Gazette I p. 1888).

However, precisely because of the confusion on whether nanomaterials are safe for human health and the environment, it was proposed in the context of the revision of the RoHS Directive by the rapporteur of the Committee on the Environment, Public Health and Food Safety (ENVI) to introduce a labelling requirement if consumers may come into contact with nanomaterials and to ban nanosilver particles and carbon nanotubes (European Parliament, 2010a).

Although this proposal did not succeed, and nanomaterials need to be checked with a high priority, this shows the direction in which nanospecific regulation is moving in this area. With the possible risks to human health and the environment, the European Parliament has also established the proposed amendments as part of the revision of the WEEE Directive. The European Commission, however, is still evaluating whether selective treatment is needed for nanomaterials in electrical and electronic equipment (European Parliament, 2010a).

On 2 June 2010, the ENVI Committee issued a report voting for a ban on nanosilver and long MWCNT, and decided that other electrical and electronic material containing nanomaterials should be labelled, and also that the manufacturers should be obliged to provide safety data to the European Commission (Nanotechnology Industries Association, 2013).

This proposal was going to go to a full plenary vote in the EU Parliament and if passed would have led to a recast of the RoHS Directive with implications for the WEEE Directive; it was proposed to (Mantovani et al., 2010):

- ∞ ‘Provide a coherent framework to include all EEE;
- ∞ Restrict by 2014 hazardous substances and materials in EEE that cause serious concern throughout their life cycle (production, use, disposal) and hamper recyclability, such as halogenated organic substances, to a maximum of 0.1% (weight by weight);
- ∞ Restrict by 2014 the use of nanosilver to the detection limit in homogenous EEE parts;
- ∞ Ensure a specific methodology for future substance restrictions focusing on end of life considerations that are in line with the specific aims of the RoHS Directive’ (EEB, 2010).

This draft report also contained, and the ENVI Committee finally adopted, a proposed definition of nanomaterials. In addition, the ENVI Committee set out notification and labelling obligations requiring operators to ‘provide all relevant data with regard to their safety for human health and the environment over their life-cycle’ and to label EEEs that contain ‘nanomaterials that can lead to exposure of consumers’ (EEB, 2010). However, today, nanomaterials must still be addressed because of the scientific uncertainty these materials pose to human health, as well as environmental risks and the lack of internationally harmonised definitions or agreed test guidelines (Working Group 3 of the NanoKommission, 2010).

Further, there is increasing scientific evidence that certain types of carbon nanotubes have, under certain circumstances, inspired reactions similar to those of other durable fibres, including asbestos. Consequently, the ENVI expressed similar concerns regarding nanosilver particles that may be dispersed into the environment. The agreed text contains a reference to nanomaterials in one of the RoHS Recast recitals, as follows: ‘As soon as scientific information is available, and taking into account the precautionary principle, the restriction of other hazardous substances, including any substances of very small size or internal or surface structure (nanomaterials) which may be hazardous due to properties relating to their size or structure, and their substitution by more environmentally friendly alternatives which ensure at least the same level of protection of consumers should be examined’ (Nanotechnology Industries Association, 2013).

The EP considered the RoHS Recast in trilogues. The first was in September 2010. The second trilogue was convened on 7 October 2010. The third and final trilogue was on 8 November 2010. The Members of the EP dropped their request for a ban on nanosilver and carbon nanotubes, as well as for the notification and labelling of EEE that contain nanomaterials, which is no longer in the act (Nanotechnology Industries Association, 2013).

The agreed-upon version of the RoHS Recast imposed no specific obligations for companies placing EEEs containing nanomaterials into the EU market. Nevertheless, the discussions in the EP and the justifications for considering nanomaterials offer insights into the possible future EU regulation of nanomaterials. In this context, the ENVI Committee’s justification of the proposed ban of nanosilver and carbon nanotubes shows that nanosilver is already being used as an antimicrobial in EEE, e.g. as a coating for mobile phones, or even released by washing machines. Apart from such uses being redundant, they endanger human health and the environment. Carbon nanotubes may be used in EEE, yet it has been shown that they can have asbestos-like properties. Respected authorities such as the UK Royal Commission on Environmental Pollution, the UK Health and Safety Executive or the German Environment Agency have raised concerns about these nanomaterials or even recommended against their use (Nanotechnology Industries Association, 2013). Importantly, the justification offers no specific hazard in need of managing, or any precise conclusion or finding by an EU scientific body.

The reasons to regulate nanoscaled materials are strong and such measures may be considered in the future, even in the absence of any specific scientific justification. A more thorough discussion regarding the basis of nanomaterials regulation in the EU, in EEE or more generally in the context of the discussions on nanomaterials is critically needed. A specific working group (Nanomaterials Working Group (ECHA-NMWG)) was created for this purpose, and preliminary conclusions are expected to be released soon (ECHA, 2015).

D.2.07 Transport and packaging

Transport law is largely controlled by material classification and labelling and is therefore not dealt with in depth here. The distribution of nanomaterials from the place of production, or from intermediate storage, for stationary storage or to the consumer can be done in portable containers by road, rail, sea or through pipelines. The safety requirements for the transport technology and safe enclosure are laid down in the United Nations treaty concerning the International Carriage of Dangerous Goods (ADR).¹⁰⁷ This corresponds with Directive 2010/61/EU,¹⁰⁸ which is transposed in Germany based on the Law on the Transport of Dangerous Goods (GGBefG),¹⁰⁹ which is harmonised step by step internationally.

How it is harmonised will be discussed below. Packaging Directive 1994/62/EC,¹¹⁰ transposed into German regulations on the prevention and recycling of packaging waste (VerpackV),¹¹¹ covers the withdrawal, deposit collection and recycling obligation requirements for the production and distribution of packaging. According to the VerpackV, packages need to be manufactured and distributed in such a manner that all limits of harmful and hazardous substances and materials stay within emissions limits when the packaging and its components are disposed of (Art. 12 no. 3). In addition, Art. 13 para. 1 of the VerpackV determines that packaging and packaging components may only be placed on the market if the concentration of heavy metals in them does not exceed a cumulative value of 100 mg/kg (SRU, 2011).

Neither the deposit collection nor the recycling obligations are currently fit for use with nanomaterials, nor are packaging concentration values for nanomaterials defined, since they are not perceived as harmful or dangerous substances, and no further obligations arise from the general requirements for manufacturing and sales. In the case of food contact materials, a variety of products manufactured using nanotechnologies are already on the market for transporting, protecting, labelling and advertising goods (SRU, 2011).

¹⁰⁷ UN Recommendations on the Transport of Dangerous Goods – Model Regulations. Volume II. Seventeenth revised edition (ST/SG/AC.10/1/Rev. 17 (United Nations 2011) New York and Geneva).

¹⁰⁸ Commission Directive 2010/61/EU of 2 September 2010 adapting for the first time the Annexes to Directive 2008/68/EC of the European Parliament and of the Council on the inland transport of dangerous goods to scientific and technical progress (OJ L 233, 3.9.2010, p. 27–28).

¹⁰⁹ Dangerous goods transport law (*Gefahrgutbeförderungsgesetz – GGBefG* (Law on the transport of dangerous goods) *Gesetz über die Beförderung gefährlicher Güter*) of 6 August 1975 (Federal Law Gazette I p. 2121), last amended by Art. 487 of the Directive of 31 August 2015 (Federal Law Gazette I p. 1474).

¹¹⁰ Council Directive 94/62/EC of 20 December 1994 on packaging and packaging waste (OJ L 365, 31.12.1994, p. 10–23) last amended by the Directive of 6.5.2015 (OJ L 115 p. 11–15).

¹¹¹ Packaging Ordinance (*Verpackungsverordnung – VerpackV* (Regulation on the prevention and Recycling of packaging waste) *Verordnung über die Vermeidung und Verwertung von Verpackungsabfällen*) of 21 August 1998 (Federal Law Gazette I p. 2379) last amended by Art. 1 of the Directive of 17 July 2014 (Federal Law Gazette I p. 1061).

These products include packaging that acts as a barrier, or has coatings to block out moisture, oxygen or UV light, packaging materials with built-in antibacterial properties or packaging materials with an indicator function that can sense and provide an indication if a food is spoiled. However, nanomaterials can also be used as process-helping materials to modify the function of surfaces in food manufacture (e.g. on conveyer belts) in order to achieve a variety of effects like ease of cleaning (lotus effect), energy efficiency, adhesion properties, etc. (SRU, 2011). However, food contact materials must comply on EU level with the general safety provisions of Framework Regulation (EC) No 1935/2004¹¹² and Regulation (EU) 2015/174.¹¹³

Overall, it can be concluded that the EU Regulations and Directives on food contact materials form a good basis for the regulation of nanomaterials. Critically, the EFSA Guidelines on safety evaluation do not at present contain provisions for nanospecific testing procedures for the authorisation of nanomaterials for use in food contact materials. The fact that, so far, no instruction or clarification has been issued to the effect that inclusion in the Community list requires nanomaterials to undergo authorisation in their own right can be criticised (BUND, 2010). A lack of labelling makes it difficult to ensure traceability down the supply chain. Beyond that, industry federation representatives see no need to take action to require prior definition of specific testing procedures as they believe appropriate and meaningful testing procedures are developed and applied in the process of case-by-case authorisation as necessary (BUND, 2010).

Food contact materials must comply with the general safety provisions of Regulation (EC) No 1935/2004 (referred to as the Framework Regulation on food contact materials). In accordance with this regulation, materials intended to come into contact with food must not endanger human health or bring about an unacceptable change in the composition of the food. This must be ensured regardless of the particle size of the substance or type of material used. The regulation also requires the business operator to immediately inform the European Commission of any new scientific or technical information that might affect the safety assessment of authorised substances in relation to human health. If necessary, the EFSA may then review the original safety assessment of the substance (SRU, 2011). This also applies to the criterion 'particle size'. Substance-specific authorisation procedures (preventive ban with authorisation option) currently exist in EU law for certain components in food contact materials made from plastics (Directive 2002/72/EC) and from regenerated cellulose film (Directive 2007/42/EC).

¹¹² Regulation (EC) No 1935/2004 of the European Parliament and of the Council of 27 October 2004 on materials and articles intended to come into contact with food (OJ L 338, 13.11.2004, p. 4) last amended by Art. 1 of the Directive of 18 July 2009 (OJ L 188, p. 1).

¹¹³ Commission Regulation (EU) 2015/174 of 5 February 2015 amending and correcting Regulation (EU) No. 10/2011 on plastic materials and articles intended to come into contact with food (OJ L 30, 6.2.2015, p. 2–9).

Both of these Directives are implemented in Germany by the Commodities Ordinance (*Bedarfsgegenständeverordnung – BedGStV*). Substances in so-called active and intelligent materials and articles will also require authorisation in future (Regulation (EC) No 450/2009). Testing requirements are based on the EFSA Guidelines for the safety evaluation of substances in food contact materials. The legislative provisions also make reference to these guidelines. According to EFSA, no health risk is present under these specific conditions of use because migration into food, and thereby consumer exposure, is not expected to occur (EFSA, 2009a).

Under Regulation (EC) No 1935/2004, food contact materials must also be labelled with special instructions for their safe and appropriate use, where this is necessary in the light of their normal or reasonably foreseeable use. Further, a legal basis for potential additional individual measures is provided, and that could be applied to nanomaterials in fields where no specific regulations exist at present. Nanospecific testing procedures should be included in the EFSA Guidelines for the safety evaluation of substances in food contact materials as a general prerequisite for authorisation of nanomaterials. Potential future options for regulating types of material or classes of substances not specifically covered in existing legislation could include tools such as an authorisation procedure (e.g. restrictions on use) and the need to label food contact materials that contain nanomaterials to enable traceability across the supply chain (BUND, 2010).

The present legal framework is basically adequate to ensure that food contact materials manufactured using nanotechnologies are safe. Whether there is a need for additional regulations for all other packaging materials will depend on new scientific findings. Authorisation of plastics includes, as a matter of principle, stipulations on the conditions of use and, where necessary, sets migration limits for the substance (NanoKommission, 2011).

D.2.08 Summary

The issues raised in this section are severable areas of law and relate to individual regulatory areas. An exception applies to the REACH Regulation and its adjacent areas of law. This regulation should be (in the sense of this work) able to change and, in the following sections, will take on a large part of the important necessary regulation of nanotechnologies. Notwithstanding the limitations discussed, any information on a risk assessment that is carried out for a nanomaterial in the context of REACH is based on test guidelines that do not take into account the specific hazards and exposure pathways of nanomaterials. Given these limitations, REACH cannot deliver on assessing the risks of nanomaterials in its current form. On the other hand, RoHS has become an important fact of life in the EU and its influence is spreading beyond EU borders (Working Group 3 of the NanoKommission, 2010).

Because of the fast-changing nature of electrical and electronic equipment, recasts will also be a routine part of the political landscape, providing regular opportunities to refine the existing directive and consider amendments and expansions to it, including EEE containing nanomaterials (Mantovani et al., 2010).

In the same way, the German Chemicals Act is, by means of special mechanisms (for instance, specific test specifications), aimed at systematic identification of substance-related risks. The reason for this is the intention of legislators to register substances at an early stage, directly after production. ‘Primary chemicals law’ is directed at data collection, whereas ‘Derived chemicals law’ is based on data from the primary chemicals law and includes specifications for identifying and preventing dangers through appropriate actions in subsequent individual use and controlling risks (as it is formulated in the REACH Regulation). Finally, in future, specifications in the REACH Regulation will have to be observed. However, at present, registration as a new substance is a possibility (NanoKommission, 2011).

In the legal treatment of nanocompounds, both under existing-substance and new-substance law, a systematic evaluation of the risks for human health and the environment emanating from these substances is only demanded when certain quantitative thresholds have been reached. Although this threshold is much lower in new-substance law (10 kilograms) than in existing-substance law (1000 kilograms), the question is raised, considering the very small volumes of nanomaterials placed on the market, whether this standard is adequate. Here, the introduction of nanospecific quantitative thresholds must be considered. Also, the criteria according to which a substance is assigned to the existing-substance or new-substance regime need to be clarified (SRU, 2011).

D.3. End use and consumption

Nanomaterials can be released into the environment in many different ways during their use or consumption, and ‘use’ can be carried out by private customers or by companies. Both consume differently and both generate different potential dangers. Generally, companies will most likely create (aggregated) point sources of nanomaterials, whereas customer use is more ubiquitous and so are the (distributed) sources of emission after consumption. For both, however, the most important emission paths concern products with nanoparticles not integrated into a solid matrix (Hansen, 2009). For example, nanomaterials from cosmetics and sunscreens that can enter the environment – into the water at the beach, for example – through washing or rubbing off. On the other hand, emissions into domestic wastewaters are possible from broadly differing sources, e.g. non-degradable nanomaterials from medicinal products that can be excreted from the body or washing powder that contains selectively active nanomaterials (Führ et al., 2007a).

Regulations covering the period of use of nanomaterials encompass the most varying consumer protection regulations, such as Directive 2001/83/EC on medicinal products for human use, Regulation 178/2002/EC on the general principles and requirements of food law and Directive 76/768/EEC on cosmetic products. The regulations aim to promote the protection of consumer health, for example, through prohibition and restriction of contents, and labelling requirements for products, and also apply to substances that pose a risk to the environment, even when they have usually only been tested for risks to human health (SRU, 2011).

Nanomaterials can be released into the environment in many different ways during their use. In this regard, the regulations for detergents as well as for fuel and fuel additives need to be examined, since emissions of nanoparticles from these two product groups are probably among the most important uncontrolled emission paths (NanoKommission, 2011).

D.3.01 Detergents

Where nanomaterials are detergents, surfactants intended for detergents or even other products belonging to detergents, EC Regulation 648/2004 on detergents¹¹⁴ applies. This regulation is transposed and supplemented by the German Detergents Act (WRMG).¹¹⁵ For this reason, as with all ‘classical’ surfactants, nanomaterials as surfactants have to be ultimately biodegradable in accordance with the requirements listed in Annex III of the EC regulation. However, it should be examined whether the test methods for ‘classical’ surfactants in accordance with Annex III and the level of biodegradability (mineralisation) measured according to one of five described specified tests (at least 60% within 28 days) also adequately cover the possible risks of nanomaterials. It can already be concluded that if nanomaterials are the organic content of detergents, which do not belong to surfactants, they are not covered (NanoKommission, 2011).

Where there are reasons for considering that nanomaterials in detergents give rise to an unforeseen risk for the environment, the German Environment Agency (*Umweltbundesamt* – UBA) is able to take action to avert risks for the environment through the prohibition or restriction of access to the market of the detergent in question. Although the general safety requirement on detergents is very stringent, it is concerning that there are no proper (specific) risk assessment procedures to decide whether nanobased products are safe or unsafe to human health or the environment (Working Group 3 of the NanoKommission, 2010).

¹¹⁴ Regulation 648/2004/EC of the European Parliament and the Council of 31 March 2004 on detergents (OJ L 104, 8.4.2014, p. 1), last amended by the Directive of 14 March 2012 (OJ L 94, 30.3.2012, p. 16–21).

¹¹⁵ Detergents Act (*Wasch- und Reinigungsmittelgesetz – WRMG* (Law on the environmental compatibility of washing and cleaning agents) *Gesetz über die Umweltverträglichkeit von Wasch- und Reinigungsmitteln*) of 17 July 2013 (Federal Law Gazette I p. 2538), last amended by Art. 319 of the Directive of 31 August 2015 (Federal Law Gazette I p. 1474).

The WRMG should also be applicable to surfactant-based cosmetic products for cleansing pursuant to Art. 2 para. 5 LFGB (German Food and Feed Code) – for example, soaps and shampoos. However, nanomaterials as detergents are subject to EC regulation on detergents and should only be covered by the WRMG when the substances or preparations involved contain surfactants that are intended for all kinds of washing and cleaning processes (Art. 2 no. 1 EC Regulation 648/2004). The important definitions of ‘substance’ and ‘preparation’ in connection with detergents as defined in Art. 2 no. 4 and 5 of EC Regulation 648/2004 are more or less identical with those in REACH (Führ et al., 2007a).

Corresponding to this, the term ‘substance’ when applied to nanomaterials is applicable also for surfactants in detergents following the definition of EC Regulation 648/2004 and the WRMG. It therefore also applies to nanomaterials as surfactants; they may be placed on the market in detergents when the criteria in Annex III on ultimate aerobic biodegradation are fulfilled following Art. 4 para. 1 of EC Regulation 648/2004. Where the level of ultimate aerobic biodegradation is lower than that stipulated, derogation may be granted under certain circumstances for ‘classical’ detergents as well as for such detergent nanomaterials intended for industrial or institutional use (Art. 4 para. 2 and Art. 6 para. 2 EC Regulation 648/2004).

Finally, EC Regulation 648/2004 and the WRMG contain no specifications for nanomaterials when organic ingredients of detergents are involved that are not surfactants or when substances are involved that are subject to anaerobic biodegradation (Führ et al., 2007b). Where there are justifiable reasons for believing that a nanomaterial in a detergent constitutes a risk to the health of humans or animals, or to the environment, the competent national authority may temporarily prohibit or restrict the placing on the market of this detergent in accordance with Art. 15 of EC Regulation 648/2004.¹¹⁶ The final decision on the placing on the market of the detergent would, however, be taken at EU level. In order for the competent authority to be able to take action, however, it would have to have knowledge of detergents on the market that contain nanomaterials and of how they are made (NanoKommission, 2011). In Germany, according to Art. 9 para. 1 WRMG, the outline formulation and the registration number must be given to the Federal Environmental Agency at the time when certain detergents are first placed on the market. This information is stored in the register of detergents at the Federal Environmental Agency. Since this requirement, due to specifications in EC Regulation 648/2004, could in future no longer be contained in the WRMG, the issuing of such restrictions for detergent nanomaterials would be made unreasonably difficult, which should be avoided (NanoKommission, 2011).

¹¹⁶ According to Art. 14 para. 2 of the WRMG this authority is the Federal Environmental Agency (*Umweltbundesamt (UBA)*).

D.3.02 Fuels and fuel additives

Nanotechnologies are being used to create novel fuel additives that aim to improve combustion cleanliness in engines. For example, adding cerium oxide nanoparticles to fuel can help decomposition of unburnt hydrocarbons and soot, reducing the amount of these pollutants emitted in the exhaust and reducing the amount of fuel used. Cerium oxide has the ability to catalyse combustion reactions by donating oxygen atoms from its lattice structure. It has also been shown that cerium oxide decreases the pressure in the combustion chamber, which reduces the production of NO_x and makes combustion reactions more efficient. Cerium oxide nanoparticles can also be used as a short-term treatment for particulate filters in diesel engines. The nanoparticles help to clear away soot that clogs up the filters and so can improve the performance of the filters and the cleanliness of the exhaust emissions (PROSPECT, 2010).

A study carried out by researchers at Purdue University found that nano-sized particles of aluminium give a greater performance benefit. The characteristics of nano aluminium in suspension are more conducive to the formation of microexplosions during combustion, which assists the air-fuel mixing and leads to cleaner, more efficient combustion. This catalytic activity is dependent on surface area, amongst other things, which is why nanoparticles can offer distinct advantages over bulk material or larger particles. In addition, the nanoparticle suspensions in ethanol-based fuels were much better than those in model hydrocarbons, suggesting that nano aluminium could be effective in additive packs for bio-ethanol fuels (Gan et al., 2011).

In a study published in 2011, researchers from Anna University investigated the potential of cobalt oxide (Co₃O₄) and magnesium-aluminium (magnalium) nanoparticles as additives for biodiesel fuels. The oxygen atoms in cobalt oxide particles can moderate the combustion reactions, much like cerium oxide. As a result, the combustion was cleaner when using the cobalt oxide additive, and emissions of carbon monoxide and unburnt hydrocarbons were reduced. The cobalt nanoadditives were also shown to reduce NO_x production (Ganesh et al., 2011).

Whilst nanoadditives have demonstrated the potential to improve fuel efficiency and the quality of exhaust emissions, they may also cause environmental issues if they are carried into the exhaust gases themselves (Soutter, 2012). Studies have shown that the addition of cerium oxide nanoparticles to fuel results in the emission of small amounts of the particles. These particles are likely to accumulate in the environment, in particular in roadside areas (EPA, 2011).

The main challenge moving forward, therefore, will be to fully assess the potential environmental impacts of releasing these nanoadditives into the environment and comparing the results with the potential improvements of emissions (Soutter, 2012).

However, Directive 98/70/EEC on the quality of petrol and diesel fuels¹¹⁷ and the amending Directive (EU) 2015/1513,¹¹⁸ incorporated into German law by the 10th BImSchV,¹¹⁹ which has to be observed in the case of nanomaterials in fuel or fuel additives, contains no nanospecific requirements. According to the directives, in order to protect the environment and the health of consumers, petrol and other fuels may only be placed on the market when they comply with the technical requirements specified in the annexes to the directives. Petrol that is intended for the German market, for instance, must at least satisfy the demands of DIN EN 228¹²⁰ or a corresponding standard of another EU member state. The minimum standards concern the many, varied substances that are contained in fuel – for example, sulphur and lead – but include no specifications for nanomaterials. Should, however, the risk assessment of nanomaterials in fuel additives show that risks to the environment could arise, the minimum standards of Directive 98/70/EEC should be adapted to apply to the nanomaterials used (Führ et al., 2007b). Still, fuel additives, together with detergents, are the most important (uncontrolled) entries and diffuse sources of nanomaterials. The exact manner of this, however, cannot be stipulated at this point, since only a small amount of data for risk assessment is available (NanoKommission, 2011).

D.3.03 Medicinal products

Nanotechnologies are considered to be one of the emerging fields in science, with great potential in a wide range of medicinal applications (Kipp, 2004), including drug delivery (Cascone et al., 2002; Duncan, 2003; Beduneau et al., 2007; Gupta et al., 2005), diagnostics and regenerative medicine (Köck, 2009; Baran et al., 2002). Similarly, in pharmaceuticals there are already numerous nanoapplications (Chen, 2008). Medicinal products are controlled by Directive 2010/84/EU¹²¹ and former Directive 2001/83/EC,¹²² where it is stated that medicinal products in general fall under an official authorisation process.

¹¹⁷ Directive 98/70/EC of the European Parliament and the Council of 13 October 1998 relating to the quality of petrol and diesel fuels and amending Directive 93/12/EEC of the Council des Rates (OJ L 350, 28.12.1998, p. 58–68); last amended by Directives 2003/17/EC (OJ L 76, p.10) and 2003/30/EC (OJ L 123, p. 42).

¹¹⁸ Directive (EU) 2015/1513 of the European Parliament and of the Council of 9 September 2015 amending Directive 98/70/EC relating to the quality of petrol and diesel fuels and amending Directive 2009/28/EC on the promotion of the use of energy from renewable sources (OJ L 239, 15.9.2015, p. 1–29).

¹¹⁹ 10th Ordinance on the Federal Immission Control Act (*10. Bundesimmissionsschutzverordnung – 10. BImSchV* (Ordinance on the Quality and the Labelling of grades of fuel oil)) of 8 December 2010 (Federal Law Gazette I p. 1849), last amended by Art. 1 of the Directive of 1. December 2014 (Federal Law Gazette I p. 1890).

¹²⁰ DIN EN 228.

¹²¹ Directive 2010/84/EU of the Parliament and of the Council of 15 December 2010 amending, as regards pharmacovigilance, Directive 2001/83/EC on the Community code relating to medicinal products for human use (OJ L 348, 31.12.2010, p. 74–99).

¹²² Directive 2001/83/EC on the Community code relating to medicinal products for human use of 6 November 2001 (OJ L 311, 28.11.2001, p. 67).

In Germany, these directives are transposed into the law on the marketing of medicinal products.¹²³ Thereby the manufacturer must present proof of the quality and harmlessness of his products to the administrative authority. Risks that can derive from medicinal products containing nanotechnologies have to be assessed within this same general authorisation procedure. However, in contrast to other products, environmental aspects also have to be considered and ecotoxicological tests have to be conducted.

One problem may be to mobilise the appropriate expertise for the evaluation of the quality, safety and efficacy of nanomedicinal products. However, the *in vitro* and *in vivo* clinical testing processes are generally seen as robust in validating that a product is safe (Führ et al., 2007b). None of the nanomedicines that have been approved up to now have encountered any particular risk, quality or efficacy problems related to nano-properties (Dorbeck-Jung et al., 2011). In this context, the European evaluation system does not take a zero-risk approach. As long as the product meets its intended purpose and the risk-benefit balance is positive, the product can be licenced. Certain risks are accepted (the applicant has to deliver a risk minimisation plan) if there are certain benefits to be gained. The measurement of the benefit depends on the kind of disease and on whether the product seems to fulfil health needs (NanoKommission, 2011).

Considering that the impact analysis to identify environmental impact is not yet prepared, a leading expert has identified this analysis as a regulatory problem of major importance because it depends on reported physical characteristics and available information on the biologic effects from specific nanomaterials, which are widely unknown (Gaspar, 2007).

The issue is the adequacy of the general drug assessment standards to evaluate the safety, quality and efficacy of future nanopharmaceuticals. It was stated that ‘the fact that the new nanopharmaceuticals can be more complex in their structure, with major differences in bio fate and increased complexity of clinical use, integrating different technology subsets from therapeutics to imaging and integrated non-invasive diagnostics will probably force the creation of a new regulatory environment’ (Gaspar, 2007). However, as opposed to this, to date, evaluation bodies have treated nanopharmaceuticals as ordinary products. In the field of nanomedicine, the specific regulatory efforts are far less mature (Führ et al., 2007a).

With drugs generally subject to a special, expensive approval process that presently does not concretely address nanomaterials, the Commission needs to create options that could make a systematic review of hazards posed by nanomaterials possible (Führ et al., 2006b).

¹²³ Medicines Act (*Arzneimittelgesetz – AMG* (Law on the marketing of medicinal products) *Gesetz über den Verkehr mit Arzneimitteln*) of 12 December 2005 (Federal Law Gazette I p. 3394), last amended by Art. 2 of the Directive of 10 December 2015 (Federal Law Gazette I p. 2210).

An additional regulatory aspect in the field of nanomedicine involves products that exceed regulatory limits or have a multiple purpose and for which, on occasion, it is not clear under which regulation they fall, e.g. drugs, medical devices or cosmetics¹²⁴ (Eisenberger et al., 2010).

A detailed assessment of toxicology, ecotoxicology, and of methodologies used to evaluate toxicity, as well as extensive post-marketing surveillance, is required by current legislation of medicinal products. This also applies to nanomaterials and nano-related products, even if they are not explicitly mentioned in current provisions (Mantovani et al., 2010).

This takes into account the fact that the European Medicines Agency (EMA) is a decentralised European Union body with responsibility for the protection and promotion of public and animal health. The EMA is generally in charge of all authorisation procedures for medicinal products, though only authorisation at national level (or mixed national and EU authorisation procedures) is feasible for effective control in some specific cases (European Commission, 2009c).

In order to assist applicants developing nanomedicinal products, in 2009 the EMA established a dedicated group on nanotechnologies within the Innovation Task Force (ITF) to focus on this field. The aim of the ITF nano group is to meet with applicants, discuss bottlenecks in the development of nanomedicinal products informally and explore possible scientific and regulatory solutions (Kayser, 2009). This allows, in the absence of guidelines, potential developers of nanomedicine products to interact with the EMA directly, in the early stages of the development process. The ITF nano group is also active in providing scientific and regulatory input on various EU initiatives and has established links with regulatory authorities on a global level. New methods and models might need to be developed for nanoscale materials, but the careful benefit/risk balance that has to be proven for pharmaceuticals is considered in general appropriate for the evaluation of nanomaterials (Merenyi et al., 2007; Köck, 2009). However, currently, there are no specific guidance documents on nanomedicines (Mantovani et al., 2010).

Finally, potential gaps could also arise with novel applications of nanotechnologies that combine particular properties, methods and functionalities for which the applicable regulatory framework (e.g. medicines, devices, advanced therapies or combinations) cannot easily be determined (European Commission, 2008d). On the other hand, a method of determination may be developed in the future, once sufficient scientific experience has been gained from scientific research for specifically identified sub-technologies within the field of nanomedicines (Mantovani et al., 2010).

¹²⁴ See also Regulation (EC) No 726/2004 laying down Community procedures for the authorisation and supervision of medicinal products for human and veterinary use and establishing a European Medicine Agency of 31 March 2004 (OJ L 136, p. 1–32).

D.3.04 Medical devices

Medical devices used as instruments, apparatus, implants, in vitro reagents or similar or related articles used to diagnose, prevent or treat diseases and conditions are regulated via specific EC Directives, based on the new approach¹²⁵ to technical harmonisation and standardisation: the Medical Devices Directive 93/42/EEC¹²⁶ (MDD), the Active Implantable Medical Devices Directive 90/385/EEC¹²⁷ (AIMDD) and the In Vitro Diagnostic Medical Devices Directive 98/79/EC¹²⁸ (IVDD), transposed into German law by the Law on Medical Devices.¹²⁹

Unless further toxicological risk studies are performed and specific guidelines introduced, many nanomedicinal devices are likely to pose short-term and long-term risks to health and the environment. Though modification of existing regulations and standards to incorporate nanomedicals seems likely, it will not address the more fundamental issue that existing risk assessment methodologies may be inadequate. While the small size of particles makes them so useful in medical applications, it is also one of the main areas of concern (Hansen, 2009).

There are also many types of nanoparticles and nanomaterials, and one of the challenges is to be able to categorise and prioritise these for the purpose of risk assessment (Hansen, 2009). Hence, if existing regulations are modified to make them more nanoconversant, existing risk methodologies will also have to be adapted to introduce agglomeration, particle size, shape and surface reactivity into the assessment criteria. In cases of products that combine medical devices and drugs or medicines, other problems are the applicability of the regulatory regime and the lack of tailored standards in the medical devices assessment (Dorbeck-Jung et al., 2011).

With regard to human medicine, nanomaterials are playing an increasing role, for example in the coating of implants with nanomaterials for better bio-compatibility and bio-stability, the use of specific fluorescent dyes in tumour diagnostics, or in relation to surgical instruments, where an alteration to the surface can cause an antiseptic effect (Mantovani et al., 2010).

¹²⁵ Council Resolution of 7 May 1985 on a new approach to technical harmonization and standards (OJ C 136, 4.6.1985, p. 1–9).

¹²⁶ Council Directive 93/42/EEC of 14 June 1993 concerning medical devices (OJ L 169, 12.7.1993, p. 1–50).

¹²⁷ Council Directive 90/385/EEC of 20 June 1990 on the approximation of the laws of the Member States relating to active implantable medical devices (OJ L 189, 20.7.1990, p. 17), last amended by the Directive of 21 September 2007 (OJ L 247, p. 21).

¹²⁸ Directive 98/79/EC of the European Parliament and the Council of 27 October 1998 on in vitro diagnostic medical devices (OJ L 331, 7.12.1998, p. 1–37), last amended by Directive of 18 July 2009 (OJ L 188, p. 14–92).

¹²⁹ Law on Medical Devices (*Medizinproduktegesetz – MPG* (Law on Medical Devices) *Gesetz über Medizinprodukte*) of 7 August 2002 (Federal Law Gazette I p. 3146), last amended by Art. 278 of the Directive of 31 August 2015 (Federal Law Gazette I p. 1474).

One of the main tasks in this sector is to ensure the safety and quality of medical devices to protect those who are in contact with such products. The law on medical devices utilises a differentiated regulatory framework against the background of a broad European regulatory approach. Safety and performance requirements applicable to medical devices range from electrical safety to bio-compatibility, also including toxicological and hygienic harmlessness, risk/benefit analysis and labelling requirements (Dorbeck-Jung et al., 2011).

An additional question concerns products that, due to their use of nanotechnologies, fall outside of the established framework of product limits and therefore are not clearly within one legal framework. With regard to medical devices, legal amendments should consider so-called ‘dual/multi-use products’ being brought onto the market under less strict provisions. The preferred way to prove compliance with these requirements would be for a manufacturer to comply with harmonised European standards and/or international standards (which may include testing) and to implement a risk management system. A manufacturer has to affix a CE marking to the product before it can be brought onto the European market (Klindt, 2001). Depending on the risk classification of the product, different conformity assessment procedures that give a manufacturer the right to affix the CE marking must be followed (Mantovani et al., 2010).

Three classes of risk are defined, from low-risk (Class I) devices (e.g. various types of non-invasive devices) to high-risk (Class III) devices (e.g. implantable devices and long-term surgically invasive devices in contact with the heart or the central nervous system). For higher risk products, a Notified Body (NB) must be consulted, who has to ensure that the manufacturer complies with the essential requirements, as listed in Annex I, of each Directive. For products of the highest risk class (Class III), the NB will always review the complete design dossier. Also, the acceptability of the overall residual risk of the product is verified by assessing the scientific evidence on safety and efficacy, as provided by the manufacturer. For the other risk classes (Classes I/II), the right to affix the CE marking could also be granted based on an assessment of the quality management system of the manufacturer, including an assessment, on a representative basis, of the documentation made in the design phase of the product(s) concerned (Mantovani et al., 2010). A report devoted to nanotechnologies was published¹³⁰ in July 2007 by the European Commission Working Group on New and Emerging Technologies, as endorsed by the Medical Devices Experts Group, and it concluded that, in general, medical device legislation is suitable for dealing with medical devices manufactured utilising nanotechnologies (N&ET Working Group, 2007).

¹³⁰ Mandate addressed to CEN, CENELEC and ETSI for the elaboration of a programme of standards to take into account the specific properties of nanotechnology and nanomaterials, M/409 EN, European Commission 2007.

At the same time, the document points out that particular attention must be given to free nanoparticles (devices where nanoparticles are not encapsulated or bound) and that specific regulation could be required in these cases. Moreover, the potential development of new or amended standards and guidelines, improvements in post-marketing surveillance systems and the collection of data and information, by means of a specific information gathering initiative, are envisaged. Currently, the group is writing a guidance document for medical devices (MEDDEV) utilising nanotechnologies (Dorbeck-Jung et al., 2011).

A similar position is expressed in the regulatory review published by the European Commission in June 2008, where it is stated that the Medical Devices Directive allows, in principle, risks associated with nanomaterials to be covered, but further specific guidance or standards should be developed. Several indications on ethical and regulatory issues related to the application of nanotechnologies both to medicinal products and medical devices are also included in the report by the European Group on Ethics in Science and New Technologies (EGE) on the ethical aspects of nanomedicine, published in January 2007 (EGE, 2007).

An important issue, that still is unresolved, is also identified in some of the other global legislation (as in the case of the FDA in the US); it regards novel nanomedical products that combine diagnostic and therapeutic functions. These devices can challenge the current classification criteria between medical devices and medicinal products and also classification into the different categories of medical devices (van Zijverden et al., 2009).

D.3.05 Cosmetics regulation

There are numerous uses of nanomaterials in cosmetic products (BfR, 2006a; BfR, 2006b). Nanoscale titanium dioxide, for example, is used as a UV filter in sun protection products. Fullerenes are anti-oxidants in face creams and nanoscale calcium phosphate is found in toothpastes (SCCP, 2007). Requirements concerning cosmetics are currently laid down at EU level in Directive 76/768/EEC on cosmetic products.¹³¹ EU legislation is implemented in Germany by the Food and Feed Code (*Lebensmittel- und Futtermittelgesetzbuch* – LFGB) and the German Cosmetics Act (*Kosmetik-Verordnung*¹³²). In accordance with these (Art. 2 of the EC Cosmetics Directive and Art. 26 of the German Food and Feed Code), only products that are safe may be placed on the market. Prior to this, every cosmetic product must therefore undergo a safety assessment carried out by a suitably qualified person (NanoKommission, 2011).

¹³¹ Council Directive 76/768/EEC of 27 July 1976 on the approximation of the laws of the Member States relating to cosmetic products (OJ L 262, 27.9.1976, p. 169).

¹³² Cosmetics Ordinance (*Kosmetik-Verordnung* (Ordinance on cosmetic products) *Verordnung über kosmetische Mittel*) of 16 July 2014 (Federal Law Gazette I p. 1054).

These provisions generally apply to cosmetics containing nanoparticulate ingredients. Consequently, ‘cosmetic product’, according to former Directive 76/768/EEC on cosmetic products, means ‘any substance or mixture intended exclusively or mainly to be placed in contact with the external parts of the human body or the oral cavity with a view to cleaning them, protecting them, keeping them in good condition, perfuming them or changing their appearance’ (though excluding modifying the shape of the body). Today, the requirements for cosmetics are governed by Regulation (EC) 1223/2009 on cosmetic products,¹³³ which repeals Directive 76/768/EEC. Under this law, safety assessment of such products is more stringent¹³⁴ and market surveillance more rigorous; however, the definition stays the same (Führ, 2009).

For the first time, this regulation also contains provisions on nanomaterials in cosmetic products. Art. 2 provides a definition of nanomaterials that is based on the definition from the EU’s Scientific Committee on Consumer Products (SCCP), and Art. 16 of the regulation sets out a notification procedure for the use of certain nanomaterials in cosmetic products (SCCP, 2006).

According to this procedure, notification must be submitted to the European Commission six months prior to placing the product on the market and must include a set of additional information, including, for example, details of particle size, toxicological profile and the quantity of the nanomaterial to be placed on the market. The Commission then assesses whether risk management measures are required. Nanomaterials intended for a use for which a positive list of permitted substances already exists (colourants, preservatives and UV filters) are required to undergo a separate authorisation procedure and are therefore exempted from the notification requirements under Art. 16 (Working Group 3 of the NanoKommission, 2010).

Furthermore, all ingredients present in nanoparticulate form in cosmetics must be indicated clearly in the list of ingredients using the appropriate International Nomenclature of Cosmetic Ingredients (INCI) nomenclature, followed by the word ‘nano’ in brackets. The European Commission must, according to Regulation (EC) 1223/2009, also compile a catalogue of all nanomaterials used in cosmetic products (Working Group 3 of the NanoKommission, 2010).

The aim of cosmetics regulation is to ensure a high level of protection for human health. Environmental concerns are addressed through the application of REACH, which allows for cross-sector assessment of environmental safety. For this purpose, the measures of the Commission and the member states should be based on the precautionary principle.

¹³³ Regulation (EC) No 1223/2009 of the European Parliament and the Council of 30 November 2009 on cosmetic products (OJ L 342, 22.12.2009, p. 59–209).

¹³⁴ The provisions of Art. 15 para. 1 and 2 (substances that are carcinogenic, mutagenic or toxic for reproduction – CMR substances) came into effect 1 December 2010.

Finally, cosmetic products available on the market must be safe under normal or reasonably foreseeable conditions of use for human health. Ensuring this is mainly the responsibility of the product manufacturer. This is, however, complemented by other tools. Thus, there are certain substances that are prohibited in cosmetic products (Annex II), or that are limited (Annex III). Substances that are dyes, preservatives and UV filters should be used only if they are listed in the Annexes IV to VI of the Cosmetics Regulation. In addition, there is a ban on using substances classified as carcinogenic, mutagenic or toxic to reproduction (CMR). However, exceptions may be permitted if the substance is classified as safe by the Scientific Committee for Consumer Safety (SCCS) (NanoKommission, 2011).

Before a cosmetic product enters the market, it must undergo a safety assessment, under which all possible impacts on exposure due to particle size must be given special consideration (Annex I of the Cosmetics Regulation). Furthermore, according to Art. 13, there is a notification requirement prior to placing the product on the market that includes the presence of substances in the nanoform and the assignment of a responsible person as a contact for further product information. In addition, public access to information about side effects or qualitative composition is granted, and if the cosmetic product hazard falls within the meaning of the CLP Regulation, its quantitative composition must also be disclosed (SRU, 2011). Furthermore, according to Art. 19 of the Cosmetics Regulation, products must also be labelled. The label must note the responsible person, special precautions for use and the ingredients. If a product does not meet the requirements, the necessary corrective measures – withdrawal or recall – must be taken.

When a product presents a risk, the authority must be informed. In order to perform these corrective actions, the traceability of the products must be ensured. For cosmetic products placed on the market, a product information file for the authorities is to be kept containing the safety report, a description of the manufacturing method and proof of the advertised effect of the cosmetic product, in addition to a description of the cosmetic (NanoKommission, 2011).

If there are serious adverse effects, then these and the already initiated corrective measures need to be reported to the competent authority. The authorities monitor the products; the economic operators on the other hand are responsible for the product information files. All of these instruments also apply to cosmetic products containing nanomaterials. In addition, tools have been introduced that are designed to ensure the safety of the use of nanomaterials and to deal with the existing knowledge deficits relating to nanomaterials. While there are uniform rules for the general obligation to provide information to the authorities and for the labelling of nanomaterials, a distinction is made in the safety assessment between UV filters, dyes or preservatives (NanoKommission, 2011).

According to Art. 2 para. 1 lit. k Cosmetics Regulation, a nanomaterial is understood as an ‘insoluble or biologically stable and intentionally manufactured material with one or more external dimensions, or an internal structure, on the scale from 1 to 100 nm’. Given the controversial discussions on an appropriate definition, the European Commission Regulation opened the possibility of adapting the definition, taking into account the current technical and scientific developments and thus made the point of contact for the following legal obligations. This is an important step for the regulation of nanomaterials in cosmetics; however, the definition has some deficiencies. Thus, the use of solubility parameters and biological stability for a definition is problematic because it opens room for interpretation (SRU, 2011).

In order to provide legal certainty, size should be used as the only parameter for the definition of nanomaterials. The stability of the material or the reason it was created only limits the definition unnecessarily. Furthermore, it was not determined how much of the particle must fall below the size limit. In addition, the definition disregards the fact that nanomaterials of the same chemical composition can, as a function of size and surface treatment, have different properties, and differentiation is therefore necessary. Thus, with regard to the definition, there is the need for change in order to ensure legal certainty and to strengthen prevention-oriented handling of all nanomaterials (NanoKommission, 2011).

The instruments of notification and labelling requirements, which generally apply to all cosmetic products in the same way, also exist for nano-features. Thus, the general notification requirement of Art. 13 of the Cosmetics Regulation also includes the requirement to mention that nanomaterials are contained in a cosmetic product and to provide the identity of those nanomaterials. Additionally, under the labelling requirement of Art. 19, any nanoscale ingredient must be clearly indicated in the list of ingredients. The names of such ingredients should be followed by the word ‘nano’. However, it is questionable whether consumers are adequately informed by this addition, because an estimation of the imminent danger potential of the cosmetic product is not implicitly enabled (Meyer, 2010a).

A designation that would accomplish this, however, does not seem practical for nanomaterials that are used as colourants, preservatives or UV filters. According to Art. 3 of the Preamble to Appendixes II to VI of the Cosmetics Regulation, substances that are listed in Appendixes III to VI do not include nanomaterials unless specifically mentioned. This has the consequence that nanomaterials to be used as dyes, preservatives or UV filters must be explicitly and autonomously included in the positive lists. Thus, it is crucial that their use is subject to inclusion in the positive list (registration of title) during the preliminary regulatory safety assessment. Therefore, nanomaterials should be featured in this list (NanoKommission, 2011).

Also, steps must be taken to ensure that nanomaterials can be admitted only if their special features can be adequately addressed in the safety assessment. A particular problem is that there are currently no standardised risk assessment methods for nanomaterials (SRU, 2011). If there are concerns about the safety of nanomaterials as a result of new information – pursuant to Art. 16 of the Cosmetics Regulation monitored by the SCCS – a new statement on safety for the relevant product categories and the reasonably foreseeable exposure condition is needed.

As part of this security evaluation by the responsible person, the provision of missing data is required. Both the request of the European Commission and the opinion of the SCCS are made publicly available. In response to the opinion of the European Commission on the existence of a ‘potential risk’ to human health – even if only insufficient data is available – a prohibition or restriction on use is possible. In addition, the context of the disclosure requirement for nanomaterials on which information needs to be provided can be changed in the light of scientific and technical progress (NanoKommission, 2011).

It is questionable, however, whether a subsequent post-market safety assessment and related measures are sufficient for all nanomaterials or whether there is a need for measures beyond the safety assessment and approval mechanism. With regard to precaution-oriented handling, the Cosmetics Regulation provides some starting points (NanoKommission, 2011).

For nanomaterials with other uses, there is an extensive notification requirement similar to registration under the REACH Regulation. For the duty of notification requirements for nanomaterials, the European Commission may order actions on the basis of the downstream market safety assessment. It is remarkable in this respect that the European Commission is always able to take measures and does not have to wait for sufficient data (Führ et al., 2007a).

Rather, measures can already be engaged on the existence of so-called potential risk. Thus, for these uses, the European Commission has the opportunity to take precaution-oriented measures (NanoKommission, 2011).

Cosmetic products are the first product group to undergo Community-wide regulation of this kind. The safety assessment and notification procedure provide an adequate basis for ensuring the safety of nanomaterials in cosmetic products. Improvements that are needed include a broader definition and making other applications of substances subject to authorisation requirements (Working Group 3 of the NanoKommission, 2010). Since the Cosmetics Regulation only came into force in July 2013, there is currently a lack of experience with implementation. However, arrangements could be made for a good approach to ensure a precaution-oriented regulation of nanomaterials (SRU, 2011).

The burden of proof directed to the producers in the approval process – as long as there are no generally accepted risk assessment methods – rendering the interest of the consumer for protection, needs to be fully effective, even within the context of merely a presumption of dangerousness (NanoKommission, 2011).

As environmental protection is not addressed and the definition of nanomaterials is very narrow, a sufficient overview of nanomaterials on the market is not assured (Herrmann et al., 2010). Therefore, a nanoproduct register is additionally useful in the field of cosmetics. The need to improve characterisation and testing methods for safety assessment has been recognised. As a general conclusion, it can be stated that existing scientific and legal strategies seem to be sufficient to cover nanomaterials; however, challenges remain as they might need to be adapted to the specific characteristics of nanomaterials (Mantovani et al., 2010).

D.3.06 (Novel) Food

According to a statement from the European Food Safety Authority (EFSA), deliberately engineered nanoscale substances are not currently used in novel foods within the European Union (EFSA, 2011; EFSA, 2008; EFSA, 2009a; EFSA, 2009b). In the future, however, it may in principle become possible to give foods particular properties using novel ingredients in the nanosize range (IFST, 2006). Therefore, to foster responsible use of nanotechnologies and engineered nanoparticles and to ensure the protection of consumers' health, an appropriate legislative basis needs to be created for the food industry (German Parliament, 2007).

The instruments for the regulation of foods and thus also of those containing nanomaterials, whose primary objectives can be found in Regulation (EC) No 178/2002 laying down the general principles and requirements of food law,¹³⁵ lead to the creation of a high level of general protection for human health (Zipfel et al., 2010).

Furthermore, in the European regulations, there is also the aim of precautionary protection (Rathke, 2009). At the national level in the food sector, this is transposed by the principles of the Food and Feed Code (LFGB).¹³⁶ To achieve the set objectives, there is consumer information in addition to instruments to ensure the production of safe food and to ensure that food is handled safely. Additional requirements apply, for example, for special subjects in the food sector.

¹³⁵ 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 (OJ L 31, 1.2.2002, p. 1–24).

¹³⁶ Food and Feed Code (*Lebensmittel- und Futtermittelgesetzbuch – LFGB* (Food, Commodities and Feed Code) *Lebensmittel-, Bedarfsgegenstände- und Futtermittelgesetzbuch*) of 3 June 2013 (Federal Law Gazette I p. 1426) last amended by Art. 8 para. 3 of the Directive of 3 December 2015 (Federal Law Gazette I p. 2178).

These are foods that have been made with previously uncommon production methods and procedures (novel foods);¹³⁷ substances that are added to food for a technological purpose, such as in production, processing or treatment (food additives); and foods for increasing the supply of certain nutrients or active ingredients to the human metabolism (food supplements) (SRU, 2011).

The Commission¹³⁸ had largely dispensed with such regulations, as the Parliament has explicitly specified the need for a definition of nanotechnologies in the first reading of the proposal for the amended regulation on novel food. However, they did debate the inclusion of nanotechnologies in the scope of the regulation, namely the safety of foods produced using nanotechnologies, and took a concept definition¹³⁹ into the proposal.¹⁴⁰

The proposed compromise between the Council and the Parliament included a definition of synthetic nanomaterials and a specification that food made using them should be subject to a separate authorisation (Mantovani et al., 2010).

Following requests by the EC, the EFSA has reviewed existing data on two applications of nanomaterials in the food industry (EFSA, 2009b) and found only insufficient data to assess the safety of silver nanoparticles in silver hydrosol; it also concluded that there are no toxicological issues concerning the use of titanium nitride nanoparticles in plastic drinking bottles. The EC requested that the EFSA develops guidance on how risks associated with engineered nanomaterials could be assessed in applications of food, feed, food supplements and food contact materials (Davies, 2008).

Several of these issues have been discussed within the ENVI in a report to the European Commission (2009). As debate is still ongoing on the adaption and revision of the legislative provisions of Regulation (EC) No 258/97 on novel foods, participants outlined deficiencies in the current requirements that might be eliminated by amending the regulation to include a definition of nanoscale additives and specific testing methods. No authorisation could be granted before such testing methods are in place. Another means of removing deficiencies in the legislation, they state, would be to introduce mandatory listing of nanoscale additives in the list of food ingredients (NanoKommission, 2011).

¹³⁷ Regulation 258/97/EC of the European Parliament and of the Council of 27 January 1997 concerning novel foods and novel food ingredients (OJ L 043, p. 1–6) last amendment Regulation 596/2009 of 7 August 2009 (OJ L 188, 18.7.2009, p. 14).

¹³⁸ COM(2007) 872: Proposal for a Regulation of the European Parliament and of the Council on novel foods and amending Regulation (EC) No. XXX/XXXX [common procedure] [SEC(2008) 12] [SEC(2008) 13].

¹³⁹ Engineered nanomaterials are pursuant to Article 3 para 2 ‘intentionally manufactured material with one or more dimensions of the order of 100 nm or less or discrete functional parts, either internally or at the surface...’.

¹⁴⁰ Proposal for a Novel Food Regulation (COM/2013/0894 final – 2013/0435 (COD)).

The regulatory frameworks for food and feed are appropriate but cannot be exercised to their full extent until methods are developed to detect and measure nanomaterials in food, feed and biological tissues, as a better understanding of exposure to animals and humans and toxicity in their environment is needed (NSMP, 2009). Consumer safety is adequately guaranteed by the authorisation procedure, which is a general prerequisite for food additives and includes compulsory re-evaluation and re-authorisation (NanoKommission, 2011).

However, the inclusion of a definition of nanoscale additives, the prior development of nanospecific testing methods and the identification of nanoscale ingredients in the list of ingredients on packaged foods is advocated. On the other hand, specific testing methods are stipulated in the course of the case-by-case authorisation procedure, along with conditions for use and labelling requirements (Working Group 3 of the NanoKommission, 2010).

The actual requirements for the approval of nanomaterials in food are still largely unclear for users or are undefined. In addition to the already known nanospecific characteristics, sufficient room must be left for the consideration of subsequent findings (NanoKommission, 2011). With regard to monitoring in the food (and feed) market and the ability to execute product recalls, food law relies heavily on the instrument of traceability, which needs to be guaranteed by the manufacturer. The only mandatory reporting to the authorities is regarding marketing authorisation for dietary supplements; information about nanoscale ingredients does not need to be supplied (Working Group 3 of the NanoKommission, 2010).

Therefore, a market overview of the nanomaterials used is not assured. To facilitate the dissemination of information in the supply chain and to provide transparency for consumers, labelling requirements for the products are of predominant importance. However, there are currently still no guidelines developed and available on how this could also refer to nanoscale ingredients (Working Group 3 of the NanoKommission, 2010). For consumer information, the food information regulation¹⁴¹ could be a significant step, after which the name of the ingredient followed by a reference to the nanoscale needs to be made. However, this would not have any effect on the dissemination of information within the supply chain. Principally, food law is appropriate for the provision-based regulation of nanomaterials; however, instruments that hold adjustments are necessary (SRU, 2011). Overall, it can be concluded that the EU Regulations and Directives on food form a good basis for the regulation of nanomaterials.

¹⁴¹ Council of the European Union (2011): 2011 Position of the Council (EU) No 7 / at first reading with a view to adopting a Regulation of the European Parliament and of the Council as regards information to consumers, amending Regulations (EC) No 1924/2006 and (EC) No 1925/2006 and repealing Directives 87/250/EEC, 90/496/EEC, 1999/10/EC, 2000/13/EC, 2002/67/EC, 2008/5/EC and Regulation (EC) No 608/2004. Brussels: Council of the European Union.

However, the fact that the EFSA Guidelines on Safety Evaluation do not at present contain provisions for nanospecific testing procedures for the authorisation of nanomaterials for use in food is critical. In addition, so far the Community has issued no instruction or clarification of whether nanomaterials are required to undergo an authorisation of their own. Furthermore, the lack of labelling makes it difficult to ensure traceability down the supply chain, which cannot be ruled out by the new legislation coming into force.¹⁴²

Finally, a definition of nanomaterials needs to be formulated. There are no current applicable definitions of nanomaterials for the entire food industry. As part of the Novel Food regulation, however, a definition of nanomaterials was provided. Should this remain in use, it is proposed that greater legal certainty should be ensured and the precautionary principle should be strengthened (Working Group 3 of the NanoKommission, 2010).

This means that where size should be used as the only parameter, the upper size limit should be set at 300 nm as a safety precaution. On the other hand, where it is determined how many of the particles must fall below a certain size limit, the proportion should be indicated in relation to the particle number, instead of weight (Hansen, 2009).

Furthermore, an approval is needed; for it to be guaranteed that nanomaterials are safe to use in foods, a separate registration would be necessary for all uses for nanomaterials. The requirement for such approval is a separate safety assessment of nanomaterials that responds adequately to their peculiarities. This requirement could be adapted or supplemented to reflect new knowledge. This could lead to a moratorium (Meyer, 2010a) as consumers may not be used as test subjects.

However, the burden of proof in the approval process should, in the interest of consumer protection, be designed in accordance with the precautionary principle, with risk assessment methods based on addressing knowledge of the special features of nanomaterials (NanoKommission, 2011).

Concerning the identification of nanoscale materials, consumers have a legitimate interest in being informed about the ingredients in their food. An important step is that nanomaterials must be marked as such in the list of ingredients; however, further steps are necessary in order to transfer information within the supply chain. Both the name and the E number (European food additive code) should indicate the presence of a nanoscale material or a product containing one. Therefore, principally, an 'n' should be added to the E number and 'nano' should follow the name of the substance in the list of ingredients (IFST, 2006).

¹⁴² Regulation (EU) 2015/2283 of 25 November 2015 on novel foods, amending Regulation (EU) No 1169/2011 of the European Parliament and of the Council and repealing Regulation (EC) No 258/97 of the European Parliament and of the Council and Commission Regulation (EC) No 1852/2001 (OJ L 327, 11.12.2015, p. 1–22).

Finally, where nanomaterials and monitoring are concerned, the current traceability system works on the identification of production batches and allows the emergency withdrawal and recall of food (Working Group 3 of the NanoKommission, 2010). In particular, the food – where necessary – must be labelled according to the lot labelling regulation (LKV).¹⁴³

However, the authorities have no knowledge of which foods contain which ingredients, or which companies they are processed or distributed by. The authorities are only involved in the context of market surveillance and the reporting requirements of food supplements.

In view of the fact that, with regard to the use and also the importance of nanomaterials, there is currently no market transparency, and as the food sector is very sensitive to health risk, the authorities need an overview of use enforced by a reporting obligation (Führ et al., 2006b).

D.3.07 Food additives

Applications of nanoscale ingredients and additives for technological purposes include, for example, preservatives or colourings. Substances of this sort fall within the scope of Regulation (EC) No 1333/2008 on food additives¹⁴⁴ and Regulation (EC) No 1331/2008.¹⁴⁵

According to a statement from the European Food Safety Authority (EFSA, 2009b), with the exception of nanostructured flow aids, deliberately engineered nanoscale food additives are not used at present within the European Union (Working Group 3 of the NanoKommission, 2010).

Food additives cannot be placed on the European market unless they have been authorised for a given technological purpose following a comprehensive safety assessment. This ensures that their use poses no hazard to human health (Working Group 3 of the NanoKommission, 2010).

The Regulation on food additives is the first piece of European legislation concerning food that explicitly includes nanotechnologies in its regulatory area. Art. 12 provides the rule that ‘when a food additive that is already included in the Community list, and there is a significant change in its production methods or on the starting materials used, or there is a change in particle size, for example through nanotechnology, the food additive prepared by those new methods or materials shall be considered as different additive and a new entry in the Community list or change of the specifications shall be required before it can be placed on the market’.

¹⁴³ Lot labelling regulation (*Los-Kennzeichnungs-Verordnung – LKV*) of 23 June 1993 (Federal Law Gazette I p. 1022) last amended 25 July 2013 (Federal Law Gazette I p. 2722).

¹⁴⁴ Regulation (EC) No 1333/2008 of the European Parliament and of the Council of 16 December 2008 on food additives (OJ L 354, 31.12.2008, p. 16–33).

¹⁴⁵ Regulation (EC) No 1331/2008 of the European Parliament and of the Council of 16 December 2008 establishing a common authorisation procedure for food additives, food enzymes and food flavourings (OJ L 354, 31.12.2008, p. 1–6).

Regulation (EC) No 1333/2008 therefore makes provision for the re-evaluation of safety and, where appropriate, re-authorisation of food additives used in a form that differs from the form previously used and assessed by the relevant authority, for example the nanoscale form. If additives in the nanoscale are intended for technological purposes or are used in the form of micelles or similar, this also falls within the scope of the provisions on food additives. They must therefore meet the requirements of the authorisation procedure (NanoKommission, 2011).

In conclusion, consumer safety is adequately guaranteed by the authorisation procedure, which is a general prerequisite for food additives and includes safety assessment and compulsory evaluation and authorisation of substances intended for use in a new form, e.g. in the nanoscale form. However, it lacks a definition of nanoscale additives and does not support the development of nanospecific testing methods. It is advocated that nanoscaled ingredients be specified in the list of ingredients on packaged foods, along with conditions for labelling and requirements.

In this context, it should also be kept in mind that the test requirements for the recording of additives in the positive list do not respond to nanospecific properties and can therefore not be oriented on preventive safety assessments. In addition to the lack of the labelling of additives based on size, it is unfortunate that the labelling requirement does not require information on nanoscale ingredients. This means that the authorities will not get any information about where food supplements at nanoscale are used in this way, and control of the market is not possible. Beyond approval, notification and labelling of food additives, the regulation contains some instruments that are important for the regulation of nutrients. Thus, only those vitamins and minerals that are listed on a positive list and which were evaluated for their safety may be used. In addition, the marketing of dietary supplements is subject to notification, allowing the authorities to get an overview of their use. Also, consumers will be informed by appropriate instructions on packaging. In principle, therefore, a preventive-oriented handling of food supplements is assured. These instruments would in principle also be applicable for added nutrients in nanoform; however, they are explicitly addressed under separate legislation (see food supplement legislation (Working Group 3 of the NanoKommission, 2010)).

It is problematic that no distinction is made for the purposes of authorisation between nano- and macro-scale nutrients and so separate consideration is not ensured in the course of the safety assessment. In conclusion, the provision of information to consumers about nanoscale additives via the list of ingredients is not assured; authorisation will not be possible until standardised, nanospecific testing methods are available. The Regulation on food additives makes no provision for the specific labelling of nanomaterials. This is in contrast to the Cosmetics Regulation, which has introduced such a requirement (Working Group 3 of the NanoKommission, 2010).

D.3.08 Food supplements

Instruments for dietary supplements and the nutrients contained in them can be found in the Dietary Supplements Regulation (*Nahrungsergänzungsmittelverordnung – NemV*),¹⁴⁶ which transposes the Food Supplements Directive 2002/46/EC¹⁴⁷ and Regulation (EU) No 1169/2011¹⁴⁸ into German law. Notification and labelling requirements are established, however, only for nutrients that are listed in a positive list of Annex I of Directive 2002/46/EC and NemV; whereas permitted sources (vitamins and minerals) are listed in Annex II. Prior approval and inclusion in the positive list is subject to a safety assessment (European Commission, 2008b).

The European Commission has issued guidance on how applications should be made regarding safety assessments. If a nutrient that is already available in Annex II NemV is used in nanoscale form, this is not regarded as a separate entry in the positive list and, thus, no separate safety assessment is required. A procedure in which nanoscale nutrients must be considered separately is lacking. Moreover, the requirements for an application and safety assessment regarding the particle shape and manufacturing process are insufficient. In order to provide the authorities with an overview of the nutritional supplements on the market, manufacturers and importers have a reporting obligation pursuant to Art. 5 NemV. Thereafter, they have to report the marketing of the supplement to the Federal Office of Consumer Protection and Food Safety (BVL) and provide a sample of the label. The BVL will immediately convey this information to the Federal Ministry of Food and Agriculture (BMEL) and the other relevant federal authorities. Principally, this disclosure requirement applies to dietary supplements that contain nanomaterials; however, it implies no obligation to provide information about whether nanomaterials are included or what they may be (BUND, 2008).

For consumer information, Art. 4 NemV provides for a mandatory labelling. According to Art. 4, food supplements may be marketed commercially only if specific instructions on the packaging in addition to the general labelling requirements are available. This includes the name of the category of nutrients or substances that characterise the product.

¹⁴⁶ Dietary supplement regulation (*Nahrungsergänzungsmittelverordnung – NemV* (Ordinance on food supplements) *Verordnung über Nahrungsergänzungsmittel*) of 24 May 2004 (Federal Law Gazette I p. 1011), last amended by Art. 64 of the Directive of 31 August 2015 (Federal Law Gazette I p. 1474).

¹⁴⁷ Food Supplements Directive 2002/46/EC of the European Parliament and of the Council of 10 June 2002 on the approximation of the laws of the Member States relating to food supplements (OJ L 183, 12.7.2002, p. 51–57).

¹⁴⁸ Regulation (EU) No 1169/2011 of the European Parliament and of the Council of 25 October 2011 on the provision of food information to consumers (OJ L 304, 22.11.2011, p. 18–63), amending Regulations (EC) No 1924/2006 and (EC) No 1925/2006 of the European Parliament and of the Council, and repealing Commission Directive 87/250/EEC, Council Directive 90/496/EEC, Commission Directive 1999/10/CE, Directive 2000/13/EC of the European Parliament and of the Council, Commission Directives 2002/67/EC and 2008/5/EC and Commission Regulation (EC) No 608/2004.

Additionally, according to Art. 4, an indication of the characterisation of those nutrients or substances needs to be included. Subsequently, a daily recommended intake dose and a warning against excess needs to be available. Otherwise, the general labelling requirements for foods are intended for the final consumer, following the Food Information Regulation (EU) No 1169/2011, and thus could include a marking of nanoscale nutrients in foods (SRU, 2011).

Furthermore, consumers will be informed by appropriate instructions on the packaging. In principle, therefore, a preventive-oriented handling of food supplements is assured. It is problematic that no distinction is made in the authorisation between nano- and macro-scale nutrients, and therefore separate consideration is not ensured in the course of the safety assessment. In this context, it should also be kept in mind that the test requirements for the recordings of nutrients in the positive list do not consider nanospecific properties and therefore cannot contribute to a preventive-oriented safety assessment (Hansen, 2009).

In addition to the lack of distinction of nutrients based on size, it is unfortunate that the disclosure requirement does not require information on nanoscale components. This means that the authorities will not get any information about where food supplements in nanoscale are used in this way. The provision of information to consumers needs to be upgraded (SRU, 2011).

D.3.09 (Food) Commodities

Commodities are defined by the German Food and Feed Code Art. 2 para. 6 (LFGB) as objects that people come into contact with – such as clothing. Specific legal regulations exist, for example, for food commodities (e.g. washing, packaging and kitchen appliances) and consumer goods with certain contact to the body (e.g. textiles, leather products, jewellery and personal care products, toys, baby products and novelty products). Instruments for their regulation are in the LFGB or in the more concrete Commodities Regulation (*Bedarfsgegenständeverordnung – BedGstV*).¹⁴⁹ If individual provisions contained therein are not more specialised, the provisions of the Equipment and Product Safety Act also apply (Geiß et al., 2005).

Food contact materials must comply with the general safety provisions of Regulation (EC) No 1935/2004 on materials and articles that come into contact with foodstuffs. In accordance with this regulation, materials intended to come into contact with food must not endanger human health or cause an unacceptable change in the composition of food. The business operator has the responsibility to ensure this, regardless of the particle size of the substance or type of material used (Working Group 3 of the NanoKommission, 2010).

¹⁴⁹ Consumer Goods Ordinance (*Bedarfsgegenständeverordnung – BedGstV*) of 23 December 1997 (Federal Law Gazette 1998 I p. 5) last amended by Art. 1 of the Directive of 24 June 2013 (Federal Law Gazette I p. 1682).

In food packaging, but also in other materials and articles that are intended to come into contact with food (food commodities), nanomaterials are already used, for example titanium nitride in PET beverage bottles (EFSA, 2009a). The instruments for the regulation of substances in food commodities can be found in a number of regulations at European and national level. The framework provides Regulation (EC) No 1935/2004, on materials and articles intended to come into contact with food, that enables the adoption of specific measures for certain food commodities. Such measures are found in Regulation (EC) No 450/2009, on active and intelligent materials and articles intended to come into contact with food,¹⁵⁰ which is connected to Regulation (EC) No 10/2011, on plastic materials and articles intended to come into contact with food¹⁵¹ (Working Group 3 of the NanoKommission, 2010).

Furthermore, Directive 2007/42/EC, on materials and articles made of regenerated cellulose film intended to come into contact with food,¹⁵² contains such measures. These provisions are implemented in Germany by the LFGB and enhanced by the Commodities Ordinance. A special case is made for food commodities made from plastics (Directive 2002/72/EC).¹⁵³ The LFGB (Art. 30 para. 1 and 2) prescribes that for commodities under normal or foreseeable use no hazard to health may result. The manufacturer and distributor of products is responsible for compliance. The LFGB empowers the competent Federal Ministry for Food and Agriculture (BMEL) – if this is required to ‘avert a risk to human health’ – to prohibit use, require the setting of thresholds or to order mandatory warnings for certain substances. This is done by the Commodities Regulation (BedGgstV), which stipulates certain restrictions on selected products and materials (e.g. maximum values, purity requirements and positive lists (Führ et al., 2006b)).

This rather broad authorisation has so far not been used elsewhere. Specific legal regulations only exist for a few product groups. Negative lists exist only for selected products and product groups that are especially closely related to the body. So far, there are no nanospecific restrictions, leading to the fact that the burden of proof lies with the authorities. A preventive-oriented burden of proof, which would allow control of substances with uncertain potential danger, is not provided (Working Group 3 of the NanoKommission, 2010).

¹⁵⁰ Commission Regulation (EC) No 450/2009 of 29 May 2009 on active and intelligent materials and articles intended to come into contact with food (OJ L 135, 30.5.2009, p. 3–11).

¹⁵¹ Commission Regulation (EU) No 10/2011 of 14 January 2011 on plastic materials and articles intended to come into contact with food (OJ L 12, 15.1.2011, p. 1–89).

¹⁵² Commission Directive 2007/42/EC of 29 June 2007 relating to materials and articles made of regenerated cellulose film intended to come into contact with foodstuffs (OJ L 172, 30.6.2007, p. 71–82).

¹⁵³ Commission Directive 2002/72/EC of 6 August 2002 relating to plastic materials and articles intended to come into contact with foodstuffs (OJ L 220, 15.8.2002, p. 18), last amended by the Directive of 27 March 2008 (OJ L 63, 7.3.2008, p. 6–13).

The information requirement to decide whether the handling of food commodities is preventive-oriented, in particular as the EFSA was assessing safety based on incomplete information, however, is generally able to request additional data in the approval process. With regard to the regulation of nanomaterials, however, their separate safety assessment is at present explicitly specified only for food commodities made of plastic. In addition, not enough is known at present about how to check the safety of nanomaterials. The communication instruments (e.g. traceability, declaration of conformity, marking) do not so far ensure that information is passed on and statements are made for food commodities containing nanomaterials (SRU, 2011).

This applies not only down the supply chain and forward to consumers but also towards the authorities. This lack of mandatory reporting leads to the authority having no overview of what quantities which manufacturer produces, and which food commodities, made with which ingredients, are on the market. This makes targeted controls by the monitoring authorities impossible (SRU, 2011). Requirements for precaution-oriented action do not yet exist.

Part of the problem is also the lack of transparency. Only with the restriction of certain nanomaterials would authorities initially receive information about their use. As this is currently not systematically the case, the final conclusions detailed below are drawn (SRU, 2011).

Regarding the definition of nanomaterials, there is currently no characterisation of nanomaterials in the field of food commodities. A definition should be included in Regulation (EC) No 1935/2004, which is binding on all food commodities. Such a definition should both provide legal clarity and also consider the action of preventive aspects (SRU, 2011).

Furthermore, it should be ensured that nanomaterials of the same chemical composition but a different size and surface treatment can be considered separately, since their properties may differ. Therefore, it is necessary to combine the nanomaterials into subgroups. In addition, a clause should be included to allow the definition to be adapted to current technical and scientific developments (Working Group 3 of the NanoKommission, 2010).

As far as the independent approval of nanomaterials is concerned, to ensure that only safe food commodities are within consumer range, and in view of the possible changes in properties of nanomaterials, it should be recorded in Regulation (EC) No 1935/2004 that nanomaterials be independently added to the positive list (Annexes I/II). It would also be useful to ensure that all uses of nanomaterials in food commodities require an authorisation. In this respect, it should further be examined how the individual measures to date cover all relevant uses. If it cannot be ruled out that nanomaterials could enter into food commodities without prior authorisation, it should be examined whether a single measure for nanomaterials can be adopted (SRU, 2011).

For monitoring, as authorities lack the necessary information to control nanomaterials effectively, a nanoproduct register that lists the manufacturers and their applications could be helpful in this respect. A reporting requirement should be required for monitoring in order to ensure market transparency. Regulation (EC) No 1935/2004 provides a legal basis for such additional individual measures that could be applied to nanomaterials in fields where no specific regulations exist at present. Nanospecific testing procedures should be included on the level of the EFSA guidelines for the safety evaluation of substances used in food contact materials as a prerequisite for authorisation of nanomaterials (SRU, 2011).

Potential future options for regulating all types of material or classes of substances are not specifically covered in existing legislation and could include tools such as an authorisation procedure subject to restrictions (e.g. restrictions on use). There is a need to introduce labelling of commodities that contain nanomaterials to enable traceability across the supply chain.

D.3.10 Biocides

Nanomaterials, in particular nanoscale metals (e.g. silver, copper, boron and their oxides), are used for their biocidal effect, for example in surface coatings, bulking agents or cleaning substances (European Parliament, 2010b). The instruments were regulated in the Biocides Directive 98/8/EC,¹⁵⁴ which was replaced by the Biocidal Products Regulation No 528/2012/EC¹⁵⁵ (European Parliament, 2010b) transposed in the German Biocide Notification Ordinance.¹⁵⁶ While nanomaterials are not expressly addressed in the proposed regulation, the Parliament explicitly proposed their regulation in its resolution and recommended corresponding changes. In a joint position, the European Parliament and the Council concluded that they need to be able to communicate some rules on nanomaterials (European Parliament, 2010b).

The following remarks refer to the proposal from the EP (European Parliament, 2010b). The provisions lay down that products must not be placed on the market unless they have successfully undergone an extensive authorisation procedure. This is practically equivalent to a preventive ban with an authorisation option (Working Group 3 of the NanoKommission, 2010).

¹⁵⁴ Directive 98/8/EC of the European Parliament and of the Council of 16 February 1998 concerning the placing of biocidal products on the market (OJ L 123, 24.4.1998, p. 1–63) last amended by Directive of 6 October 2009 (OJ L 262 p. 40–42).

¹⁵⁵ Regulation (EC) No 528/12 of the European Parliament and of the Council of 22 May 2012 concerning the making available on the market and use of biocidal products (OJ L 167, p. 1–123).

¹⁵⁶ Biocide Administration Ordinance (*Biozid-Zulassungsverordnung – ChemBiozidZulV* (Regulation on the authorization of biocidal products and other chemicals legal procedures to biocidal products and biocidal active ingredients) *Verordnung über die Zulassung von Biozid-Produkten und sonstige chemikalienrechtliche Verfahren zu Biozid-Produkten und Biozid- Wirkstoffen*) of 4 July 2002 (Federal Law Gazette I p. 2514) last amended by Art. 15 of the directive of 22 August 2006 (Federal Law Gazette I p. 1970).

The reason for this strict control prior to placing on the market is that, regardless of their chemical properties, biocidal products are basically assumed to have potentially harmful effects on human or animal health or an unacceptable impact on the natural balance. In the context of the authorisation procedure, applicants must submit research studies as evidence to prove that this is not the case. In these areas of legislation, a two-tier process is implemented: assessment of active substances and inclusion in a positive list valid throughout the EU and an authorisation of substances or products at national level. As a minimum requirement for authorisation, a product must contain only substances included in the positive list. Nanomaterials are part of this, despite the lack of explicit anchoring (Working Group 3 of the NanoKommission, 2010).

With the designated risk assessment, however, nanospecific risks cannot be properly identified and evaluated. The recommendation is therefore for a specific risk assessment with promising test strategies and test methods that are addressed within a specific guideline (UBA, 2009a). While the proposal from the Commission (European Commission, 2009b) provides no nanospecific regulations, they are explicitly included in the list of demands in the parliamentary resolution on biocides. According to the Commission, the term ‘active substance’ includes nanomaterials in any case (European Commission, 2009a). However, less attention is paid in current product safety law to environmental protection. As part of the risk assessment and risk management, risks that could come from nanomaterials are taken into account (Hansen, 2009).

A review of the adequacy of the risk assessment and risk management is carried out, depending on the legal framework, either pre-market by monitoring and notification procedures (such as in medical products, novel foods or pesticides) or in the context of market surveillance (e.g. for cosmetics and consumer goods subject to the Directive on general product safety (European Commission, 2008b)). Specific regulatory efforts with explicit inclusion of nanospecific regulations exist in the areas of cosmetics, medical devices and food (Eisenberger et al., 2010).

The Biocidal Products Regulation (BPR) provides for a ‘comparative assessment’ of less harmful products. This also means that active substances or products having effects that are on the borderline between acceptable and unacceptable may be granted provisional authorisation with the note that ‘concerns remain’; they must then undergo comparative assessment. The aim of this provision is to substitute them with active substances or products of less concern. However, comparative assessment tied to requirements for candidates of substitution under the former Biocidal Products Directive has rarely been applied in practice, although it has been in force since 1998 (Working Group 3 of the NanoKommission, 2010). For the preventive-oriented regulation of nanomaterials in biocides, it is concluded that the following measures are necessary.

For substance approval, the nanoscale active ingredient must be subjected to its own safety assessment and should be independently subject to authorisation. Since uncertainty still exists both in terms of risk assessment and the detection methods for nanomaterials, the burden of proof should be adapted for the purposes of the precautionary principle. An authorisation may hereafter be granted if the risk assessment methods are based on the specific characteristics of nanomaterials adequately addressed by current knowledge, and methods of detection are presented. They should be subject to a re-examination as soon as general test requirements have been defined to consider whether the exclusion criteria must be complemented (Hansen, 2009).

If product approval is concerned, since nanomaterials can be used as active ingredients as well as for other purposes in biocidal products, and therefore a detailed study of the product is required, the risks to the environment and health should be reviewed separately in the use of nanomaterials in biocidal products. Furthermore, it cannot be assumed that nanoscale-active ingredients that additionally have a low solubility in water or in physiological media, as well as a high biopersistence, have a low risk potential. In addition, criteria for candidates for substitution should be discussed to enable application of comparative assessment (Hansen, 2009).

For identification, in order to ensure consumer information, both biocidal and treated articles and materials should be labelled. In this respect, labelling for all treated articles and materials should be mandatory, with all biocides to be named, along with the nanoscale-active ingredients, and 'nano' put after the name (European Parliament, 2010b).

In addition, it should also be mandatory to designate the labelling of nanoscale agents, treated materials and objects and also to identify other nanoscale ingredients in biocidal products (European Parliament, 2010b).

In order to obtain approval for an active substance and/or a biocidal product, a dossier for each one must be submitted. For the active substance, the dossier must fulfil specific information requirements, set out in Annex II of the BPR, whereas biocidal products must fulfil the information requirements set out in Annex III. The data elements in Annex II and III comprise a Core Data Set and an Additional Data Set. The Core Data Set is the basic data that, in principle, must be provided for all active substances. There may, however, be cases where it is not possible to generate all data elements belonging to the Core Data Set. This applies in special cases where physical or chemical properties render it impossible or unnecessary to provide certain data. The Additional Data Set to be provided depends on the physico-chemical properties of the chemical in question, the type of products the active substance is applied in and the exposure patterns that are related to that use (Working Group 3 of the NanoKommission, 2010).

For each endpoint in the Core Data Set, at least one key must be submitted, and the study has to be reliable and adequate for use in the risk assessment (ECHA, 2013). According to Annex II of the BPR, the tests submitted to support the approval of an active substance must be conducted according to the methods laid out in Regulation (EC) No 440/2008, which lays down test methods pursuant to REACH. For most Core Data Sets, the test methods described in this regulation are equivalent to relevant OECD guidelines for the specific tests and, if a test method is inappropriate or not described in this regulation, it is possible to use other scientifically suitable methods. However, justification for the appropriateness of these alternative methods is required. It is stated that ‘when test methods are applied to nanomaterials, an explanation shall be provided of their scientific appropriateness for nanomaterials’ (Hansen, 2009).

Finally, where applicable, even where technical adjustments have been made in order to respond to the specific characteristics of nanomaterials, there are currently no actual OECD standard test guidelines for health, hazard and ecotoxicity testing of nanomaterials (OECD, 2010). For these, or for any future new materials, Material Safety Data Sheets should be made mandatory in order to ensure that information on nanoscale-active ingredients in the supply chain is not lost; all nanomaterials, regardless of whether they are contained in a substance classified as a hazardous biocidal product, should be included, as well as all relevant information and reviews, and recommended follow-up risk management measures. Uncertainties in the assessment should be communicated. Finally, for monitoring, it should be made possible for the authorities to gain an overview of the biocides containing nanomaterials being marketed and the nanospecific data already available on them (Working Group 3 of the NanoKommission, 2010).

D.3.11 Plant protection products

Bringing plant protection products on the market was governed by the Plant Protection Directive 91/414/EEC,¹⁵⁷ repealed on 14 June 2011 by the European Plant Protection Regulation (EC) No 1107/2009,¹⁵⁸ transposed into German Law in the German Plant Protection Act.¹⁵⁹ This legal framework provides for the evaluation, registration, marketing authorisation and control of plant protection products and active ingredients contained therein to reduce cost and effort, increase efficiency and lead to more environmentally sound applications (SRU, 2011).

¹⁵⁷ Council Directive 91/414/EEC of 15 July 1991 concerning the placing of plant protection products on the market (OJ L 230, 19.8.1991, p. 1–32).

¹⁵⁸ Regulation (EC) No 1107/2009 of the European Parliament and of the Council of 21 October 2009 concerning the placing of plant protection products on the market and repealing Council Directives 79/117/EEC and 91/414/EEC (OJ L 309, 24.11.2009, p. 1–50).

¹⁵⁹ German Plant Protection Act (*Pflanzenschutzgesetz – PflSchG* (Law on Protection of Cultivated Crop) *Gesetz zum Schutz der Kulturpflanzen*) of 6 February 2012 (Federal Law Gazette I p. 148, 1281) last amended 31 August 2015 (Federal Law Gazette I p. 1474).

Pesticides are subject to authorisation in the country where they are first placed on the market. Only those plant protection products containing active substances that are approved and that do not entail risks for humans, animals or the environment may be authorised. Neither the current Plant Protection Directive nor the new Plant Protection Regulation contains nanospecific regulations (Working Group 3 of the NanoKommission, 2010). A separate labelling of nanomaterials is not provided for. According to the Plant Protection Regulation, pesticides need to be specifically designated according to the Chemicals Act (Art. 65). Any additional specific rules for the labelling of plant protection products must be adopted from the Commission (Art. 84). As far as potential groundwater contamination is concerned, in the context of the authorisation procedure, plant protection products (and biocidal products) are regulated primarily on the basis of the precautionary principle (Hansen, 2009).

The risk assessment ‘toolkit’ for (chemicals, biocidal products and) plant protection products includes the option of making assumptions on precautionary sources based on ‘realistic worst case’ scenarios where exposure data are lacking, while a lack of data on the impact side is compensated for by using weighting factors. The aim of this procedure is to ensure that eventual gaps in existing knowledge do not lead to an underestimation of the risk (Hansen, 2009).

In addition, based on the limit for active pesticidal substances in drinking water (Art. 4 in conjunction with Annex I Groundwater Directive), authorisation is granted only if the amount of the substance entering the groundwater is established to be $< 0.1 \mu\text{g/l}$, regardless of any other effects on the natural balance. This concentration limit seems relatively high if the properties of nanomaterials are considered and, for nanoparticles, should be changed to a lower concentration (Working Group 3 of the NanoKommission, 2010).

Under the Regulation on Plant Protection Products, the precautionary principle is supplemented in a specific way by an additional legislative tool – exclusion criteria – in the interests of hazard prevention. This tool is retained in the Commission Proposal on the Revision of European Law on Biocidal Products. In both cases, the exclusion criteria relate to the assessment of the active substances. Exclusion criteria mean that where a substance is found to possess particular intrinsic properties that give cause for concern regardless of potential exposure or other risks, then that substance is automatically excluded from the Community list (Annex I); in other words, it cannot be approved as a permitted substance. Exclusion criteria are carcinogenic, mutagenic, toxic to reproduction, endocrine-disrupting, persistent, bioaccumulative or toxic qualities.¹⁶⁰

¹⁶⁰ Regulation (EC) No 1107/2009 concerning the placing of plant protection products on the market, Art. 4 para. 1 in conjunction with Annex II No 3.7.2 includes a provision stipulating that an active substance can only be approved if it is not considered to be a PBT.

The first step in the assessment of a substance by the authorities is to establish whether such properties are present; if this is confirmed, the assessment process is terminated and a decision is issued that the substance cannot be authorised unless it fulfils one of the exemption criteria permitting inclusion of the substance in Annex I of the Community list. To ensure the greatest possible degree of harmonisation of the various provisions, taking into account existing approaches (such as a uniform definition at European level) in the context of the Biocidal Products Directive and the Regulation on Plant Protection Products – regardless of the products and substances concerned – is advocated (Working Group 3 of the NanoKommission, 2010).

The Biocides Regulation contains the necessary instruments for the regulation of substances. Protection is ensured by the fact that not only the agents but also the biocidal products shall be authorised with this level of protection. However, this depends on the conditions for approval. Additionally, instruments are available within the supply chain to provide consumers with information, and the authorities are provided with a view of the market by the fact that in addition to the active compounds, the biocide itself must be admitted. This should also apply to plant protection products, although most instruments do not take into account the peculiarities of nanomaterials. Consequently, no independent approval of nanoscale-active ingredients is required – something that could have provided an indication of nanoscale – and it is not guaranteed by the MSDS that information about nanoscale substances is passed on within the supply chain. In addition, the authorities receive no nanospecific information, nor is this communicated through the register. A preventive-oriented handling of nanomaterials in plant protection products is therefore not guaranteed. However, the European Parliament criticises most of these deficits in its resolution and has made appropriate suggestions (SRU, 2011).

D.3.12 Summary

The definition of nanomaterials in the regulations is an important step. However, a change is needed in the definition to create more legal certainty and also to strengthen precaution and therefore, initially, size should be used as the only parameter and consequently the criteria ‘insoluble’ and ‘biologically resistant’ should be omitted. According to current knowledge, there is reason to raise the size limit of 100 nm, as this should be subject to constant review. In order to clarify the information about size, it should be determined how many of the particles must fall under this size limit, while the proportion in relation should be indicated on the particle quantity. Furthermore, it should be ensured that nanomaterials of the same chemical composition but different size and surface treatment can be considered separately, since their properties may differ. Therefore, it may be necessary to group the nanomaterials into subgroups (Hansen, 2009).

The labelling intended by the regulations is welcomed as the right step in the direction of consumer information. In some cases, however, it is argued that the addition of ‘nano’ in the ingredient list is very meaningful and, additionally, the particle size should also be specified. Since the assessment of the risks is based on various factors actually associated with nanomaterials (e.g. size, surface treatment, involvement in a matrix), an indication as such cannot do justice to the complexity. Therefore, it is considered necessary to give the manufacturer or retailer the obligation of starting to inform consumers with simple measures.

It seems justified that most regulations provide a precautionary clause which allows the European Commission to take action, even if there is only a ‘potential risk’ to human health. To determine the ‘potential risk’ of nanomaterials, criteria for a preliminary risk assessment are first needed, since in principle, the regulations contain no provisions concerning specific testing procedures; the suitability and adequacy of tests undertaken is assessed in the context of the authorisation procedure and laid down by the relevant authorities, as are the conditions for use and, where necessary, specific requirements regarding their use and suitability.

Overall, it is concluded that the EU Regulations and Directives form a good basis for the control of nanomaterials. The fact that the safety evaluation EFSA Guidelines do not currently contain provisions for nanospecific testing procedures for the authorisation of nanomaterials is critical. Also, the fact that so far no instruction or clarification has been issued to the effect that nanomaterials are required to undergo authorisation or inclusion in lists or annexes is an issue. However, the lack of labelling makes it difficult to ensure traceability down the supply chain.

D.4. Post consumption: disposal and reuse

The analysis focuses on legislation on waste, in particular waste flow and the disposal of waste as well as demands on waste incineration plants. As far as legislation on water is concerned, reference is made to comments in previous sections. With regard to the post-consumption phase and the disposal of products in whose manufacture nanomaterials were used, there is a lack of knowledge concerning many scientific issues (Tellenbach-Sommer, 2010); for example, whether and in which form and size nanomaterials can escape from a used product.

Waste legislation makes use of several instruments in order to implement the prevention, recovery and disposal of waste (Franßen, 2007). Principally, the instruments are also useful in terms of waste containing nanomaterials, but lack – due to the lack of knowledge about the behaviour of nanomaterials in the various waste paths – material specifications for them. Beyond that, waste containing nanomaterials is – like other waste – not treated separately. Nanomaterials are rather treated as the material or substance in which they are contained (Franco, et al., 2007).

This is not suitable in terms of the requirements of the precautionary principle, as a separate consideration of certain wastes containing nanomaterials should be indicated because of possible changes in properties of nanomaterials during their degradation. However, to avoid waste, requirements for the design of products are especially relevant, in particular prohibitions and limits for substances. However, only the dangerous properties of known pollutants are addressed and therefore only exposure that is already recognised as dangerous has to be avoided. Consequently, the measures cannot address unknown risks of nanomaterials (Führ et al., 2007a).

In the same way, the potential range of effects of nanomaterials is not currently taken into account in the regulations, for example emissions from waste incinerators or landfill, since neither their behaviour during disposal nor its harmful effects can be reliably predicted. Here, precautionary bans or the scientific evidence for an evaluation are missing (SRU, 2011).

Overall, it therefore cannot be assured that, with the current instruments, a possible impact on human health and the environment from nanomaterials can be ruled out. This is because the substantive provisions are aimed at risk prevention rather than on safety. Although an attempt is made to avoid exposure, and risk as a whole, it is effective only for those substances that are already classified as hazardous (SRU, 2011). Finally, there has been little discussion in the literature on the importance of nanomaterials for waste management (Ostertag et al., 2007).

D.4.01 Disposal of waste

Legislation on waste is substantially determined by Community regulations, which is why these are in the foreground of the following analysis. The analysis focuses on the legislation of waste, in particular on waste flow and disposal, as well as on its incineration. Whether and how the individual nanomaterials, in the form of liquid, solid or sludgy discards, are classified as hazardous or non-hazardous waste under European law is unclear. The classification for each individual waste product is carried out by a normative classification according to the European List of Wastes¹⁶¹ (LOW) (former the European Waste Catalogue¹⁶² (EWC)), which in Germany has been transposed into the German Ordinance on the European List of Waste.¹⁶³

¹⁶¹ Directive 2008/98/EC of the European Parliament and of the Council of 19 November 2008 on waste and repealing certain Directives (OJ L 312, 22.11.2008, p. 3–30).

¹⁶² Commission Decision 2000/532/EC of 3 May 2000 replacing Decision 94/3/EC establishing a list of wastes pursuant to Article 1(a) of Council Directive 75/442/EEC on waste and Council Decision 94/904/EC establishing a list of hazardous waste (OJ L 226, 6.9.2000, p. 3–24), last amended by Decision of 18 December 2014 (OJ L 370, 30.12.2014, p. 44–86).

¹⁶³ Waste Catalogue Ordinance (*Abfallverzeichnis-Verordnung – AVV* (Ordinance on the European Waste Catalogue) *Verordnung über das Europäische Abfallverzeichnis*) of 10 December 2001 (Federal Law Gazette I p. 3379) last amended 24 February 2012 (Federal Law Gazette I p. 212).

Waste included in Annex I or II of former Directive 91/689/EEC¹⁶⁴ was considered throughout the EU as dangerous. Today, all the types of waste provided with an asterisk (*) are still considered to be hazardous waste (SRU, 2011). The classification is based on the H-criteria (flammable, irritant, harmful, toxic, carcinogenic, corrosive, mutagenic and toxic for reproduction). Nanospecific properties have not previously been listed in Annexes I and II (waste with a hazardous property and source type (or are dangerous and part of Annex III)).

This classification of waste applies to hazardous substances (Annex to Decision 2000/532/EC LOW).¹⁶⁵ Thus, the methods employed in the latest version of Annex V to Directive 67/548/EEC in accordance with Art. 1 para. 4 to Directive 91/689/EEC, i.e. the hazardous criteria, such as mutagenic or ecotoxic, are still included (SRU, 2011). Nanospecific risks can so far be considered for classification only as their ingredients have substances listed in Annexes I and II or have hazardous properties listed in Annex III to Directive 91/689/EEC.

This may also be true for production waste of nanomaterials. It will be decisive that nanospecific risks in chemicals regulation will actually be determined so that they can be taken into account in a classification according to the waste legislation (SRU, 2011). If assessments of hazardous substances and their classification according to waste law do not exist, or produce waste from nanomaterials to which an existing waste code may not be assigned, there is the possibility to subsume this under chapter 16 (wastes not otherwise specified) in the LOW (SRU, 2011).

In particular, for waste from nanomaterials with a significant level of concern, a separate specific waste code for their safe disposal appears necessary, as long as a corresponding classification under hazardous substances does not exist. According to the Recycling Law (KrWG),¹⁶⁶ separate storage can be necessary for waste with the aim of recycling in accordance with Art. 9 para. 1. Thereby complied with are the standards in Art. 7 para. 2 to 4 and Art. 8 para. 1, which have in particular the aim of ensuring a safe and proper, environmentally sound recycling of wastes and of protecting natural resources (SRU, 2011).

¹⁶⁴ Council Directive 91/689/EEC of 12 December 1991 on hazardous waste (Official Journal L 377, 31.12.1991 p. 0020–0027).

¹⁶⁵ See also Art. 6 para. 7 Decision 2000/532/EC: ‘The classification as well as the R numbers refer to Council Directive 67/548/EEC of 27 June 1967 on the approximation of laws, regulations and administrative provisions relating to the classification, packaging and labelling of dangerous substances (OJ L 196, 16.8.1967, p.1) and its subsequent amendments. The concentration limits refer to those laid down in Directive 88/379/EEC of 7 June 1988 on the approximation of laws, regulations and administrative provisions of the Member States relating to the classification, packaging and labelling of dangerous preparations (OJ L 187, 16.7.1988, p. 14) and its subsequent amendments set’. See for German law also the comments in No 3 of the Annex to AVV.

¹⁶⁶ Recycling Law (*Kreislaufwirtschaftsgesetz – KrWG* (Law to promote circular economy and ensuring the environmentally friendly management of waste) *Gesetz zur Förderung der Kreislaufwirtschaft und Sicherung der umweltverträglichen Bewirtschaftung von Abfällen*) of 24 Februar 2012 (Federal Law Gazette I p. 212), last amended 20 November 2015 (Federal Law Gazette I p. 2071).

For waste disposal, the separated handling results from Art. 15 para. 3 whereas regarding the scope and limitation of separation, the requirements of Art. 10 KrWG are referenced. A separate storage of waste oils, which cannot be recycled, is required to the extent that it is necessary to maintain the exclusion of the waste from recycling and to maintain a public welfare friendly disposal of waste (Art. 10 para. 1 KrWG) (SRU, 2011).

Moreover, the Federal Administrative Court¹⁶⁷ affirmatively supports so-called ‘intercategorical separate storage’. This concerns the mixing of waste for disposal and waste for recycling and is also governed by Art. 9 para. 2 and 10 para. 1 no. 2 KrWG. As long as there is an evidence of the hazardous composition of wastes from the production or use of nanomaterials, and there is a alarming potential, the wastes should be kept separate, both at source and in further disposal (SRU, 2011). This procedure makes it possible to exclude such waste from the material cycle until a safe method of disposal or elimination is found, depending on further knowledge on the economics and dangers of the landfill disposal route and threats to groundwater. In addition, an obligation to tender delivery or transfer duty could exist for hazardous waste containing nanomaterials, in accordance with Art. 17 para. 4 KrWG.

The construction and operation of landfills is subject to an authorisation following Art. 9 of the Landfill Directive 1999/31/EC,¹⁶⁸ and a special permit procedure for all classes of landfills according to the general approval requirements in Art. 9 of Directive 2006/12/EC¹⁶⁹ and Directive 2008/1/EC must be performed. The transposition of those directives is through the German Landfill Ordinance¹⁷⁰ and the Ordinance on the depositing of waste.¹⁷¹

The European Landfill Directive distinguishes between different classes of landfills for hazardous waste, non-hazardous waste and inert waste. The allocation of waste to a landfill class is done according to specific grouping criteria, which are set out in Council Decision 2003/33/EC (Working Group 3 of the NanoKommission, 2010).¹⁷²

¹⁶⁷ Federal Administrative Court (BVerwG) – 3 C 4/00 – of 15.6.2000, para. 19.

¹⁶⁸ Directive 1999/31/EC of the Council of 26 April 1999 on the landfill of waste (OJ L 182, 16.7.1999, p. 1–19).

¹⁶⁹ Directive 2006/12/EC of the European Parliament and of the Council of 5 April 2006 on waste (OJ L 114, 27.4.2006, p. 9–21)

¹⁷⁰ Landfill Ordinance (*Deponieverordnung – DepV (Ordinance on landfills and long-term storage) Verordnung über Deponien und Langzeitlager*) of 27 April 2009 (Federal Law Gazette I p. 900), last amended 2 May 2013 (Federal Law Gazette I p. 973).

¹⁷¹ Waste Storage Ordinance (*Abfallablagerungsverordnung – AbfAbIV (Regulation on the environmentally sound deposition of municipal waste) Verordnung über die umweltverträgliche Ablagerung von Siedlungsabfällen*) of 20 February 2001 (Federal Law Gazette I p. 305), last amended 13 December 2006 (Federal Law Gazette I p. 2860).

¹⁷² Decision of the Council 2003/33/EC of 19 December 2002 establishing criteria and procedures for the acceptance of waste at landfills pursuant to Article 16 of and Annex II to Directive 1999/31/EC (OJ L 11, 16.1.2003, p. 27).

They are oriented by the limits and behaviour of certain pollutants and a threshold for the total content of organic parameters (LOI or TOC). Whether these criteria cover potential nanomaterials risks and thus allow a general and safe disposal of nanomaterials is not clear (Führ et al., 2007b). As a solution, a landfill class for nanomaterials could be developed. However, it seems better at this point to exclude nanomaterials from landfills unless their safety assessment can be done properly. To start with, this will require more information about the materials and their behaviour (SRU, 2011).

Consequently, nanomaterials and nanoparticles that move from the landfill into groundwater are not covered by the landfill operators measuring and monitoring programs during the operational phase or after the final closure of a landfill. Nanomaterials from the landfill will leachate with, for example, non-degradable carrier nanomaterials such as C-60 fullerenes, leading to a mobilisation of pollutants in waste or soil. However, they would be covered by existing measurement and monitoring programmes (Working Group 3 of the NanoKommission, 2010).

In order to capture nanoparticles, which pose a threat to the groundwater itself, suitable parameters within measuring and monitoring programmes will have to be explored. This could be established in the requirement for groundwater measurement in Annex III No 4 B of the Landfill Directive (SRU, 2011).

In view of these deficiencies, and to propose several changes, a distinction must firstly be made between the different problems of waste from production and municipal waste. Nanomaterial-containing industrial waste arising from the production and processing of nanomaterials can be detected separately directly at its source. Nanomaterial-containing municipal waste, however, presents a particular challenge in this respect, as it is impractical to establish separate collection or treatment. Therefore, the existing rules for the recovery and disposal of waste should be reviewed to incorporate sufficient features regarding nanoscale substances. Therefore, the actions detailed below, which would allow a precaution-oriented handling of nanomaterial-containing waste production, are proposed (SRU, 2011).

Regarding classification as hazardous waste, based on the lack of knowledge of the behaviour of nanomaterials in the waste path, and the peculiarities of nanomaterials, it is justified for the purposes of precautionary considerations to assume that a nanomaterial production site produces hazardous waste containing nanomaterials (correspondence is already provided in Switzerland (Jordi, 2010)). However, they already receive treatment if they are classified as dangerous substances according to the CLP Regulation and the waste is therefore appropriately classified as dangerous (European Commission, 2008e; European Commission, 2008b).

If necessary, this requires the award of one or more separate waste codes, which also requires inspections (European Parliament, 2009; Führ et al., 2006a). Classification as a hazardous waste carries special responsibilities (such as reporting requirements, use of certain methods of treatment or mixing prohibitions (Working Group 3 of the NanoKommission, 2010)) that need to be designed to ensure careful handling.

Regarding the handling of nanomaterial-containing waste, handling nanomaterial-containing production waste according to the rules that apply to other wastes is not recommended. There is a need for research. Manufacturers and users also have a duty to collaborate on possible solutions. Nanomaterial-containing waste should be treated separately from source (SRU, 2011).

Manufacturing and processing plants should therefore be obliged to collect production waste containing nanomaterials separately, and to store and deliver it to the appropriate treatment. For landfill, with regard to the disposal of production waste containing nanomaterials, it should first be checked if the criteria are suitable to determine the hazards of the nanomaterials risks and assign the correct class of landfill (European Parliament, 2009; Führ et al., 2006a).

Nanospecific characteristics should be considered and precautions should also be taken – e.g. how to deal with ignorance and uncertainty (SRU, 2011). It should also be clarified whether nanomaterials with existing measurement and monitoring programmes can be recorded by a separate entry for nanomaterials in the established List of Waste 2000/532/EC, a revision of the criteria for the acceptance of waste at landfills in Decision 2003/33/EC, or by a review of the relevant emission limit threshold for waste incineration as based on particle number and/or surface complement of the mass values (SRU, 2011).

For take-back systems, a basic distinction between municipal waste containing nanomaterials and waste that does not is neither practical nor effective (SRU, 2011). However, it should be investigated whether the separate collection of certain nanomaterial-containing wastes could be arranged because of the anticipated amount or special characteristics.

Where the measurement methods are concerned, the – to be developed – measuring method for nanomaterials must be suitable with regard to the drop path (for example, exhaust air from treatment processes, waste gases from incineration). It is first necessary to explore the behaviour of nanomaterials in sewage sludge (Führ et al., 2006b; Burkhardt et al., 2010).

If there are relevant findings, prohibitions or thresholds can be formulated and incorporated into the regulation. The thresholds would require the determination of appropriate parameters able to map the dangers of nanomaterials (Hansen, 2009).

Furthermore, in view of nanomaterials, it is necessary to develop methods of measurements for the analysis of the sludge. Then the competent authorities could – if they are aware of the problem – also order the investigation of the sludge with respect to nanomaterials. If it turns out that certain nanomaterials raise special problems, they should be checked within the scope of study to be performed (SRU, 2011).

Finally, where waste incineration is concerned, it is principally necessary to determine the applicability of the conventional limits¹⁷³ for nanomaterials or the need for nanospecific limits. In this context, it should also be clarified if the emissions should be measured by the mass concentration in particles per cubic metre (Führ et al., 2006b; European Parliament, 2009). Moreover, as there might be no suitable filters for the retention of nanomaterials, it should be verified if an incentive for their development can be created. In addition to the limit values, the requirements for the combustion process must also be developed. This applies to minimum temperature and minimum residence levels (Führ et al., 2006b).

In terms of nanomaterial-containing wastes, the provisions of the 17th BImSchV on the incineration and co-incineration of waste¹⁷⁴ are particularly vital for the immission control by approval process instrument, or, if it is not subject to licensing, the enforcement by construction permit (SRU, 2011).

The 17th BImSchV transposes the Waste Incineration Directive 2000/76/EC into German law. A declaration of nanowaste should be made possible. This regulation is the basis for a proper separation, allocation and management of waste. As part of the planning and approval process, according to Directive 2011/92¹⁷⁵ an environmental impact assessment must be carried out under special circumstances, and the requirements of the Ordinance on landfills and long-term storage (*Deponieverordnung* – DepV) must also be observed (SRU, 2011).

The DepV applies to the construction, operation, closure and aftercare of landfills and long-term storage and treatment, disposal or storage of waste. In order to ensure adequate disposal, landfill sites are divided into different classes (landfill class 0 to 4) and waste is assigned to them against the criteria of Annex III No 2 DepV (Working Group 3 of the NanoKommission, 2010).

¹⁷³ Directive 2000/76/EC of the European Parliament and of the Council of 4 December 2000 on the incineration of waste (OJ L 332, 28.12.2000, p. 91–111).

¹⁷⁴ 17th Ordinance on the Federal Immission Control Act (*17. Bundesimmissionsschutzverordnung – 17. BImSchV* (Ordinance on Incineration and Co-Incineration of Waste) *Verordnung über die Verbrennung und die Mitverbrennung von Abfällen - 17. BImSchV*) of 8 December 2010 (Federal Law Gazette I p. 1849), last amended by Art. 1 of the Directive of 2. May 2013 (Federal Law Gazette I p. 1021, 1044, 3754).

¹⁷⁵ Directive 2011/92/EU of the European Parliament and of the Council of 13 December 2011 on the assessment of the effects of certain public and private projects on the environment (OJ L 26, 28.1.2012, p. 1–21).

Conditions for the deposition can be found in Art. 6, according to which (indicated by the waste code) certain special requirements apply to hazardous waste. Waste that cannot be disposed of in landfill is regulated by Art. 7. Little is known about the long-term behaviour of nanomaterials in landfills (Franco et al., 2007). In particular, in view of the fact that the hazard potential of nano-containing waste is largely unknown, a reasonable estimation on the proper disposal under the right conditions cannot currently be guaranteed (SRU, 2011).

Therefore, a deposition of nanomaterials should only generally be allowed under strict precautionary measures, and the immobilisation of particles should be required.

D.4.02 Recycling of waste

Recycling aims to process waste into products, materials or substances, whether for its original purpose or for a different purpose, and includes the reprocessing of organic materials. Therefore, when products are recycled out of waste containing nanomaterials, there are specifications for the design of products that must be followed (Eichert, 2010).

Otherwise, in this context, the German Sewage Sludge Ordinance (*Klärschlammverordnung – AbfKlärV*)¹⁷⁶ is of interest, which transposes the EC Sewage Sludge Directive,¹⁷⁷ amongst others,¹⁷⁸ into German law and makes it possible to confront the possible dangers of nanomaterials in sewage sludge from domestic waste.

The variety of recyclable, nanomaterial-containing consumable products shows that the recycling sector needs to be involved in studies on the health and environmental effects of nanomaterials caused by their widespread use (SRU, 2011). In this context, a distinction should be made between two categories of material flows in recycling:

- a. The first group of (recycled or reprocessed) material flows is very heterogeneous and characterised by the fact that different products are recorded together as a waste group. In addition, in the various product forms, many different, often unknown, nanomaterials are processed. This group includes electrical and electronic equipment, end of life vehicles, waste paper and a large proportion of plastics and plastic materials (SRU, 2011).
- b. The second category of (recycled) material flows contains individual, usually known nanomaterials being processed in a relatively homogeneous product group (SRU, 2011).

¹⁷⁶ Sewage Sludge Ordinance (*Klärschlammverordnung – AbfKlärV*) of 15 April 1992 (Federal Law Gazette I p. 912) last amended by Art. 74 of the Directive of 31 August 2015 (Federal Law Gazette I p. 1474)24 February 2015.

¹⁷⁷ Directive 86/278/EEC of the Council of 12 June 1986 on the protection of the environment and in particular of the soil, when sewage sludge is used in agriculture (OJ L 181, 4.7.1986, p. 6–12).

¹⁷⁸ Council Directive 91/271/EEC of 21 May 1991 concerning urban waste-water treatment (OJ L 135, 30.5.1991, p. 40–52) last amended by the Directive of 27 March 1998 (OJ L 67 of 7.3.1998, p. 29–30).

It is certain today that the variety of different nanomaterials that are involved in different recyclable products and the uncertainty as to the assessment of potential risks of treatment represents a challenge for the future. The planned use of other nanomaterials in products also indicates the following (SRU, 2011): while at the present time the number of different materials used is still relatively manageable, this field will expand massively in the future.

In addition, the individual particles could in the future not only be one element with a simple structure (such as nanosilver (Baker et al., 2005)) but also complex compounds with several elements. Studies on the relevance of nanomaterials in recycling have specified that it is almost impossible to identify the proportion of nanomaterials in the product groups. This could be true for the proportion of nanomaterial-containing products in entire product groups, where, due to large gaps in knowledge, research is necessary. Consideration of the potential health risk of nanomaterial-containing emissions in general, and in relation to recycling processes in particular, leads to the conclusions (SRU, 2011) detailed below.

While the possibility of exposure to nanoparticle-containing dusts in recycling processes cannot be excluded, in theory there is a risk that, without effective preventive measures, health damage can be caused by dust potentially containing nanomaterials as a function of dose and duration of emission load. Due to large gaps in knowledge on the properties of nanomaterials and deficits in dust measurement (which will exist for the foreseeable future) in recycling industry companies, the issues of informing workers, identifying emission sources and the jobs that may be affected by them, and an effective and comprehensive recommended health protection procedure for recycling employees need to be resolved (SRU, 2008).

In recycling processes in which nanomaterial-containing consumer products are processed, exposure to nanoparticle-containing ultrafine particles should be reduced to a minimum through technical and appropriate organisational measures, and as far as possible avoided or minimised by suitable particle protection filters for respiratory protection (possibly even respirators). This should be, according to the IG BCE, preventively maintained for at least a level of protection from persistent ultrafine dust (SRU, 2011), because for such dusts, the general dust limit does not provide adequate protection. The complication, however, is that for ultrafine particles,¹⁷⁹ there are no specific rules. Furthermore, there is increasing evidence that the level of exposure should not exceed thresholds of 100 µg/m³. In production and processing, where acute and high exposure loads occur, long-term exposure limitation for even lower doses should be considered (Hansen, 2009).

¹⁷⁹ Particles with sizes < 250 nm, referred to as fine dust; < 100 nm, referred to as ultra-fine dust.

Large gaps in knowledge on potential toxicity and also difficulties in the measurement and detection of nanoparticles, and therefore a lack of legal requirements, mean that, today, a high value is placed on prevention in the areas of manufacturing and treatment processes. Accordingly, a number of guides for implementing nanomaterials handling regulations are available.

The need for research on the basis of test results on the importance of nanomaterials in recycling is related to the general need for more research on nanomaterials. Some further nanoscale research needs are outlined below. One issue regarding the re-release of nanomaterials by dusts generated in the recycling process is that there are, so far, no confirmed findings. In particular, it is unclear whether nanomaterials bound in solid matrices regain their original shape through grinding or milling (Ostertag et al., 2007).

Nanoscale ultra-fine dust could be a potential risk to humans and the environment. Therefore, there is a need to clarify the properties and behaviour of potentially risky nanomaterials in reprocessing and recycling processes. The individual material flows in the recycle loop should be examined in detail to ascertain the nature and amount of nanomaterials involved and to obtain more information on the extent of the risks associated with a re-release of nanomaterials. The consideration of the possible effects of nanomaterial-containing products on the environment and health should also go beyond the (first) recycling process, because the nanomaterials – with corresponding consequences for labour protection – pass through the subsequent value chain and out into (global) circulation (e.g. waste paper, plastics, rubber or other). Therefore, it should be clarified which nanomaterials are recycled (e.g. recycling of PET (Polyethylene terephthalate (bottles) into fibres for clothes), reused and then possibly eventually go through another site for a second round of processing and recycling (EFSA, 2009a).

This is particularly relevant as it would mean that ultrafine particles containing nanomaterials were being released without anyone knowing when or where it was occurring. Recycling aims to process waste into products, materials or substances, whether for the original purpose or a different purpose, and includes reprocessed materials. Therefore, when products are recycled using nanomaterial-containing waste, their specifications must also be identified. In this context, it needs to be determined, before the start of recycling, what can be used again for the same purpose without any further treatment, what needs treatment and what cannot be reused. Specific requirements for this should be developed (SRU, 2011).

The Sewage Sludge Ordinance transposes the Sewage Sludge Directive 86/278/EEC into German law and contains prerequisites for the application of sewage sludge on agriculturally or horticulturally used soils (Durth, 2005).

In landscaping, i.e. coal mining, landfill cover, parks or gardens, the less stringent Soil Protection Ordinance applies. Otherwise, conditions for the application of sewage sludge must be complied with by operators of wastewater treatment plants or those who want to apply the sludge. They have to relate to the nature of the sewage sludge (Art. 4 Sewage Sludge Ordinance) and its preconditions (Art. 3). Requirements for wastewater treatment plants, however, have not been formulated. The application of sewage sludge on certain soils is prohibited, for example, on vegetable and fruit growing areas, and if the soil exceeds the specified limits for some heavy metals. Furthermore, a prohibition applies if the content of certain organic persistent pollutants or certain heavy metals in sewage sludge exceeds the specified limits. A requirement for the application is the investigation of the ground and the sludge (Führ et al., 2006b).

Nanospecific properties are not considered in either the restrictions on certain application areas and the limits for these or in the sludge limits (Führ et al., 2006b). This also applies for the sampling of soil and sewage sludge. It is positive, in this context, that the authorities have the option of extending the investigation of sludge from conventional pollutants to also include other ingredients. A systematic application of nanomaterials is hereby not guaranteed due to a lack of knowledge on the level of the applicable authorities (SRU, 2011).

This is not compatible with the objectives of preventive soil protection (Art. 1 of the Federal Soil Protection Act) and the avoidance of long-term accumulation of persistent substances. In itself, the agricultural utilisation of sewage sludge is not suitable because the risk of long-term accumulation of pollutants is linked to agricultural soils (SRU, 2004; SRU, 2008). When applying sewage sludge containing nanomaterials, substances enter the soil without sufficient knowledge of their ecotoxicological effects or information about their persistence.¹⁸⁰

In order to prevent the release of problematic substances into the environment and to minimise harm, limits and other obligations or requirements, or even substance specific prohibitions, are needed. Their observance needs to be ensured by monitoring and in some areas even by an official prior testing requirement. In many areas, however, the existing requirements are not appropriate. This is especially true if limits or thresholds are set too high or too low, or a transfer of inappropriate assessments is not inhibited (Stokes, 2009).

For example, at the prohibition or permission of a release of a substance, or the setting of a limit, initially there is always the question of whether this also applies to the nanoform and if this is even reasonable. Thus, certain substances have been classified as non-hazardous, without any specification being made on the nanoform of the substance (SRU, 2011).

¹⁸⁰ See for example the persistence of silver nanoparticles.

D.4.03 Summary

Nanomaterials are already used in different products and so are able to move from municipal solid waste into the environment. The extent to which nanomaterials in products – if they can be substituted by more environmentally friendly and suitable substances – may be prohibited or restricted in terms of the waste path should be examined. In this respect, under certain circumstances an alternative test needs to be carried out (SRU, 2011).

In some regulation drafts, bans were at least discussed and this placed the focus on the security of nanomaterials. However, waste legislation monitoring is ensured by state surveillance with repressive and preventive components and by internal monitoring. Under this system of government surveillance, obligations to provide information, consent and cooperation coexist with extensive documentation requirements. Internal monitoring is specifically ensured by the appointment of a company officer for waste. Forced to comply in this respect are the operators of facilities where hazardous waste is regularly to be found. It must be clarified to what extent nanomaterials can be released (e.g. shredding, sorting, heating, agglomeration, etc.) in the processing of waste. Research is also needed to see how much nanomaterials may interfere with or prevent recovery. Nanomaterial-containing waste is treated as if it was the material used in the macro form, with the macro form's appropriate properties; this makes proper handling of nanomaterial waste difficult from the beginning (SRU, 2011).

Currently, the assignment criteria for the different classes of landfill do not have any special features that address the presence of nanomaterials. If, however, waste containing nanomaterials is disposed of in an incinerator, the waste incineration directive has to be considered. Alongside Directive 2000/76/EC on the incineration of waste, the 17th BImSchV is implemented in Germany. However, this has the same deficiencies as other industrial systems¹⁸¹ (Führ, 2009).

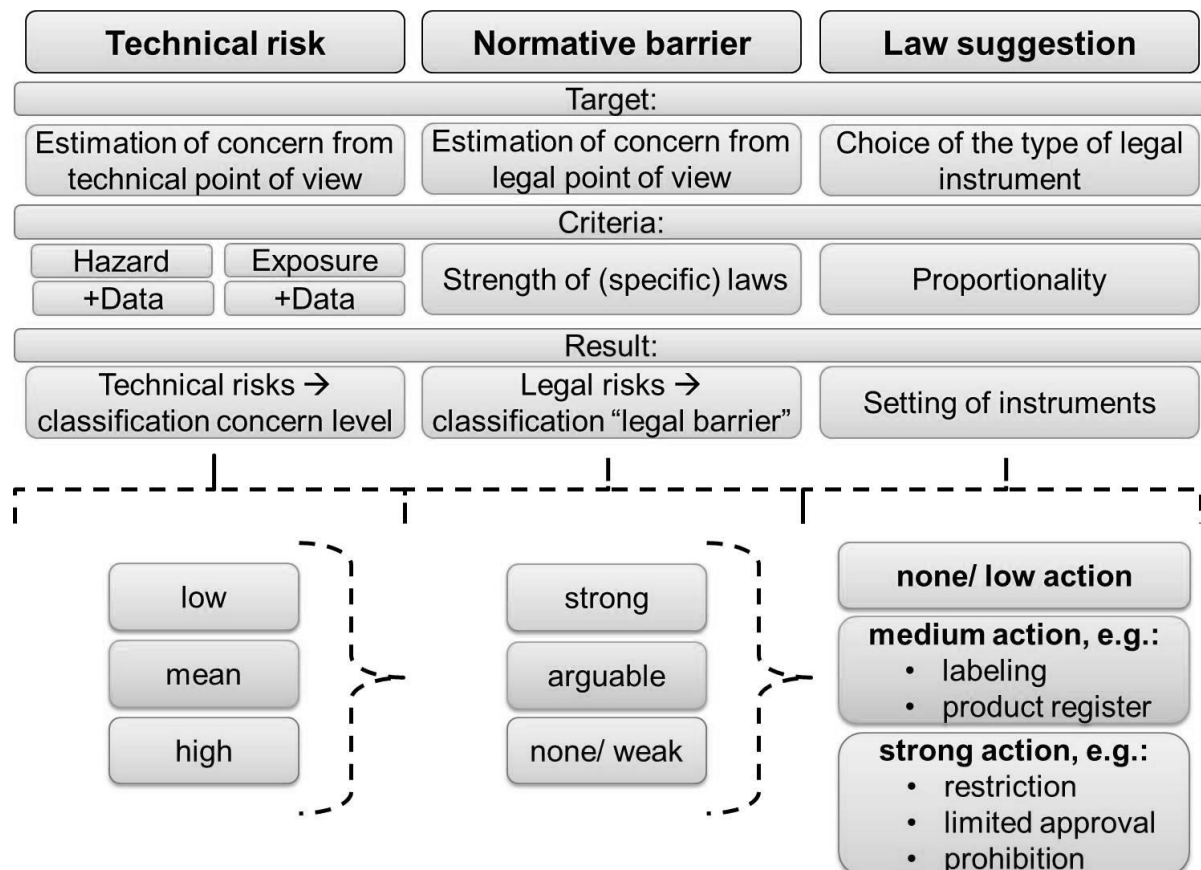
Energy recovery, i.e. the use of the energy content of waste to generate electricity and heat, falls into the category of 'other use'. In addition, information on the minimum temperature and minimum residence time, in terms of the behaviour of nanomaterials, has not been fully investigated in the combustion process. Due to these deficits, authorities have issued no decision-making aid for permitting incineration or co-incineration. If they want to make specific standards with regard to the incineration of waste containing nanomaterials, they have to prove their adequacy (SRU, 2011).

¹⁸¹ It would be necessary to examine the extent to which dust exposure limits and their metrological monitoring are able to detect nanoscale releases; assuming these are emitted to an appreciable extent.

E. Conclusion

The aim of this PhD thesis was, firstly, to explore the feasibility of the legal risk defence for the purpose of dealing with the complex emerging threats of nanomaterials. Secondly, it was to investigate whether existing regulation is adequate in the short and the long term, and, finally, to provide recommendations on how to legislate for nanotechnologies while protecting human health and the environment (Ladeur, 1995). In this respect, it was shown that the process of risk control within the legal system often does not meet the procedural requirements of the precautionary principle and that the rules applicable in the various fields of law have to be adjusted. However, the political and social use of nanotechnologies is not only a question of the legal limitation of risks; it is to a large extent also ‘beyond regulation’ (Gammel et al., 2009).

The analysis of the existing regulation showed that, basically, there are a number of potential gaps, each relating to the specific nanomaterial and application in question (Franco et al., 2007). Though no explicit mention of nanomaterials is made in most EU legislation, in general, nanomaterials are covered by the broad scope of the various pieces of legislation. However, whether nanomaterials are covered when it comes to the specific physical parameters for determining, measuring and defining a material is highly questionable at the moment.



E.1. Achieved goals of this thesis.

In conclusion, with regard to nanomaterials as special forms of substances, there are still many knowledge gaps regarding their properties and effects. Current regulation has a number of limitations for dealing with the short- and long-term feasibility of control, due to the unique features of nanomaterials. The analysis of the regulatory framework found that there are a number of shortcomings in the relevant rules that could make a continuous precaution-oriented handling of nanomaterials impossible. These deficits are partially due to the peculiarities of nanomaterials but partly also due to the fact that the precautionary principle has – as understood by the European Commission (European Commission, 2000) – not been consistently implemented in all areas of regulation. Potential alternatives were discussed for the instruments found in various regulations that differ according to the protected legal interest, the likelihood of exposure or the area of application of the specific substances (NanoKommission, 2011).

The analysis of the applicability of the current regulation on nanomaterials similarly showed that (eco) toxicological data and risk assessments are often necessary to support current regulation. However, the knowledge level for most nanomaterials is so poor that an effective support cannot be delivered (Hansen, 2009). All this is due to the fact that the regulation is not fit to deal with the (unidentified) risks of nanotechnologies. While the protection of the environment should be ensured mainly through the instruments of the precautionary principle and environmental law, and in some cases by those of product legislation, the health of the consumer is assured by the instruments of substance law (e.g. food, medicinal products or cosmetics regulation), the instrumentation of product law and indirectly also by that of environmental law. Principally, the individual areas of law cannot be considered in isolation because the regulations partially complement or build upon each other, for example to serve the registration and updating requirement of REACH's risk determination. Based on the knowledge thereby obtained, risk management can also take place with the help of environmental and product law (SRU, 2011).

However, incentives for the implementation of a substance-related risk determination can also be found through the approval process in laws concerning biocides, plant protection products or medicinal products, leading to the fact that nanomaterials within these regulation areas are relatively well controlled. While some products, e.g. food additives, may be used only after a regulatory safety assessment and authorisation, which, in the main, only relates to the development of new products, the manufacturers themselves have to make sure they comply with the overall safety level. In contrast, the provisions of substance law, product law and environmental law try to capture the total material flows in order to ensure appropriate handling. Whether the instruments of the different areas of law lead to a reasonable regulation of substances as a whole depends, therefore, on several different factors (NanoKommission, 2011).

Firstly, the specific law should be applied to the specific circumstances. Furthermore, it must be appropriately selected for the legal obligations of the starting point. In addition, its design must be adapted to the specificities of substances in nanoscale. The instruments for dealing with the risks posed by these substances have different starting points in different fields of law, for example: properties or contexts of use of a substance in REACH and the CLP Regulation, the facility in the FICA, and the discharge of wastewater or substances in a water body in the Water Management Act. Thus, for nanospecific law, the regulatory loopholes must be specifically closed during registration; beyond that, security should be strengthened, for example, the authorisation requirement must be enforced if there is an example of concern or if preventive aspects in the classification are considered (SRU, 2011).

In the context of product legislation, some areas are already regulated in a heavily preventive-oriented manner (food, food commodities, cosmetics, biocides), but must – if this has not already been done – address the peculiarities of nanomaterials. Further, it must be ensured that nanomaterials are considered independently from their macro-scale counterparts and that, for the approval process, appropriate testing requirements are provided by the authorities. For the majority of products, there are no strict requirements yet (SRU, 2011) and, at this point, there is no certainty that nanomaterials justify special duties or obligations in practice (Hansen, 2009).

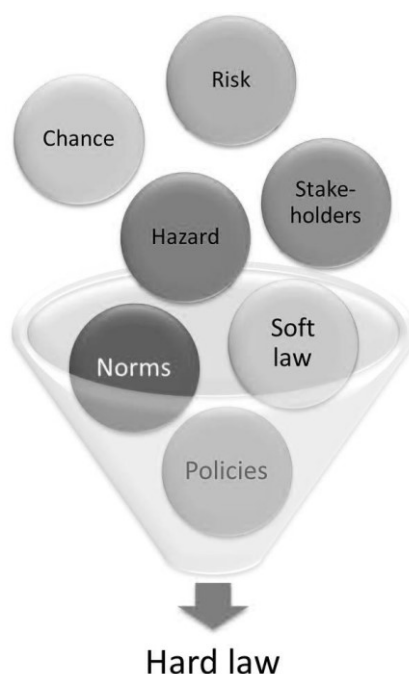
As opposed to this, environmental law is already configured in a precaution-oriented manner in many areas. However, some additional steps are required. In particular, it must be ensured that not only substances that have been proven dangerous are covered by individual approval or permit obligations. With regard to nanomaterials, a number of requirements are still missing, such as concrete limits or thresholds. To enable a precaution-oriented handling of nanomaterials, therefore, the specifics of nanomaterials (e.g. possibly altered characteristics, size) must be incorporated into individual areas of law, and instruments or guidelines for dealing with knowledge deficits must be created. In this respect, the current efforts at European level, which are mainly driven by the European Parliament, are necessary (NanoKommission, 2011).

This is mainly because nanospecific regulations are not systematic, but are taken as part of an amendment process that is pending anyway. In addition, the positions of the European Parliament and the Council of the European Union in the still-ongoing proceedings are not yet aligned. Measures need to be adopted, on the one hand, to change individual sector-specific regulation and, on the other, to pull certain cross-sector valid necessities ‘in front of the bracket’ (SRU, 2011); this should include the following:

- ∞ Definition of nanomaterials, wherein the scope for each sector-specific regulation can be determined separately in accordance with this definition.

- ∞ A general clause that the precautionary principle should be applied in view of the still-existing gaps in knowledge to ensure the safe use of nanomaterials.
- ∞ Reporting requirements for the use of nanomaterials in products and a subsequent constructive nanoprodut register.

With this approach, a dual regime would be invoked to address the need to link with existing regulations (Beyerlein, 2006; Führ et al., 2006b) while creating coherent and transparent adoption. It is especially important for the internal market to enact legislation at European level. Should this, however, not be feasible in the foreseeable future, a regulation at national (German) level by an omnibus bill¹⁸² is conceivable. Here, however, there are issues of competence, as, at European level, in particular in substance and product law, regulations have already been controlled. This is because action by the European legislator principally causes a barrier effect at national level (Braams, 2008; Calliess et al., 2011), due to the priority of application (Albrecht et al., 2015). Action by the member states in order to gain protection both within the internal market competence and within the framework of the EU's environmental competence is possible in compliance with the restrictions set out therein.¹⁸³ The remaining scope for national action should be explored and it should be examined to what extent it is needed for the reinforcement of European regulations. The aim should be to establish a coherent and transparent legislation for nanomaterials and to allow risk precaution at all levels (Wolf, 1991).



E.2. Conclusion of this thesis

¹⁸² An omnibus bill is a proposed law that covers a number of diverse or unrelated topics. It is a single document that is accepted by a legislature but packages together several measures into one or combines diverse subjects.

¹⁸³ Former Art. 114 para. 4 to 6 and Art. 193 Treaty on the Functioning of the European Union (AEUV).

It is a prerequisite for the responsible development of technology that an appropriate balance between innovation research and risk research is reflected (Führ et al., 2006a). The knowledge gap between engineering and awareness of possible consequences for health and the environment should be kept as narrow as possible. It is inevitable in an innovation-dependent modern industrial society that sometimes decisions on how much risk needs to be taken must be made, although knowledge gaps make a comprehensive scientific assessment of the possible consequences impossible. In the knowledge base for dealing with the risks of established technologies, approaches to develop preliminary risk assessment are usually found at an early stage, and they should be used and continuously be developed. The precautionary principle and its idea of reversed burden of proof can also legitimise a legislative risk decision, so that the launch of a new technology or work based on a new product or process (until proven harmless) is prohibited in the interest of health and environmental protection (Hansen, 2009).

Certain areas of substance, product and environmental law, which are currently still excessively oriented to the concept of danger, should be designed to be more preventive oriented, so that measures can be taken to minimise risks, even if there is only an abstract concern that considerable negative effects on human health or the environment are anticipated. This applies not only to chemical substances but also for previously weakly regulated products (SRU, 2011).

In a risk-mature society, seemingly one-sided confidence-building and ‘calming’ communication strategies can be counter-productive when communicating alleged collateral risks. Only communication that involves risks and uncertainties, but also communicates chances systematically, builds up citizens’ confidence. Important confidence-building measures for the consumer and the responsible authorities should, furthermore, provide sufficient information on where they will come into contact with the new technology and give the authorities the capacity to monitor the available risks. The presented model is based on established methods and concepts of risk regulation (Risikokommission, 2003; IRGC, 2006), and thereby established legal terms are used. The four steps described below can be distinguished (SRU, 2011).

The first step is for the scientific risk assessment and the assessment of potential concerns; there are both specific and general nano-(eco)-toxicological concerns to potentially take into account. If only very few substance criteria are present, this can provide evidence for a preliminary risk assessment. These criteria are: particular solubility, persistence, ability to cross barriers, propensity to form stable aggregates and reactivity. Additionally, exposure also comes into question, especially in terms of quantities and release during production, use and disposal.

In the second step, the normative risk assessment is based on the risk assessment, but refers to more aspects (cost and benefit considerations, availability of alternatives, etc. (SRU, 2011)).

However, criteria should also be considered that – although they do not directly relate to the amount of damage – are of great importance for social acceptance (Lösch et al., 2009), such as the familiarity of the risk or whether it can be individually avoided. Based on the risk assessment, the regulatory objective can be decided: is government intervention necessary at all? If so, does it aim to improve information and traceability and create freedom of choice for consumers, or does it limit or even prohibit the marketing and use of nanomaterials? The criteria for this decision are mainly based on the proportionality, transparency and attainment used with existing regulations. During the subsequent risk management, the main question is not if but how regulation should be carried out (Hansen, 2009). Finally, the appropriate instrument type is selected (third step) and applied (fourth step). For example, consumer information can be improved by either a product label or a public product register (SRU, 2011).

Are concerns expressed regarding the general liability for the uncharted risks of nanotechnologies taken seriously? It would be advisable to strengthen the opportunities of public law on legal principles like precaution-oriented handling, which aim to provide the necessary knowledge of risk. Civil law *lex lata* is able to contribute little, since, in most sectors of law, manufacturers as well as plant operators remain largely exempted from liability. Even if risks from a failed development were covered by liability, the problems in the area of proof would still be existent, especially in terms of causality. To provide the necessary risk knowledge about the new technology, the mix of regulations described, possibly associated with some instruments of competition law – contrary to traditional case law – seems most capable overall.

For due diligence, the specific laws contain most characteristics of the precautionary principle, for example, the FICA (Art. 5 para. 1 no. 2), the Act on nuclear power (Art. 7 para. 2 no. 3 AtG), as well as the Act on genetically modified organisms (Art. 6 para. 2, Art. 13 para. 1 no. 3, and Art. 16 para. 1 no. 3 GenTG). Further definitions of the precautionary principle and corresponding preventive structures are also found in the Environmental Impact Assessment Act (UVPG Art. 1),¹⁸⁴ the Water Management Act (WHG Art. 7a para. 1) and also in the Recycling Law (Art. 14 KrWG). Moreover, the European Court of Justice (ECJ) also seems to consider the precautionary principle as a general legal principle of Community law (Führ et al., 2007a). Here, precaution is based primarily on situations of uncertainty, so it is especially applicable when the scientific evidence is insufficient, inconclusive or uncertain and indications through preliminary objective scientific evaluation show that there is also a certain cause for concern (SRU, 2011).

¹⁸⁴ Environmental Impact Assessment Act (*Gesetz über die Umweltverträglichkeitsprüfung – UVPG*) of 24 February 2010 (Federal Law Gazette I p. 94) last amended by Art. 2 of the Directive of 21 December 2015 (Federal Law Gazette I p. 2490).

E.1. Remarks

This thesis has highlighted ways in which to create a successful precautionary handling of nanotechnologies in practice and the changes necessary for this. Key findings are transferable in principle to other areas of risk and new knowledge, such as synthetic biology or the environmental and health effects of endocrine disruptors.¹⁸⁵ The implementation of the precautionary principle is concretised in the cycle of risk identification, risk assessment and risk management (Hansen, 2009) and is determined by the capacities and priorities in the field of risk research, criteria for the assessment of risks under conditions of uncertainty, the decision-making process and government intervention to minimise risks and risk communication (SRU, 2011).

The identified gaps fall, however, into two somewhat different categories. The first category concerns whether nanomaterials are covered by current legislation when it comes to definitions of a substance – novel food, hazardous waste, etc. – and threshold values that are not tailored to the nanoscale, but based on their counterpart bulk material – e.g. REACH. The second category relates to the lack of metrological tools and toxicological data, and the fact that occupational and environmental exposure limits cannot effectively be established with existing methodologies as required by some pieces of legislation – e.g. medicinal products regulation or the safety at workplace directives to be transposed into German law. Different compulsory information tools have already been evaluated in different areas of substance law, product law or environmental law, and proposals were made for their further development and nanospecific adaption. In particular, a product register seems to be promising for the establishment of both information for authorities and consumer information (SRU, 2011).

Given the above structural challenges in mitigating risks by administrative law, using voluntary information instruments on several occasions could contribute to better monitoring and anticipation of hazards. One of the objectives of voluntary material and product information may include a better overview for the authorities of substances and uses, allowing appropriate prioritisation of risk research and regulation, traceability in the case of problems or new findings, and responsibility in the value chain. Beyond how the substance or preparation must be used and disposed of, greater freedom of choice for consumers to weigh the benefits and the risks against each other and to make an individual risk decision is also an objective (NanoKommission, 2011).

¹⁸⁵ Chemicals that, at certain doses, can interfere with the endocrine (or hormone) system in mammals. Any system in the body controlled by hormones can be derailed by hormone disruptors. Specifically, endocrine disruptors may be associated with the development of learning disabilities, severe attention deficit disorder, cognitive and brain development problems; deformations of the body (including limbs); breast cancer, prostate cancer, thyroid and other cancers; sexual development problems such as feminising of males or masculinising effects on females, etc.

An adequate base of information is the key prerequisite for an effective implementation of the precautionary principle. Data, in particular on the use of nanomaterials in consumer products, should be based on reliable sources of information. Reliability in this context means data that is of a suitable quality, a reasonable extent and that is reasonably current is available (Hansen, 2009). Whether voluntary initiatives provide this reliability is doubtful. In general, it can be stated that purely voluntary initiatives are mainly effective where there is a significant self-interest in the target groups to participate. With initiatives to improve market transparency, it is not expected that this is the case since there are strong barriers that preclude participation.

The main obstacles include the interest of companies in preserving trade secrets, their desire to control external communication itself and the administrative burden associated with the provision of product information. Previous negative experiences with voluntary registers for nanomaterials in the US and the UK confirm this scepticism. Also, the conclusion of voluntary agreements provide the opportunity to ensure more binding, tighter limits. Given the variety and heterogeneity of the affected industries, the implementation of a comprehensive product register as part of a voluntary commitment hardly seems realistic (Herrmann et al., 2010).

Voluntary information services could, however, supplement the mandatory information tools. Product labelling can naturally provide only very rough information and a product register – in order to limit the administrative burden and to protect trade secrets – would contain only selected information on substances and products. More detailed information for consumers could be made accessible to the target groups on a voluntary basis. There are already attempts to establish such information services in German-speaking countries, such as, for example, the nano product database of BUND (BUND, 2011), initiated under the information project of the Hessian Ministry of Economics and its platform ‘Informationsplattform NanoSicherheit’ (Hessisches Ministerium für Wirtschaft, Verkehr und Landesentwicklung, 2011) and a website funded by the Federal Ministry of Research’s DaNa project (DaNa, 2011).

The existing services, however, are not beneficial from a consumer perspective because they do not provide a comprehensive description of products containing nanomaterials, their ingredients, their possible risks and their associated uncertainties. Moreover, companies become more strongly involved in the responsibility of the provision of such services (SRU, 2011).

Finally, for REACH, the main areas of concern seem to be that it is unclear when the nanoequivalent of a bulk substance should be registered under REACH, and production thresholds for when (eco) toxicological information has to be submitted are not currently met for many nanomaterials (although they could be in the near future (SRU, 2011)).

Furthermore, even though companies are urged to use existing guidelines, both the EC (European Commission, 2008b) and its Scientific Committee on Emerging and Newly-Identified Health Risks (SCENIHR, 2007), as well as others, have pointed out that current test guidelines (OECD, 2010; OECD, 2009) supporting REACH are based on conventional methodologies for assessing chemical risks and may not be appropriate for the assessment of risks associated with nanomaterials. Somewhat similar issues have been raised for pharmaceuticals, where the concern is that current product standards may not be suitably designed to address various aspects relating to novel applications of nanotechnologies in nanomedicine (SRU, 2011).

In addition, if the estimated environmental concentration of medical products is below 0.01 ppb and ‘no other environmental concerns are apparent’, no further action needs to be taken for the medical product in terms of environmental risk assessment. Such pre-defined action limits could potentially be problematic since the new properties of nanobased products are expected to also affect their environmental profiles. Chaundry et al. (2006) observed that potential gaps in the regulation of nanomaterials seem to fall into two main categories.

For the first category, the key piece of regulation relating to a sector, application, product or substance fails to address an aspect of particular interest – for instance, if a piece of legislation is intended to address the human health impacts but fails to address possible environmental impacts of nanomaterials or nanoproducts. For the second category, a piece of legislation is intended to address a specific aspect of particular interest to a sector, application, product or substance but fails to address it due to exemptions (e.g. threshold, volume or tonnage related, lack of foresight, limitations in technical or scientific knowledge, etc. (Chaundry et al., 2006)).

As a final point, the EU regulations portrayed contain different definitions of nanomaterials. At first sight this appears justified, considering that different nanomaterials require different treatment. However, excessive divergences in the various legal materials are harmful for legal unity (NanoKommission, 2011). This is one of the reasons why the European Commission issued a non-binding recommendation containing a working definition for nanomaterials. Although the recommendation itself takes as a premise that existing provisions are to be left untouched, the Commission is required to consult its own recommendations when drafting new regulations or revising existing legislation (European Commission, 2010).

Within the scope of the Cosmetics Regulation, which came into force prior to the recommendation, a nanomaterial ‘means an insoluble or biopersistent and intentionally manufactured material with one or more external dimensions, or an internal structure, on the scale from 1 to 100 nm’. What is striking is that it focuses exclusively on the spatial dimension of the ‘intentionally’ created materials and not properties inherent in nanomaterials (SRU, 2011).

In the same way, Regulation (EU) No 1169/2011 on the provision of food information to consumers also only includes intentionally made nanomaterials. Extraordinarily enough, this definition does not follow the recommendation for the definition of nanomaterials made by the Commission, although they were issued simultaneously. Consequently, it deviates considerably from the definition given in the Cosmetics Regulation, where the size restriction is only limited upwards (characteristics of the nanoscale could appear in structures larger than 100 nm as well).

The EU has responded to criticism regarding the cosmetics law's strict 1–100 nm delimitation not being an appropriate criterion in this way. By including larger structures, such as agglomerates and aggregates, the definition also reacts to the fact that, apart from size, specific properties are relevant. However, it retains 'properties that are characteristic of the nanoscale'. These include those related to the large specific surface area of the materials, and specific physico-chemical properties that are different from those of the non-nanoform of the material.

Also opposing the definition in the Cosmetics Regulation and Regulation No 1169/2011 on the provision of food information to consumers, the definition of nanomaterial in the Biocide Directive follows that proposed by the Commission in its recommendation. According to this, nanomaterial is a natural or manufactured active or non-active agent '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 1–100 nm. Fullerenes, graphene flakes and single wall carbon nanotubes with one or more external dimensions below 1 nm should be considered as nanomaterials' (SRU, 2011).

A particle is considered to be 'a minute piece of matter with defined physical boundaries'; agglomerates are 'a collection of weakly bound particles or aggregates where the resulting external surface area is similar to the sum of the surface areas of the individual components' and an aggregate is 'a particle comprising of strongly bound or fused particles' (SRU, 2011).

To conclude, the existing regulations for substances are not sufficient for a preventive-oriented regulation of nanomaterials. It is often unclear how to deal legally with nanomaterials because, although they are by definition substances and are basically regulated, they are – with few exceptions – not legally considered independently of their macro-scale counterparts. This is not justified in view of the possible changes in properties and nanospecific characteristics. Nanomaterials should therefore be treated on principle as separate substances because the regulatory arrangements for macro-scale materials are not readily applicable to nanomaterials (limits in mass concentrations, quantity thresholds in kilograms). In addition, as nanomaterials are substances about which not much is known, special tools for risk prevention may be required (Hansen, 2009).

For this reason, nanomaterials should be made the point of reference for regulations. In a first step, nanomaterials should be uniformly defined. The European Commission's proposal to adopt a common European definition for nanomaterials will provide a framework for policy and regulation that needs to be supported. Precautionary measures up to a size of 300 nm should be standard. The size limit should clearly only refer to the primary particles. The agglomerates and aggregates of the primary particles should be embraced without a size limitation in the definition. For specific regulatory purposes, this definition can be adjusted if necessary. In a second step, it should be made clear that the so-defined nanomaterials will be treated as separate substances (legal fiction) if this makes sense in terms of the individual rules of the legal range for substances. If modifications and additional instruments are required, these can be introduced specifically for the precaution-oriented regulation of nanomaterials (SRU, 2011).

A solution for a single sufficient (specific) definition of nanotechnologies cannot be achieved across the board due to the single scopes of the different laws. From today's perspective (just as in the case of the measurement of particle size by suitable methods of measurements), individual decisions and definitions that meet the needs of each particle individually have to take place. This cannot be achieved by a political decision alone; clear scientific research and results are demanded by science. Without such a scientific basis (which does not exist at this time), a much-needed political decision alone (also referred to in this work) seems inappropriate (SRU, 2011).

E.2. Recommendations

In the previous sections, the extent to which the risks of nanomaterials are adequately covered by the existing regulatory system was discussed. For various relevant areas, there are gaps whose closure requires an adaption of legal regulations and standards, and a precautionary handling of nanomaterials is also hampered by the fact that many areas of regulation continue to be based on the model of safety. However, they are failing to succeed regarding risks of nanotechnologies.

Overall, new technologies (Grunwald, 2003; Guston et al., 2002) challenge traditional regulatory approaches, and, when dealing with nanotechnologies, existing problems increasingly emerge (e.g. deficits in implementation of the precautionary principle, difficulties in uncertainty and lack of flexibility). Soft and non-regulatory management tools can be a valuable supplement, but not a substitute, for effective preventive-oriented regulation. However, they must be potent and designed in a 'socially robust' way (Nowotny et al., 2001), for example with clearly defined objectives and reasonable commitment. Many governance approaches, however, have significant deficits (Kurath, 2009). Still, there are some promising approaches to promoting a broader social debate in this field of technology and thereby avoid a polarised debate.

Nonetheless, in spite of the insufficient link between research and science, some industries have been very reluctant to enter into a dialogue. Efforts to promote the responsible use of nanomaterials by companies using voluntary instruments should be continued. However, these are only promising in areas where sufficient incentives exist for companies to participate (SRU, 2011). The main concern here is the expected ubiquitous distribution of (some) nanoparticles. In contrast to point sources (which could be handled by regulation), the biggest problem (which seems very hard to handle) seems to be emissions by consumers and thereby by a diffuse entry, leading to various questions like problematic identity (SRU, 2011).

The problem is always the difficulty in verifying whether something is safe or otherwise. Neither the legislators nor the industry want to take responsibility for this burden of proof. However, industry would be more likely (due to advanced knowledge) to be able to deal with it. Since early discussions about nanotechnologies-related risks, risk assessment has been put forward as the number one approach (along with life cycle analysis to some extent (Klöpffer et al., 2006)) with regard to understanding the risks associated with the application of one kind of nanomaterials, namely nanoparticles, in our society (Hansen, 2009).

However, an official in charge of regulatory aspects of nanotechnologies at the EC has even been cited as arguing that there is no regulatory void on nanotechnologies (EurActiv, 2008). This is because EU rules impose a risk assessment on all products, and nanomaterials were no exception to this obligation (EurActiv, 2008). Hence, the importance of risk assessment in providing the backbone in relation to current and future regulation of nanomaterials should not be underestimated (SRU, 2011).

What is worrying is that the present analysis of risk assessment identified a number of limitations and flaws in relation to each of the four elements of the risk assessment framework when applied to nanomaterials. Currently it is impossible to systematically link reported nanoparticle properties to observed effects for effective hazard identification (Hansen, 2009).

For dose-response assessment, it was unclear whether a no-effect threshold can be established, what the best hazard descriptor(s) of nanoparticles are and what the most relevant endpoints are. There is a serious lack of characterisation of the nanoparticles tested, which makes it difficult to identify which key characteristics – or combinations of key characteristics – determine the hazards documented in (eco) toxicological studies of nanoparticles. The inherent properties identified as possible hazard descriptors by Hansen et al. (2007) and others may possibly be reduced as knowledge advances in the field, and it is likely that the toxicity of nanomaterials is determined by combinations of these (Wittmaack, 2007; Hansen et al., 2007).

Nevertheless, perhaps properties not yet identified in the scientific literature may be relevant for hazard identification of nanomaterials. Although the lack of this characterisation is troublesome, it is hardly surprising, as nanotoxicology is a very young field of research stemming from ultra-fine particle research (Oberdörster et al., 2005). A true understanding of the hazardous properties that materials begin to exhibit at the nanoscale requires a level of interdisciplinary research that has not yet been reached (Hansen, 2009).

Risk characterisation, being at the end of the line, the sum of all these limitations are conveyed to calculating risk quotients for nanoparticles. Considerable work is still required if future risk assessment of current nanomaterials and nano-related products is going to be relevant and reliable. Despite some efforts to respond to the limitations of risk assessment and uncertainty, coordinated action seems slow in emerging as a number of reports make specific recommendations on developing responsive research strategies (Oberdörster et al., 2005; Maynard, 2006; Moore, 2006; Tsuji et al., 2006).

Calls for proposals in the European Seventh Framework Programme reflect some of these recommendations, while countries like Australia are beginning to develop integrated environment, safety and health research programmes. Research strategies that target recognised areas of uncertainty, and address many of the issues raised previously, should be relatively easy to develop, as the critical questions to be addressed are generally agreed upon (NNI, 2008; Hansen et al., 2008). Besides the dangers of missing important areas entirely, there are a number of additional problems when it comes to risk assessments of future nanomaterials, their application and their variety – especially at the current pace of technological development.

However, new technologies bring almost inevitable ignorance and – by extension – uncertainty. Some of them will therefore not be described as risk technology, corresponding to a legal development towards decisions based on precise risk. Classic examples of risk law are nuclear law (AtG), the law on chemicals, pharmaceutical legislation and the law on ‘green’ genetic engineering (GenTG). Nevertheless, the fact that a technique, a method, a substance or a product thereof is new does not trigger any (extensive) measures of state control *per se*. In many cases, the law was designed, in the light of not knowing the future development, following the trial-and-error method; however, this method is only suitable for small, mostly reversible and political developments – in regard to state protection obligations under Art. 2 para. 2 and Art. 20a of the German constitution (GG) – if legally appropriate. If, however, it can be expected that particular projects, techniques and procedures will from the beginning have serious, far-reaching and/or irreversible impacts on humans and the environment, the trial-and-error method is not consistent with the German constitution (Führ et al., 2007a).

The classic task of the state to provide security is mirrored (Art. 20a GG, Art. 191 para. 2 TFEU) by these new challenges of the risk society, including constitutional and European law, enshrined in the precautionary principle. The political and legal use of nanotechnologies or nanomaterials can be examples of how to deal with ignorance and uncertainty in the risk society.

The need to assess the risk of nanoparticles on a case-by-case basis is often mentioned as a means of taking the unique properties of nanomaterials into consideration (SCENIHR, 2007; Environmental Defense and DuPont, 2007). The European Commission has even been cited as stating that product authorisation must be conducted ‘on a case-by-case basis’ (EurActiv, 2008). While chemical risk assessment is based on the fact that chemical identity governs the fate and effects of a chemical, the situation for nanomaterials may well differ. By definition, properties of nanomaterials cannot be determined by their chemical composition alone, and nanomaterial hazard identification – specifically for nanoparticles – has come under scrutiny (Kühling, 2007).

However, science is still in the ‘pre-hazard identification’ phase, meaning that there is no way of determining all the hazards of nanoparticles correctly (Kühling, 2007). As noted by Kulinowski, executive director at the Center for Biological & Environmental Nanotechnology at Rice University, ‘we have to remember that so much of what needs to be done is still in the discovery stage’ (Hanson, 2008). However, there seems to be a general agreement that the hazards depend on surface area, surface charge, surface chemistry, state of agglomeration and chemical composition (Hansen et al., 2007); the surface in particular has been mentioned as a new ‘nanorelevant’ property (SRU, 2011).

However, for the time being, all of the abovementioned particle characteristics may impact the overall hazard, and since the causal relationships still need to be discovered, further research is needed in this area before relevant data allows hazard identification purposes to be defined. Even with well-defined data demands, experiences from chemical risk assessments show that case-by-case risk assessment of nanoparticles will be very time and resource intensive. However, an opposing moratorium would be rejected by the European Commission as strongly counter-productive (European Commission, 2004; Herrmann et al., 2007), which helps with the applicability of the precautionary principle, as discussed above (European Commission, 2008a).

For nanomaterials, however, this situation is further complicated by the fact that hazard characteristics are unlikely to only be linked to chemical identity; a large number of combinations of characteristics may influence the overall hazard. For instance, there are 20 different structural types of single-walled carbon nanotubes alone, and their length can vary from 5–300 nm. According to Schmidt, four different processes currently exist for manufacturing all of them (Schmidt, 2007).

There are five methods of purifying them, and ten surface coatings are typically applied – hence there are up to 50,000 potential combinations of single-walled carbon nanotubes – and each version may have different chemical, physical and biological properties that determine its overall hazard. This example may serve to show how complex and demanding case-by-case evaluations could become. However, not all of these single-walled nanotubes are expected to be of commercial relevance. On the other hand, there are numerous other kinds of nanoparticles such as fullerenes, quantum dots, metals and metal oxide nanoparticles.

To conclude, in the capital market, for example, risk management has been an obligation since 1998, due to changes in Art. 91 para 2 of the German Stock Corporation Act.¹⁸⁶ Private standards offer the possibility of regulating necessary issues where the state is not able to regulate or to execute. If the concerns expressed about the uncharted risks of nanotechnologies are to be taken seriously, it would be advisable to provide the necessary knowledge of risk to strengthen the public law opportunities on the precautionary principle. The civil law is *lege lata* scarcely capable of this, as both manufacturers and plant operators are largely exempt from liability risks (except in the field of pharmaceuticals). Even if development risks were to be covered by liability, evidence is problematic, especially in terms of causality. Thus, a mix of regulations, as mentioned previously, seems to be the most promising (Spindler, 2009).

If a conclusion can be drawn, it is that civil law has great difficulty in fitting uncertainty on the impact of new technologies into the traditional doctrine and burden of proof between the parties. Specifically, a lack of knowledge about the causal relationships and lack of linkages to scientific and technical standards lead victims' claims to go unheard or be procedurally unimplementable. Similarly, the *prima facie* case fails because of missing knowledge about sequences of events. Without an appropriate burden of proof, there are insufficient incentives for manufacturers and operators to take responsibility for the necessary knowledge (Spindler, 2009). On the other hand, the burden of proof could often go too far, as the manufacturer or operator does not always have the 'better' knowledge of risk; often only probabilities of nanotechnological risk can be given.

Proportionate liability under German law is still unknown and would create problems of a dogmatic and legal economic nature. Here, only the procedural method continues to be of assistance. This is the case in medical liability in particular, namely in the distribution of secondary pleading by which the injured party only has to prove a kind of 'reasonable suspicion', and the manufacturer or operator needs to relieve it (Spindler, 2009).

¹⁸⁶ Art. 91 para 2 Stock Corporation Act (*Aktiengesetz – AktG*) of 6 September 1965 (Federal Law Gazette I, p. 1089) last amended by Art. 7 of Directive of 20 November 2015 (Federal Law Gazette I p. 2029).

For example, Peine stated in the example of the Equipment Safety Act,¹⁸⁷ which serves as a transposition of European Directive 2001/95/EC on general product safety into German law, that the difficulty, complexity and dynamics (Breuer, 1976) of technology make reference to technical regulations necessary and legitimate to gain control over the complexity of the future. Here, the German Constitution is the framework for political action that does not omit the technological future (Peine, 2011).

Developers, manufacturers, importers and users bear a significant responsibility in ensuring that nanomaterials pose no environmental and health risks. This is especially true in areas where the limited knowledge, gaps and detectability problems of dynamic technology development make it difficult for the government to fully comply with its duty to protect. Voluntary initiatives improve market transparency; however, they do not always work, because of their limitations (trade secrets, control of external communication). Rather, initiatives should therefore aim for the responsible use of nanomaterials (e.g. guides, best practice initiatives, etc.) that improve companies' risk management. Both state actors and industry members are aware of the importance of public participation and have initiatives to promote communication and dialogue.



E.3. Two-level approach for handling nanotechnologies.

¹⁸⁷ Art. 1 of the German Equipment Safety Act (*Gesetz zur Neuordnung der Sicherheit von technischen Arbeitsmitteln und Verbraucherprodukten*) (Federal Law Gazette I p. 2–219) last amendment on 7 July 2005 (Federal Law Gazette I p. 1970).

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- Regulation (EC) No 1907/2006 of the European Parliament and of the Council of 18 December 2006 concerning the Registration, Evaluation, Authorisation and Restriction of Chemicals (REACH), establishing a European Chemicals Agency amending Directive 1999/45/EC and repealing Council Regulation (EEC) No 793/93 and Commission Regulation (EC) No 1488/94 as well as Council Directive 76/769/EEC and Commission Directives 91/155/EEC, 93/67/EEC, 93/105/EC and 2000/21/EC (OJ L 396, 30.12.2006, p. 1–849) last amended by Regulation (EC) No 1272/2008 of the European Parliament and of the Council of 16 December 2008 on classification, labelling and packaging of substances and mixtures, amending and repealing Directives 67/548/EEC and 1999/45/EC last amended of the Directive of 29 May 2007 (OJ L 136 p. 3–280) 2, 3, 22, 42, 49, 51, 53, 55, 61, 63, 64, 65, 66, 67, 68, 69, 70, 71, 72, 73, 74, 75, 83, 84, 86, 94, 97, 111, 127, 128, 132, 133, 134
- Regulation (EC) No 1935/2004 of the European Parliament and of the Council of 27 October 2004 on materials and articles intended to come into contact with food (OJ L 338, 13.11.2004, p. 4) last amended by Art. 1 of the Directive of 18 July 2009 (OJ L 188, p. 1) 82, 83, 105, 106, 107, 108
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- Regulation (EC) No 726/2004 laying down Community procedures for the authorisation and supervision of medicinal products for human and veterinary use and establishing a European Medicine Agency of 31 March 2004 (OJ L 136, p. 1–32). 90

- Regulation (EU) No 2015/2283 of 25 November 2015 on novel foods, amending Regulation (EU) No 1169/2011 of the European Parliament and of the Council and repealing Regulation (EC) No 258/97 of the European Parliament and of the Council and Commission Regulation (EC) No 1852/2001 (OJ L 327, 11.12.2015, p. 1–22) 101
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- Regulation No 258/97/EC of the European Parliament and of the Council of 27 January 1997 concerning novel foods and novel food ingredients (OJ L 043, p. 1–6) last amendment Regulation no 596/2009 of 7 August 2009 (OJ L 188, 18.7.2009, p. 14) 99, 101
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