Comparison of the approaches to regulate environmental, health, and safety risks of nanomaterials in the chemicals, food, and pesticides/biocides sectors in the EU and the US

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TIIVISTELMÄ

ITÄ-SUOMEN YLIOPISTO

Tiedekunta **Yhteiskuntatieteiden ja kauppatieteiden tiedekunta**		Yksikkö **Oikeustieteiden laitos**	
Tekijä **Mirella Miettinen**			
Työn nimi **Nanomateriaalien ympäristö-, terveys-, ja turvallisuusriskien sääntely EU:ssa ja USA:ssa – ohjauskeinojen vertailu kemikaali-, ruoka- ja torjunta-ainesektoreilla**			
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Tiivistelmä

Analysoin työssäni nanomateriaalien ympäristö-, terveys- ja turvallisuusriskien sääntelyä EU:ssa ja USA:ssa ja vertailen kemikaali-, ruoka- ja torjunta-ainesektoreilla käytettyjä sitovia ja joustavia ohjauskeinoja. Tutkimuskysymyksinä ovat: ’Pystyvätkö nykyiset ohjauskeinot vastaamaan nanomateriaalien sääntelylle tällä hetkellä asetettuihin poliittisiin tavoitteisiin?’ ja ’Onko EU:n ja USA:n sääntelykehyksissä eroavaisuuksia, jotka voivat aiheuttaa konflikteja tulevaisuudessa?’. Menetelmällisesti työni sisältää lainopillista ohjauskeinotutkimusta ja vertailevaa oikeustiedettä. Tutkimus paljastaa, että tämänhetkiset tavoitteet nanomateriaalien sääntelylle EU:ssa ja USA:ssa ovat tiivistetysti: 1) tiedon kerääminen, 2) johdonmukaisuuden lisääminen riskinarvioinnissa ja riskien hallinnassa, ja 3) avoimen, joustavan, ja ennakoitavan sääntelykehyksen luominen. Sääntelykehysten analyysin perusteella nanomateriaalien ympäristö-, terveys- ja turvallisuusriskejä säännellään sekä EU:ssa että USA:ssa tällä hetkellä lähinnä olemassa olevin sitovin normein. Itsesääntelyä on ollut ja on yhä käytössä jonkin verran, mutta sekä viranomaiset että teollisuus ovat sitä mieltä, että nykyinen sitova sääntely kattaa myös nanomateriaalit. Tutkimus kuitenkin osoittaa, että nykyisten ohjauskeinojen kyky vastata asetettuihin tavoitteisiin on rajallinen. Viranomaiset sekä EU:ssa että USA:ssa ovat saaneet vain vähän tietoa nanomateriaaleista ja niiden ominaisuuksista. Ongelma on, että monet sitovat normit (esimerkiksi REACH-asetus ja Toxic Substances Control Act) eivät sisällä viittausta nanomateriaaleihin, ja jos sisältävät tai jotkin normeista soveltuvat nanomateriaaleille ilman viittausta, niin täsmällisen ohjeistuksen puuttuminen hankaloittaa niiden noudattamista. Lisäksi joustavien ohjauskeinojen, kuten REACH-ohjeiden, velvoittavuus on kyseenalaistettu teollisuuden puolelta. Teollisuus ei ole myöskään ollut halukas raportoimaan tai testaamaan nanomateriaaleja vapaaehtoisesti. Lisäksi johdonmukaisen riskinarvioinnin ja riskien hallinnan kehittäminen on alkutekijöissään sekä EU:ssa että USA:ssa. Pääpaino on yhä riskinarviointimenetelmien harmonisoinnissa, mitä vaikeuttaa yhä vallitseva tieteellinen epävarmuus ja siitä johtuva puutteellinen ohjeistus. Viranomaisten menettelytavat riskinarvioinnissa eroavat EU:ssa ja USA:ssa esimerkiksi sen suhteen, käytetäänkö nanomateriaalille yhtenäistä määritelmää, mikä vaikeuttaa harmonisointia. Viimeaikaisen kehityksen johdosta nanomateriaalien ympäristö-, terveys- ja turvallisuusriskien sääntely EU:ssa ja USA:ssa on eriytymässä edelleen. EU nojaa yhä enemmän varovaisuusperiaatteeseen, mitä ilmentävät sektorilainsäädäntöön sisällytetyt nanomateriaaleja koskevat lausekkeet ja todistustaakan siirto teollisuudelle. USA pitää kiinni tapauskohtaisesta riskinarvioinnista, eikä ole pääsääntöisesti sisällyttänyt nanomateriaaleja koskevia ehtoja lakeihin. Erilaiset lähestymistavat tulevat todennäköisesti aiheuttamaan konflikteja ainakin ruokasektorilla tulevaisuudessa.

Avainsanat

nanomateriaalit; ohjauskeinot; kemikaalit; ruoka; torjunta-aineet; ympäristö-, terveys- ja turvallisuusriskit

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ABBREVIATIONS

ACC	American Chemistry Council
Adv. Drug Deliv. Rev.	Advanced Drug Delivery Reviews
Am. Jur.	American Jurisprudence
ANSI	American National Standards Institute
ASTM	American Society for Testing and Materials
B.C. Int'l & Comp. L. Rev.	Boston College International and Comparative Law Review
Beilstein J. Nanotechnol.	Beilstein Journal of Nanotechnology
BPR	Regulation (EU) No 528/2012 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 N:o L 167, 27.6.2012, p. 1-123
CBA	Cost-benefit analysis
CCR	California Code of Regulations
CEFIC	European Chemical Industry Council
CEN	European Committee for Standardization
CFR	Code of Federal Regulations
CFS	Center for Food Safety
Caltech	California Institute of Technology
CJEU	Court of Justice of the European Union
CLP	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 N:o L 353, 31.12.2008, p. 1-1355
CNT	Carbon nanotube
COM	Communication from the Commission
Colum. Sci. Technol. L. Rev.	Columbia Science and Technology Law Review
CoRAP	Community Rolling Action Plan
CPSC	Consumer Product Safety Commission
DTSC	Department of Toxic Substances Control
EC	European Commission
ECHA	European Chemicals Agency
EDF	Environmental Defense Fund
EESC	European Economic and Social Committee
EFSA	European Food Safety Authority

EFSA J.	EFSA Journal
EHS	Environmental, Health, and Safety
EJCL	Electronic Journal of Comparative Law
Environ. Health Perspect.	Environmental Health Perspectives
EPA	Environmental Protection Agency
et seq.	et sequentia (’and the following’)
EU	European Union
FDA	Food and Drug Administrator
FFDCA	Federal Food, Drug, and Cosmetic Act, 21 U.S.C. § 301 et seq., 25.6.1938
FIC	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, 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/EC, 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, OJ N:o L 304, 22.11.2011, p. 18-63
FIFRA	Federal Insecticide, Fungicide and Rodenticide Act, 7 U.S.C. § 136 et seq., 25.6.1947
FR	Federal Register
General Food Law	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, OJEC N:o L 31, 1.2.2002, p.1-24
Global Envtl. Politics	Global Environmental Politics
GHS	Globally Harmonised System
GM	Genetically Modified
GMO	Genetically Modified Organism
GRAS	Generally Recognized As Safe
HSC	California Health and Safety Code
Ibid.	ibidem (‘in the same place’)
Industrial Robot: Intern. J.	Industrial Robot: An International Journal
ISO	International Organization for Standardization
ICTA	International Center for Technology Assessment

J. Phys. Chem. C	Journal of Physical Chemistry C
JRC	Joint Research Centre
J. Risk Res.	Journal of Risk Research
Jurimetrics J.	Jurimetrics: The Journal of Law, Science and Technology
MeU	Memorandum of Understanding
Nanotech. L. & Bus.	Nanotechnology Law & Business
Nature Mater.	Nature Materials
NCC	NanoSafety Consortium for Carbon
NGO	Non-Governmental Organization
NIA	Nanotechnology Industries Association
NIST	National Institute of Standards and Technology
NMSP	Nanoscale Materials Stewardship Program
NNCO	National Nanotechnology Coordination Office
NNI	National Nanotechnology Initiative
Novel Food Law	Regulation (EU) 2015/2283 of the European Parliament and of the Council 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 N:o L 327, 11.12.2015, p. 1-22
NRDC	Natural Resources Defense Council
OECD	Organization for Economic Cooperation and Development
OEHHA	Office of Environmental Health Hazard Assessment
OIG	Office of Inspector General
OJ	Official Journal of the European Union
Pace Envtl. L. Rev.	Pace Environmental Law Review
PHSA	Public Health Service Act, 42 U.S.C. § 201 et seq., 1.7.1944
PL	Public Law
PPP	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 N:o L 309, 24.11.2009, p. 1-50
REACH	Regulation (EC) No 1907/2006 of the European Parliament and of the Council of 18 December 2006 concerning the Registration, Evaluation, Authorization, and Restriction of Chemicals, OJ N:o L 136, 29.5.2007, p. 3-278

Reg. Toxicol. Pharmacol.	Regulatory Toxicology and Pharmacology
RPA	Risk & Policy Analysts
RPR	Review of Policy Research
SEC	Commission Staff Working Document prior to 2012
SWD	Commission Staff Working Documents
TFEU	Consolidated version of the Treaty on the Functioning of the European Union, OJ, N:o 326, 26.10.2012, p. 47
TC	Technical Committee
Tech. Anal. Strat. Manag.	Technology Analysis & Strategic Management
TEU	Consolidated version of the Treaty on European Union, OJ, N:o 326, 26.10.2012, p. 13
Treaty of Lisbon	Treaty of Lisbon amending the Treaty on European Union and the Treaty establishing the European Community, signed at Lisbon, 13 December 2007, OJ, C 306, 17.12.2007, p. 1-271
TSCA	Toxic Substances Control Act, 15 U.S.C. § 2601 et seq., 11.10.1976
TTIP	Transatlantic Trade and Investment Partnership
UC CEIN	University of California Center for Environmental Implications of Nanotechnology
US	United States
U.S.C.	United States Code
USD	United States Dollar
WPMN	Working Party on Manufactured Nanomaterials
WPN	Working Party on Nanotechnology
WTO	World Trade Organization
Yale J. Int'l L.	Yale Journal of International Law

FIGURES AND TABLES

1 INTRODUCTION

1.1 Background

Nanotechnology refers to any science and technology at the level of atoms and molecules which enables the understanding and mastering the properties of the materials at the nanoscale.[1] Nanotechnologies are 'enabling' technologies and have the potential to create disruptive innovations in every industrial sector. During the last decade, nanotechnologies have produced numerous novel *nanomaterials*[2] with applications in electronics, energy, agriculture, food/feed industry, textiles, cosmetics, biomedicine, etc. Nanomaterials form a heterogeneous group, which main categories in terms of industrial impact and public exposure today include inorganic non-metallic nanomaterials (e.g., silicon dioxide, titanium dioxide), carbon based nanomaterials (e.g., carbon black, carbon nanotubes (CNT)), metal nanoparticles (e.g., nanosilver), and organic macromolecular or polymeric structures. In addition, more targeted applications such as drug carriers or theranostic particles, robotic devices, and molecule-by-molecule designs for the functional nanostructures, have been developed.[3] In 2015, over 1800 consumer products that contained nanomaterials were on the marketplace. Nanomaterials in the consumer products are typically suspended in different fluids such as water, skin lotion, oil, or car lubricant. However, carbonaceous nanomaterials are most often embedded in solid products. One third of the consumer products utilize nanomaterials for antimicrobial protection. Other main application areas are protective coatings, environmental treatment (e.g., water or air treatment in the home), cosmetics, and dietary supplements. Nanosilver is the most commonly used nanomaterial in the consumer products but almost half (49 %) of the products on the market do not provide the composition of the nanomaterial that they contain.[4]

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[1] *COM (2004) 338*, final, p. 4. Precisely, the 'nanotechnology' itself does not exists, see *Hodge – Bowman – Maynard* 2010, p. 6.

[2] Throughout this study, term nanomaterial refers to engineered nanomaterials, incidental and naturally occurring nanomaterials are excluded.

[3] *SWD (2012) 288*, final, p. 10. As an introduction to theranostic nanoparticles, see *Xie – Lee – Chen* Adv. Drug Deliv. Rev. 2010, p. 1064-1065. *Bogue* Industrial Robot: Intern. J. 2015, p. 102 reviews the recent progress in the development of nanorobots. *Wang et al.* J. Phys. Chem. C 2013, p. 3440 presents examples of the application fields of molecule-by-molecule designed functional nanostructures.

[4] *Vance et al.* Beilstein J. Nanotechnol. 2015, p. 1769-1775. It has to be noticed that the real number of nanomaterials on the market is much higher due to limitations of the inventory.

Along with growing markets of nanomaterials, concerns about their safety has risen and efforts to multidisciplinary assessment of the impact of nanomaterials on the health and environment have been established.[5] Nanomaterials have properties that though beneficial for industrial applications may induce adverse health effects such as cyto- and genotoxicity, inflammation and cancer.[6] The size of nanomaterials can modify physicochemical properties and increase interaction with biological tissues. For example, small size increases surface area and may create structural defects that alter the electronic properties. This may result in reactive functional groups on the surface of the particles. These surface groups can make nanoparticles hydrophilic or hydrophobic, lipophilic or lipophobic, or for instance catalytically active. That affects the interaction of the nanoparticles with the biological medium through for example adsorption of proteins or other organic molecules, double-layer formation, or dissolution.[7] It has been stated that better understanding of the role of physicochemical properties of the nanomaterials in determining their environmental fate, transport, bio-accumulation, and hazard generation at the nano-bio interface is needed to make more informed decisions about the steps that should be taken for the safe use of nanotechnologies.[8]

While nanomaterials have already penetrated on the global market, regulatory systems for them face profound challenges, starting from the debate of the definition of "nanomaterial".[9] The other regulatory challenges include but are not limited to: uncertainty and complexity, inapplicability of traditional regulatory triggers and metrics (such as bulk composition or mass concentration thresholds), merging benefits and risks, potential for double standard, and the pacing problem.[10] The research on the nanomaterial regulation has been concentrated on the national level and global governance efforts have been largely limited to scientific and technical standardization and coordination initiatives through the Organization for Economic Cooperation and Development (OECD) and the International Organization for Standardization (ISO).[11] The EU and the US have studied the need for promoting more comprehensive, international regulatory policy.[12] At the same time, however, the EU has set more

[5] *Maynard et al.* Nature 2006, p. 267-269; *Xia et al.* Small 2013, p. 1429.
[6] *Savolainen et al.* Toxicology 2010, p. 93.
[7] *Nel – Xia – Mädler - Li* Science 2006, p. 622-623. The size of nanomaterials can be perceived if compared to the diameter of human hair that is approximately 80 000 nm.
[8] *Nel et al.* Nature Mater. 2009, p. 543, 556.
[9] *Dana* Pace Envtl. L. Rev. 2013, p. 468 argues that getting regulatory definitions right is crucial in creating an effective regulatory frameworks for nanomaterials.
[10] *Breggin et al.* 2009, p. 14; *Marchant et al.* Jurimetrics J. 2012, p. 256-265.
[11] *Bowman – Hodge* Colum. Sci. Technol. L. Rev. 2007, p. 7-13; *Falkner – Jaspers* Global Envtl. Politics 2012, p. 49-53.
[12] *Breggin et al.* 2009, p. 24.

nano-specific rules and labelling requirements for example in the food sector. This trend may result in regulatory discrepancies between the legal systems which hinders transatlantic harmonization. During the ongoing Transatlantic Trade and Investment Partnership (TTIP) negotiations nanomaterials have not been on the agenda as their own group but are included in the EU's initial position paper on chemicals as new and emerging issue that requires co-operation to avoid trade irritants in the future.[13]

1.2 Research questions, methods, and outline of the study

The aim of this study is to compare the approaches to regulate environmental, health, and safety (EHS) risks of nanomaterials in the EU and the US. The focus is on the adequacy of the policy instruments and on the occurrence of discrepancies between the regulatory frameworks in the EU and the US. The specific research questions are:

i) Are the applied policy instruments able to correspond to the desired goals?
ii) Is there discrepancies in the regulatory frameworks in the EU and the US?

The main research methods are *legally oriented policy instrument study* and *comparative jurisprudence*. Although the perspective is legal, sources from other disciplines are also utilized due to multidisciplinary nature of the challenges related in the regulation of nanomaterials. The regulation of emerging technologies, such as nanotechnology, is a complex task that cannot be successfully accomplished by the judicial actors alone but should involve stakeholders from various fields of science and levels of the society.[14] The analysis and comparison of the approaches applied to regulate the emerging technologies in different judicial systems is useful for recognizing discrepancies that may result in conflicts, and to estimate if there are deficiencies in the attainment of the desired goals. Consequently, the comparative approach of the study is functional.[15] In the context of environmental law this study is positioned as more interdisciplinary than purely jurisprudential and is targeted at a wider audience than just the narrow legal community.

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[13] *EC* 2014, p. 3. The EU's Directorate General for Internal Policies has committed a study of environment, public health and food safety related legislative areas of the TTIP negotiations, including nanomaterials, see *European Parliament* 2014, p. 52-57. At the 14th round of the TTIP negotiations the EU announced a proposal for a Chemical Sector Annex text, see *EC* 2016, p. 12.

[14] This 'multi-level governance' results in the emergence of different hybrid regulation mechanisms, as well as the promotion of self-regulation and flexible regulatory frameworks, and is a new challenge for the environmental law research, see *Määttä* 2015, p. 26. See also *Siems* 2014, p. 248-259 on the privatization of the transnational law and interrelationships between the numerous governmental and private levels.

[15] The core of the functional comparative law is a socio-economic or socio-legal problem, and whether the legal rules in the legal systems in question are able to address the problem, see *Siems* 2014, p. 14-15, 20, 26.

The research is outlined to *chemicals, food, and pesticides/biocides* due to recent regulatory developments concerning nanomaterials in these sectors. The other legislation relevant for the EHS aspects of nanomaterials, for example worker protection, medical devices, cosmetics, and environmental protection are excluded.[16] In addition, residues in food, and dietary supplements are not in the scope of this study. The comparative analysis is restricted to the regulative responses for nanomaterials, thus the analysis of the law and regulatory practices in the EU and the US as such is not an objective. The regulations in the US are studied only at federal and state level, the latter limited to examples of regulations in California. Furthermore, national initiatives to regulate nanomaterials in the member states of the EU are outside of the study. The aim is to concentrate on the most relevant regulations, a comprehensive examination of all existing regulations in the chosen sectors is not pursued.

After a short *history of nanotechnology and nano-regulation*, the *policy instruments* for the regulatory oversight of nanomaterials in the EU and the US are introduced and the concepts of uncertainty, risk, and precaution in the context of nanomaterials are elaborated. Next, the current *regulation* of nanomaterials in the chemicals, food, and pesticides/biocides sectors in the EU and the US is examined. Then, the *ability of the applied instruments to correspond to the desired goals* is analyzed. Finally, the regulatory approaches in the EU and US are compared *to identify discrepancies* that may, for example, result in trade irritants in the future.

[16] *COM (2008) 366*, final, p. 3-8 with annexed *SEC (2008) 2036*, final, p. 5-36 provide an overview of the EU legislation applicable to nanomaterials.

2 POLICY INSTRUMENTS FOR THE REGULATION OF NANOMATERIALS

2.1 Short history of nanotechnology and nano-regulation

The origin of nanotechnology is usually adhered to Richard Feynman's lecture 'There is plenty of room in the bottom'[17] in 1959 though there were many developments that contributed to the formation of nanotechnology.[18] The word 'nanotechnology' was created in 1974 when a Japanese scientist used it to refer the ability to manipulate matter at the atomic level.[19] Fifteen years later the first paper on nanotechnology regulation was published but a report of the Royal Society in 2004[20] acted as an actual catalyst for the nano-regulation debate.[21]

During the course of the years, several risk management approaches have been proposed including workplace controls, voluntary programs, international harmonization, insurance coverage and pools, liability, and precautionary measures.[22] It has become clear that the regulation of nanomaterials is a 'wicked' public policy problem – the stakeholders are unable to agree on the nature of the problem or on the most appropriate solution to be applied.[23] One conclusion of the debate has been that new oversight tools that comprise broader understanding of the specific challenges that nanomaterials pose, and clearer language both within and outside conventional regulatory frameworks to address these challenges, are needed.[24] The new governance model should be robust, anticipatory and flexible, incorporate both hard and soft regulation, and engage multiple participants. So far, however, regulatory authorities in the EU and the US have stated that current legislation is sufficient to regulate nanomaterials.[25]

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[17] *Caltech* 2001, section Richard P. Feynman: Plenty of room at the bottom, December 1959. Feynman talked about the problem of manipulating and controlling things on a small scale, for example using electron microscopes.
[18] *Toymey* 2010, p. 46-54.
[19] *Hodge – Bowman – Ludlow* 2007, p. 3.
[20] *The Royal Society & the Royal Academy of Engineering* 2004, p. 1-127.
[21] *Bowman – Hodge* Colum. Sci. Technol. L. Rev. 2007, p. 7.
[22] *Marchant et al*. Jurimetrics J. 2012, p. 266-276.
[23] *Maynard – Bowman – Hodge* Nature Mater. 2011, p. 554.
[24] *Ibid*; *Marchant et al*. Jurimetrics J. 2012, p. 276-277.
[25] In the US, see *Executive office of the US President* 2011, p. 3. In the EU, see *COM (2012) 572*, final, p. 11.

2.2 Hard regulation

2.2.1 Primary sources of law in the EU and the US

'Hard regulation' refers to binding legal instruments and laws. In the US it includes the constitutions[26], statutes[27], regulations[28], and common law[29]. Due to dual sovereignty each state sets its own laws and has own constitution. In addition, the US federal government enacts laws and has a constitution. Each system consists of three independent branches: the legislative, executive and judicial. The legal branch enacts laws, executive branch administer the laws by secondary regulations and guidance, and plaintiffs can challenge both laws and regulations in the courts. Some areas of law are governed by both federal and state systems.[30]

In the EU, the primary source of law are treaties. The latest revision, the Treaty of Lisbon[31] which entered into force in 2009, formed the Treaty on European Union (TEU)[32] and the Treaty on the Functioning of the European Union (TFEU)[33]. According to Article 288 of the TFEU, other hard regulation instruments are regulations, directives and decisions adopted to exercise the EU's competences.[34] Similar to the US, the EU has legislative branch, executive branch and independent judiciary. Article 289 of the TFEU states that an ordinary legislative procedure in the EU is a joint adoption by the European Parliament and the Council that then acts by qualified majority. In addition, any member state may maintain or introduce more stringent protective measures as far as they are compatible with the treaties. Primary executive authority is the European Commission (EC) together with the Council. The member states implement the EU law but the EU has also created particular regulatory agencies that may complement or substitute the executive efforts of national agencies. The Court of Justice of the European Union (CJEU) verifies that interpretation of the EU legislation is consistent

[26] 16 Am. Jur. 2d Constitutional Law § 1.
[27] 73 Am. Jur. 2d Statutes § 1.
[28] *Ibid.*
[29] 15A Am. Jur. 2d Common Law § 1. Common law "includes those rules of law which do not rest for their authority upon any express or positive statute or other written declaration, but rather upon statements of principles found in the decisions of the courts. - - The great fundamental object and principle of the common law was the protection of the individual in the enjoyment of all his or her inherent and essential rights and to afford him or her a legal remedy for their invasion".
[30] As an introduction to the US legal system, separation of powers, different sources of primary law, and hierarchy of authority, see *Steenken – Brooks* 2016, p. 7-105.
[31] OJ, N:o C 306, 17.12.2007, p. 1-271.
[32] OJ, N:o C 326, 26.10.2012, p. 13.
[33] OJ, N:o C 326, 26.10.2012, p. 47.
[34] For a broader description of the primary sources of law and their interrelations in the EU, see for example *Craig – de Búrca* 2015, p. 105-121.

in all member states and rules in legal disputes between the member states, EU institutions, business or individuals.

The treaties give emphasis to the importance of a requirement 'high level of protection' in the EU policy. It is found in Article 3 of the TEU and provides a contrast to the importance of economic objectives in the EU.[35] A high level of human health protection shall be ensured in the definition and implementation of all EU policies and activities according to Article 168 of the TFEU. Defining a high level of protection is a part of the political task of determining acceptable risk.[36] In addition, Article 191(2) of the TFEU states that environmental policy of the EU shall aim at a high level of protection, and be based on the 'precautionary principle', among others. Due to their inherent relevance to the challenge of regulation of nanomaterials I will elaborate on the concepts of uncertainty and risk, and discuss the precautionary principle and precaution in the EU and the US in the next subchapters before moving to soft regulation instruments.

2.2.2 Uncertainty and risk in the context of nanomaterials

Although the modern society generates enormous amount of new information and technological development is rapid, the threads that the emerging technologies such as nanotechnology pose to health and environment are poorly known and uncertainty that surrounds potential risks may inhibit the effective resolving of the possible new environmental problems.[37]

The concept of risk can *sensu stricto* be determined with the probability of an unfortunate event to take place. However, uncertainty affects both the probability of the occurrence of the risk and the extent of damage it may result in. Standard probability calculations cannot be used because any case is contentious until the relevant scientific knowledge has become stable. Thus, *sensu lato* determination in which risk is a two-sided concept: on one hand the

[35] *Lee* 2014, p. 5.
[36] *Ibid.*, p. 5, 37-38. Especially a cost-benefit analysis (CBA) contributes to the acceptable risk question by telling whether or not regulation is worthwhile.
[37] *van Asselt and Vos* J. Risk. Res. 2006, p. 316 state that knowledge and uncertainty are no communicating vessels and new information can also increase uncertainty by revealing the presence of uncertainties that were previously unknown or underestimated. See also *de Sadeleer* 2002, p. 153 of the concept of ignorance and its consequences.

possible occurrence of the event; on the other hand the resultant loss or damage, has been applied in the context of uncertain risks.[38]

Risk can be thought as an object of regulation but also as a technique of decision-making. Scientific risk assessment has been frequently required before administrative bodies can take protective measures.[39] Risk assessment, the first part of risk analysis[40], consists of hazard identification, hazard characterization, exposure assessment and risk characterization. Scientific uncertainty may affect each of these components. It may arise from the variables chosen (conceptual uncertainty), measurements made, samples drawn, models used, causal relationships employed, controversy of the existing data or lack of data, and it can be related to either qualitative of quantitative parts of the analysis.[41] In addition, multidisciplinary cutting-edge nature of many nanotechnology applications still increases the challenge the assessors face. Comprehensive risk assessment requires experts from various disciplines and the experts must be able to speak the same language, which may be problematic in highly specified fields of science. Furthermore, risk assessment cannot be purely scientific or policy neutral though a division between the decision-making responsibility of political institutions and the advisory role of experts has been tried to set in many jurisdictions.[42] Subjectivity and contingencies related to expert assessments under scientific uncertainty has risen criticism of risk analysis of nanomaterials as democratically deficient.[43]

The uncertainties make it challenging to apply traditional procedures of risk management such as the cost-benefit analysis (CBA) and best available technology approaches.[44] Consequently, two main strategies to respond the uncertain risks have been established: a precautionary principle[45] and 'wait-and-see'[46] approach. While precautionary debate is commonly characterized as a battle between the EU promoting and the US opposing it, recent studies

[38] *de Sadeleer* 2002, p. 150-161.
[39] *Lee* 2014, p. 29.
[40] Risk analysis involves risk assessment, management, and communication.
[41] *COM (2000) 1*, final, p. 13-14; *Walker* B.C. Int'l & Comp. L. Rev. 2003, p. 9.
[42] *Walker* B.C. Int'l & Comp. L. Rev. 2003, p. 198; *Lee* 2014, p. 39.
[43] *Miller – Wickson* RPR 2015, p. 493.
[44] *Marchant – Sylvester – Abbott* NanoEthics 2008:2, p. 43-45.
[45] *de Sadeleer* 2002, p. 124-138. This *in dubio pro securitate/natura* -model has also been recognized as one of the core principles of the Finnish environmental law and policy, see *Kuusiniemi* 1992, p. 221.
[46] In 'wait-and-see' approach regulatory authors want to delay regulatory action until sufficient scientific knowledge about risks is available and meanwhile rely on *ex post* remedies such as tort law administrated by the courts, see *Wiener – Rogers* J. Risk. Res. 2002, p. 320 and *Glady Jr. – Garcia – Moses* Jurimetrics J. 2012, p. 319-320.

do not support the separation.[47] In the next subsection the main features of precautionary approaches adopted in the EU and the US are examined.

2.2.3 Precautionary principle and precaution in the EU and the US

Precautionary principle appeared during the 1970s in domestic environmental policy in many industrialized countries and has been part of international environmental policy since the 1980s.[48] Alterations in the interpretation and application of the precautionary principle between the countries may lay down a barrier for internationally harmonized regulation of nanomaterials.

The TFEU does not define the precautionary principle. A legislative definition in the EU law is set up in Article 7 of the Regulation (EC) No 178/2002 laying down the general principles and requirements of food law, establishing the European Food Safety Authority (EFSA) and laying down procedures in matters of food safety (General Food Law)[49]. The Article states that where 'following an assessment of available information, the possibility of harmful effects of health is identified but scientific uncertainty persists, provisional risk management measures' may be adopted 'pending further scientific information'. Thus, application of the precautionary principle is a part of risk management which is also established in the EC's earlier communication on the precautionary principle.[50] General principles of risk management apply to precautionary principle and include proportionality, non-discrimination, consistency, examination of the potential benefits and costs of action or lack of action[51], and scientific review.

The US has not officially implemented the precautionary principle but precaution has been included in several individual federal and state laws and standards. Furthermore, the redundancy of the US legal system can be considered as a precautionary feature as well. Regulation by the federal statutes, state prohibitions or labelling requirements, and the threat of liability lawsuits may all relate to a particular product or material.[52] However, courts in the

[47] For example *Wiener* 2011a, p. 28 summarizes that based on the review of the case studies over the past several decades neither the US nor the EU can claim to be more precautionary.
[48] *COM (2000) 1,* final, p. 10-11; *Falkner – Jaspers* Global Envtl. Politics 2012, p. 37.
[49] OJEC, N:o L 31, 1.2.2002, p. 9.
[50] *COM (2000) 1,* final, p. 12, 17.
[51] This examination may include an economic CBA if appropriate.
[52] *Renn – Elliott* 2011, p. 228.

US have up till now rejected the claims that the precautionary principle as such constitutes enforceable customary international law.[53]

There is variation in the degree of precaution in risk regulation across risks, agencies, and member states in both the EU and the US.[54] In addition, it is good to notice that regulatory authorities and policymakers have a wide range of activities available under the head of the precaution, ranging from research projects and public information measures to instruments that produce legal effects. One action that the precautionary principle enables if prior approval of the substance or product is required in the EU, is placing the burden of proof to produce scientific evidence for business community. This may create a significant discrepancy between the regulatory frameworks in the EU and the US, at least in the chemicals sector, as I will point out in section five.

2.3 Soft regulation

During the last two decades the traditional hard regulation has been broadened out to contain instruments and activities that extend well beyond the law. 'Soft regulation' instruments include for example self-regulation, co-regulation, standards, economic incentives, information measures, guidelines, recommendations, communications, and codes of conduct.[55] The instruments most frequently applied for nanomaterials are explained below. In section 3, the soft regulation measures currently active or otherwise relevant for this work are considered, a comprehensive examination of all the measures applied in the EU and the US is not included.

Self-regulation. In the EU, self-regulation has been defined in the Interinstitutional agreement on better law-making as 'the possibility for economic operators, the social partners, non-governmental organizations (NGO) or associations to adopt amongst themselves and for themselves common guidelines (particularly codes of practice or sectoral agreements)'.[56] The agreement also sets down the conditions which the use of self-regulation has to meet, such as consistency with the EC law, added-value for the general interest, and negligible effect on competition or unity of the market.[57] Furthermore, the use of self-regulation is not

[53] *Wiener* 2011a, p.11.
[54] *Wiener* 2011b, p. 521.
[55] *Hodge – Bowman – Maynard* 2010, p. 9.
[56] *C (2003) 321/01*, p. 3.
[57] *Senden* EJCL 2005, p. 17.

appropriate in the circumstances where fundamental rights or significant political options are in question, and where the particular rules have to be applied consistently in all member states.

Some self-regulation schemes have been established for nanomaterials in the EU and the US. They include voluntary industry initiatives, NGO initiatives, industry-government partnerships, industry-NGO partnerships, and industry-government-NGO collaborations.[58] Self-regulation may provide a way to keep pace with technology developments. However, its success depends on numerous factors including representativeness, transparency, legal compliance, and effectiveness of implementation and monitoring.[59] The challenges of self-regulation in the context of nanomaterials include decision-making under uncertainty and high pay-off situations, intellectual property protection, and corporate self-interest.[60] All of these points may result in that the companies are not raring to put self-regulation schemes into practice.

Standards. Standardization is currently the most visible effort on the way to transnational harmonization of the nano-regulation. Many international organizations are working on the issue. The most active in the field are the OECD and the ISO. The OECD has two working parties targeting to the object, a Working Party on Nanotechnology (WPN) and a Working Party on Manufactured Nanomaterials (WPMN). The WPN advises upon emerging policy issues of science, technology and innovation related to the responsible development of nanotechnology. The issues considered in the WPN include regulatory frameworks relevant to nanotechnology, specifically related to food and medical products.[61] The WPMN concentrates on the EHS aspects of manufactured nanomaterials mainly in the chemicals sector, and aims to ensure that the approaches to hazard, exposure, and risk assessment are built on the science-based and internationally harmonized standards. Its activities include a database on manufactured nanomaterials, a testing program for priority nanomaterials, promotion of cooperation on voluntary and mandatory regulatory programs, guidance development, and facilitation of transnational information sharing.[62] Another leading organization, the ISO has

[58] *Marchant – Abbott* Nanotech. L. & Bus. 2013, p. 403-405.
[59] *EESC* 2015, p. 8.
[60] *Lee – Jose* Tech. Anal. Strat. Manag. 2008, p. 119-123.
[61] *OECD* 2015, p. 6.
[62] *Abbott – Marchant – Corley* Jurimetrics J. 2012, p. 290-291; *OECD* 2016a, p. 9.

established a technical committee on nanotechnologies (TC 229) that has published 50 international standards concerning terminology and nomenclature, metrology and instrumentation, reference materials, test methodologies, modelling and simulations, and science-based EHS practices.[63]

Information measures. Information, in addition to being the foundation for regulation, can be exploited to change the behavior of the individuals or organizations.[64] It is more than true that better knowledge decreases ignorance and may improve performance. Information measures include numerous actions for instance consumer information through labelling, enhanced access to information through freely available registers, different schemes to gather and exchange information, and publicly funded research projects, among others. For example, since 2006 the OECD has released 71 publications in the Series on the Safety of Manufactured Nanomaterials to provide up-to-date information on the OECD activities related to the EHS aspects of engineered nanomaterials.[65] In addition, several web-platforms have been established to enhance information exchange and public awareness on nanomaterials.

Guidelines, recommendations, communications, and codes of conduct. These soft regulation instruments have been used by both the regulatory authorities and the industry in the EU and the US to contribute towards responsible development of nanotechnology. *Senden* has labeled this group *soft law* to distinct it from the concepts of self- and co-regulation and has proposed the following definition: "Rules of conduct that are laid down in instruments which have not been attributed legally binding force as such, but nevertheless may have certain - indirect - legal effects, and that are aimed at and may produce practical effects".[66] These instruments are anticipated to encourage stakeholders voluntarily accomplishing the preferred objectives. In the EU, particularly recommendations from the EC can be considered as steering instruments to support self-regulation initiatives.

In addition, EU legislation is frequently supplemented by guidance documents intended to assist proper implementation. *Korkea-aho* has studied the implementation stage of the EU

[63] *ISO* 2016, section ISO/TC 229 Nanotechnologies.
[64] *Lee* 2014, p. 104-105.
[65] *OECD* 2016, section Publications in the Series on the Safety of Manufactured Nanomaterials.
[66] *Senden* EJCL 2005, p. 22.

legislation and has stated that soft law measures can be helpful for example for the courts by providing accurate information that can be exploited to make their review more robust. Non-binding guidance can have legal effects mainly in two situations: it is imperative, sets new obligations and expands on primary or secondary legislation; or it is prepared to give more information on EC's exercise of discretionary powers.[67] Soft law actions can also be accompanied by monitoring schemes to follow the fulfillment. However, the only sanction usually imposed is the threat of future legislation if the objectives are not achieved.[68]

[67] *Korkea-aho* Legisprudence 2012, p. 397, 413.
[68] *Senden* EJCL 2005, p. 16, 23-24.

3 REGULATION OF NANOMATERIALS IN CHEMICALS, FOOD, AND PESTICIDES/BIOCIDES SECTORS IN THE EU AND THE US

3.1 Policy goals for regulation of nanomaterials in the EU and the US

The EC released in 2004 the communication "Towards a European strategy for nanotechnology" that still is the core of the EU's nanotechnology policy.[69] Based on the proposed safe, integrated, and responsible approach the EC formulated an action plan for nanosciences and nanotechnologies in 2005.[70] Putting together the strategy and the action plan, the following goals for regulation of the EHS risks of nanomaterials in the EU can be identified: data generation for life cycle based risk assessment; development of risk assessment and risk management methodologies; and establishment of open, coordinated, and proactive approach.

In the US, National Nanotechnology Initiative (NNI) coordinates the nanotechnology-related research, development and policy activities of different federal agencies. The NNI has released a strategy for nanotechnology-related EHS research. The aim of the strategy is to guide the agencies that produce and use scientific information to develop risk and life cycle analyses that inform regulatory decisions.[71] Based on the strategy and 'Policy principles for the U.S. decision-making concerning regulation and oversight of applications of nanotechnology and nanomaterials'[72], four goals for the federal regulation in the context of this study can be recognized: information gathering; setting up evidence-based decisions; increased flexibility; enhancement of consistency in risk assessment and risk management.

Altogether, the primary policy goals for the regulation of the EHS risks of nanomaterials at this stage in the EU and the US can be summarized to be: 1) information gathering, 2) consistency in risk assessment and risk management, and 3) establishment of open, flexible, and proactive approach.

[69] *COM (2004) 338,* final, p. 1-25.
[70] *COM (2005) 243*, final, p. 1-12.
[71] *NNCO* 2011, p. 2.
[72] *Executive office of the US President* 2011, p. 4.

3.2 Divergence in the definition of 'nanomaterial'

Prerequisite for effective regulation is a well-defined trigger for nano-specific risk assessment. However, internationally agreed definition for 'nanomaterial' does not exist. The EC established in 2011 a recommendation for the definition of nanomaterial[73] but nevertheless different definitions have been formulated in product specific regulations.[74] The EC has performed an evaluation of options to clarify the definition. The evaluation report indicated that the scope of the definition should remain unchanged and there is little evidence to support deviating from size as the sole defining property of a nanomaterial.[75] In the recent legislative actions, an aim to harmonize the definition in the EU can be recognized, as I will indicate later under the individual regulations.

In contrast, the US agencies have been reluctant to set any strict definition for nanomaterial and have promoted broader approach that takes into account the specific properties of the nanomaterials. For example, the Food and Drug Administration (FDA) argues that as with other emerging technologies, advances in both basic and advanced nanotechnology may be unpredictable, rapid, and unevenly distributed across product applications and risk management tools. The broadly inclusive initial approach may become more nuanced in light of experience, scientific information, and public input.[76] The similar approach has been adopted by the Environmental Protection Agency (EPA), too. I will highlight the problems that arise from the broad approach later in the text.

The discrepancy in the attitudes towards common definitions or even complete lack of definitions indisputably generate different triggers for nano-specific risk assessment between the EU and the US. This may increase potential for double standard and result in conflicts for example in the trade relations in the future.

[73] *C (2011) 696*, final, p. 40.
[74] *Boverhof et al.* Reg. Toxicol. Pharmacol. 2015 have compared definitions of the term nanomaterial in EU and non-EU countries.
[75] *Rauscher et al.* 2015, p. 3.
[76] *Hamburg* Science 2012, p. 299-300.

3.3 Chemicals

3.3.1 The EU - Hard regulation with soft contents

Hard regulation. The main legal instruments to regulate nanomaterials in chemicals sector are the Regulation (EC) No 1907/2006 of the Registration, Evaluation, Authorization, and Restriction of Chemicals (REACH)[77] and the Regulation (EC) No 1272/2008 of the Classification, Labelling, and Packaging of substances and mixtures (CLP)[78]. Though the REACH and the CLP do not include explicit requirements for nanomaterials, they belong to 'substances'[79] defined in the regulations. The European Chemicals Agency (ECHA) administers the registration and notification of nanomaterials under these regulations and shares authority with the member states and the EC to evaluate, authorize and restrict nanoforms of substances.

Article 1(3) of the REACH states that its provisions are underpinned by the precautionary principle. The REACH is basically grounded on "no data, no market", principle (Article 5). The registration is required for substances manufactured or imported in quantities of one tonne or more per year per manufacturer or importer (Article 6(1)). Though, the ECHA's guidance document states that when a registrant manufactures of imports the substance in the nanoform as well as in the bulk form, the registration dossier should include the information of the substance in both the bulk form and the nanoform.[80]

Manufacturers or importers of chemicals have to prove the safety of their products before market entry is allowed (Articles 10-14). Today, however, the registration of nanomaterials is in reality voluntary and it is unclear for registrants if and how they should cover nanoforms of substances in the registration dossiers.[81] The EC is formulating modifications for the REACH Annexes to ensure clarity on whether and what nanoforms are covered in registration dossiers, and to adjust information requirements for nanomaterials. Public consultation closed in September 2013 but up till now any draft of the revised annexes is not available.[82]

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[77] OJ, N:o L 136, 29.5.2007, p. 3-278.
[78] OJ, N:o L 353, 31.12.2008, p. 1-1355.
[79] According to Article 2 of the REACH it does not apply e.g., to radioactive substances, non-isolated intermediates, waste, food additives or flavors, medicinal or cosmetic products. Article 1 of the CLP states that the regulation does not apply to medicinal or waste, cosmetic products, food additives or flavors among others.
[80] *EC* 2012, p. 26-27.
[81] *RPA et al.* 2014, Annex II.
[82] *EC* 2013, section Consultations.

In May 2016, the ECHA published a new guidance draft to define 'nanoform'[83], the minimum criteria for distinguishing between different nanoforms, and the minimum set of parameters (size, shape, surface chemistry) which have to be reported to characterize a nanoform. At the same time, other new guidance drafts relating to nanomaterials (e.g., on information requirements) were published as well.[84] In addition, the ECHA has initiated substance evaluation activities on nanomaterials with the member states under the Community Rolling Action Plan (CoRAP)[85]. The first final substance evaluation decision for a nanomaterial, silicon dioxide, was completed in 2015. Other nanomaterials included in the CoRAP are silver, titanium dioxide, zinc oxide, cerium oxide, and multi-walled CNTs.[86]

Classifying and labelling chemicals in the CPL is based on the United Nations' Globally Harmonised System (GHS). According Article 5(1) of the CLP, manufacturers, importers and downstream users of a substance shall identify the relevant available information for the purposes of determining whether the substance entails a physical, health or environmental hazard. The information shall relate to the forms or physical states in which the substance is placed on the market and in which it can reasonably be expected to be used. Article 9(1) of the CLP states that the information identified shall be evaluated by applying to it the criteria for classification for each hazard class. When evaluating, the forms or physical states in which the substance or mixture is placed on the market and in which it can reasonably be expected to be used shall be considered and the test methods employed to obtain the data compared in order to determine whether the use of different test methods affects the evaluation (Article 9(2,5)).

The ECHA's guidance document points out that in cases where for example particle size (including nanomaterials), shape, specific surface area, density, or crystal structure may influence the test result, the tests must be performed on the substance or mixture in the appropriate physical form.[87] Consequently, nanomaterials that fulfill the criteria for classification as hazardous under the CLP have to be labelled, independently of the tonnage in which the substances are manufactured or imported. Nevertheless, the results of the DG Environment's

[83] *ECHA* 2016a, p. 4, 6. The ECHA defines that nanoform is a form of substance that meets the requirements of the EC definition of a nanomaterial and always has a specific shape and a specific surface chemistry as additional parameters.
[84] *ECHA* 2016, section Ongoing consultation REACH.
[85] *ECHA* 2016, section CoRAP.
[86] *ECHA* 2015b, Annex 1, p. 3.
[87] *ECHA* 2015, p. 88.

Nano Support Project Task 1 published in 2012 indicated that the tested materials and test methods are inadequately reported to enable performing the evaluation.[88]

Case law. There are currently no cases in the CJEU database concerning nanomaterials or nanoforms of substances in which the ECHA is a party.[89]

Soft regulation. Guidelines, recommendations, communications, and codes of conduct. The EC promotes voluntary safety initiatives through its Code of conduct for responsible nano-sciences and nanotechnologies research.[90] The recommendation relies on the precautionary principle and underlines the importance to anticipate potential EHS impacts. In addition, the recommendation for the definition of nanomaterial is an important soft regulation action from the EC.[91] Moreover, the EC has released several communications concerning regulative aspects of nanomaterials. Furthermore, for example the REACH regulation is implemented through ECHA's guidance documents which have been considered as soft law instruments.[92] In the industry, some companies, for example BASF, have own Code of Conducts to ensure responsible handling of nanomaterials.[93]

Self-regulation. The database of Self- and co-Regulation initiatives hosted by the European Economic and Social Committee (EESC) does not include any initiatives concerning nanomaterials.[94] However, already in 2006 industry-government partnership started to work together and resulted in the Responsible Nano Code in 2008.[95] The code is principle-based and was intended to provide guidance on the best practices while the appropriate national and international regulatory frameworks are evaluated and developed.[96] The first certified risk management and monitoring system for nanomaterials, CENARIOS® (Certifiable Nano-specific Risk Management and Monitoring System), was launched in 2008.[97] Today, also Stoffenmanager®, a quantitative exposure model applied to evaluate exposure to chemical substances at the workplace, has a nano module.[98]

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[88] *Climent et al.* 2012, p. 101-109.
[89] *CJEU* 2016, section Search for a case.
[90] *C (2008) 424,* final, p. 4, 6.
[91] *C (2011) 696*, final, p. 40.
[92] *Korkea-aho* Legisprudence 2012, p. 398-399.
[93] *BASF* 2015, section Nanotechnology Code of Conduct.
[94] *EESC* 2016, The database on Self- and Co-Regulation Initiatives.
[95] *NIA* 2008, The Responsible Nano Code – Update May 2008.
[96] *Abbott – Marchant - Corley* Jurimetrics J. 2012, p. 294-295.
[97] *TÜV SÜD* 2016, section Nanotechnology.
[98] *Cosanta B.V.* 2016, section The Stoffenmanager Nano Module.

In addition, the Responsible Care® is a global chemical industry's initiative to improve health and environmental performance, enhance security, and to communicate with stakeholders about products and processes. The European Chemical Industry Council (CEFIC) is committed to contribute to the responsible development of nanomaterials applications in the European chemical industry and has studied the implementation of the Responsible Care® in the production and use of nanomaterials. One of the CEFIC member associations, the 'Producers association of carbon nanotubes in Europe' has formulated the 'Code of Conduct for the production and use of carbon nanotubes' to develop CNTs by following the Responsible Care® precepts. A Product Stewardship program within the chemical industry is Responsible Care for products and has been applied to nanomaterials in some companies. Overall, however, the CEFIC shares the opinion of the EC that the current regulatory framework adequately covers nanomaterials.[99]

Standards. The ECHA is active in the WPMN of the OECD and currently chairs the 'Steering group for testing and assessment'. The steering group oversees the revision of the existing and development of new test methods for hazard assessment of nanomaterials. One of the latest documents of the WPMN concludes that most of the test methods for the measurement of physicochemical properties of nanomaterials are not standardized to this day, which hampers their use in the risk assessment.[100]

Through the OECD sponsorship program several member states are involved in the collection and analysis of information regarding nanomaterials with the objective to review the GHS. The revision is scheduled to be completed by the end of year 2016 and the possible alterations implemented may lead to its improved applicability to the classification, labelling and packaging of nanomaterials under the CPL.[101]

The European Committee for Standardization (CEN) has set up a technical committee (CEN/TC 352) on nanotechnologies that works closely with the ISO/TC 229. The CEN/TC

[99] *CEFIC* 2012, p. 2-11.
[100] *OECD* 2016b, p. 26-27.
[101] *ECHA* 2015b, Annex 1, p. 4.

352 has published 14 standards and one is under approval.[102] The published standards include for example 'Guidance on voluntary labelling for consumer products containing manufactured nano-objects' (CEN ISO/TS 13830:2013).

Information measures. The REACH should be a transparent system via publicly accessible chemical database maintained by the ECHA. However, due to above mentioned weaknesses concerning nanomaterials, the EC is considering to enhance the transparency of available information through a possible introduction of a nanomaterials registry, the option already adopted by some member states.[103] The EC has conducted a public consultation that closed in August 2014. In the summary document industry respondents were of the view that an EU-wide nanomaterials registry would have a negligible effect controlling the potential risks posed by nanomaterials but is instead likely to create additional burden and create negative public perception of nanotechnologies. However, the industry respondents acknowledged that the EU-wide registry would be preferable to national registries. The opinions of citizens and NGOs were opposite to that of industry. They argued that EU-wide nanomaterials registry would provide valuable information on the use of nanomaterials through their life cycle, as well as would contribute to exposure assessment and in identifying proper risk management measures.[104]

The EC's Joint Research Centre (JRC) has launched a web-platform with links to information relevant to nanomaterials.[105] In addition, the JRC hosts a repository of representative industrial nanomaterials[106] that was initially formed to support the WPMN's testing program, and a NANOhub database and information platform[107] that complements the repository for test method development and assessment. Several other national or international web-platforms have been created to enhance information on nanomaterials, too. As an example of an industry-initiated information activities, BASF has arranged Dialogforum Nano since 2009/2010 as a continuous stakeholder dialogue on nanotechnologies.[108]

[102] *CEN* 2016, section Published standards.
[103] *Gellert – Mantovani – Hert* 2015, p. 343.
[104] *EC* 2014, Summary of the public consultation on transparency for nanomaterials on the market, p. 17.
[105] *EC* 2015, Web platform on nanomaterials.
[106] *EC* 2016, JRC Nanomaterials repository.
[107] *EC* 2016, NANOhub.
[108] *BASF* 2016, Dialogforum Nano 2014/2015.

Research projects are also one form of information measures. The ECHA is currently involved in NanoReg[109] which latest outcome is a technical report for harmonized terminology for EHS assessment of nanomaterials.[110] The CEFIC sponsors research on the safety of nanomaterials through its 'Long range research initiative'. The results are shared with regulatory organizations and academia to drive effective risk assessment and risk management. In addition, companies conduct their own nano-safety research and participate in multi-stakeholder research projects.[111]

3.3.2 The US – From voluntary to mandatory approach

Federal regulation. Regulatory authority for the EHS aspects of nanomaterials and nanotechnology-based products in the chemicals sector is allocated to the EPA. Additionally, Consumer Product Safety Commission (CPSC) has the regulatory jurisdiction over thousands of consumer products under the Consumer Product Safety Act (15 U.S.C. § 2051 et seq., 1972), the Federal Hazardous Substances Act (15 U.S.C. § 1261 et seq., 1960), the Poison Prevention Packaging Act (15 U.S.C. § 1471 et seq., 1970), and Consumer Product Safety Improvement Act (15 U.S.C. § 2051 et seq., 2008). The CPSC is able to produce standards for product safety and recalls of products that are unsafe but it has no pre-market review authority.

The EPA regulates nanomaterials in chemical substances under the Toxic Substances Control Act (TSCA, 15 U.S.C. § 2601 et seq., 1976).[112] A general regulatory authority under the TSCA is established in 15 U.S.C. § 2604(a) that requires manufacturers[113] of chemical substances to file a Pre-Manufacture Notice (PMN) or a Significant New Use Notice (SNUN) 90 days prior to manufacturing or introducing a new chemical or a significant new use of an existing chemical. Nanoscale forms of chemical substances that are not in the TSCA inventory are considered new substances that require reporting using the PMN. Nanoscale materials with the same molecular identity as a chemical substance already in the TSCA inventory

[109] "A common European approach to the regulatory testing of nanomaterials" (NanoReg) is funded under FP7-NMP in years 2013-2017, project reference in the Community Research and Development Information Service is 310584.
[110] *Gottardo et al.* 2016, p. 8-9.
[111] *CEFIC* 2012, p. 5-8.
[112] The TSCA is amended by PL 114-182, June 22 2016, 130 Stat 448. Discussion hereafter refers to the amended statute. According to 15 U.S.C. § 2602(2)(B) the TSCA does not apply to drugs, food, food additives, pesticides, and cosmetics among others.
[113] Here, manufacturers refer collectively to all covered entities, see 15 U.S.C. § 2602(9), (14).

are considered existing and do not require the PMN.[114] For significant new uses, the EPA has to set a Significant New Use Rule (SNUR) before the reporting requirements apply (15 U.S.C. § 2604(a)(2)). In 2010, the EPA proposed a SNUR that would have been covered all nanoscale materials[115] but withdrew the proposal in 2011.[116] The SNURs exist now for example for different CNTs[117] and graphene nanoplatelets[118].

Information that has to be provided in the PMN and the SNUN includes but is not limited to, the chemical identity, available test data regarding environmental or health effects, the uses or intended uses, production volume, byproducts, disposal practices, and estimate on human exposure (15 U.S.C. § 2604(d)). Pre-manufacture testing is not required for the PMN or the SNUN but during the review process the EPA can require to conduct testing by a rule, order, or consent agreement (15 U.S.C. § 2603(a)). The authority to require development of new information on chemicals is expanded from the old statute that presumed lengthy rulemaking. The EPA recommends that the applicants of the SNUNs consult with the agency prior submitting to discuss what data may be valid in evaluating risks posed by the substance.[119]

The new statute requires the EPA to take an action and publish the result of its determination on new chemicals or significant new uses of the existing chemicals before the chemical is allowed to enter in the market (15 U.S.C. § 2604(a)(3)). The chemicals are evaluated against risk-based safety standard without the CBA. If the EPA finds during the review process that the chemical presents an unreasonable risk, it shall take the action against such risk (15 U.S.C. § 2604(f)). 15 U.S.C. § 2604(h) and EPA's implementing rules contain exemptions to PMN and SNUN requirements including: low volume[120], low release and low exposure[121],

[114] *EPA* 2008, p. 2-3. EPA has stated that molecular identity is based on the types and number of atoms and chemical bonds in the molecule, and the connectivity and spatial arrangement of the atoms in the molecule. Chemical substances that differ in any of these features are considered to have different molecular identities.
[115] *EPA* 2010, section Regulatory plan Fall 2010.
[116] *EPA* 2011, section Regulatory plan Spring 2011.
[117] 40 CFR § 721.10155-721.10156, 40 CFR § 721.10755-721.10756.
[118] 40 CFR § 721.10844.
[119] *EPA* 2015, section Filing a significant new use notice (SNUN) under TSCA; *EPA* 2015, section Control of nanoscale materials under the Toxic substances control act.
[120] 40 CFR § 723.50 grants and exemption from the PMN if 10 000 kg or less of chemical substance is manufactured or imported per year.
[121] *Ibid.*

polymers[122], research and development[123], and test marketing[124]. In most cases the exemptions have record-keeping requirements.[125]

In April 2015, the EPA proposed a rule under 15 U.S.C. § 2607(a) of the TSCA to require reporting and recordkeeping of certain chemical substances when they are manufactured or processed as nanoscale materials.[126] The proposal involves one-time reporting for the existing nanoscale materials and one-time reporting for new discrete nanoscale materials before they are manufactured or processed. The proposed rule would apply to chemical substances that are manufactured or processed in a form where the primary particles, aggregates or agglomerates are in the size range of 1-100 nanometers and exhibit unique and novel characteristics or properties because of their size.[127] The reporting requirements are focused on intentionally manufactured chemical substances at the nanoscale. A nanoscale form of a particular chemical substance with a different morphology, shape or coating would be qualified as discrete nanoscale material. In addition, chemical substances that are manufactured or processed in a nanoscale form as a component of a mixture, encapsulated material, or composite have to be reported, too. Furthermore, the EPA is proposing a different exemption rule based on low volume than the existing one, consequently defining a small manufacturer or processor as any company with sales less than USD 4 million.[128] The EPA is currently preparing the final rule that should be published in October 2016.[129]

State regulation. The federal and state governments typically cooperate to implement national environmental laws.[130] However, state governments may also enact their own environmental statutes. The Chemical Information Call-in Statute in California Health and Safety

[122] 40 CFR § 723.250.
[123] 40 CFR § 720.36. Any chemical substances manufactured in quantities less than 454 kg annually will be presumed to be manufactured for research and development purposes, see 40 CFR § 710.3.
[124] 40 CFR § 720.38.
[125] 40 CFR § 723.50; see also 15 U.S.C. § 2607(a),(c).
[126] *EPA 2015, 80 FR*, p. 18330. EPA states to use the information gathered through this reporting rule to determine if any further action under the TSCA is needed.
[127] The relevant properties include zeta potential, specific surface area, dispersion stability, and surface reactivity. The EPA states that size cannot be used as a determinant for nanoscale substance so that variation in size ranges between production batches would not trigger reporting requirement, see *EPA 2015, 80 FR*, p. 18334.
[128] The EPA argues that the 100 000 lb (45 400 kg) threshold for purposes of reporting in the existing exemption do not contemplate typical production volumes for chemical substances manufactured at the nanoscale, see *EPA 2015, 80 FR*, p. 18335.
[129] *EPA* 2016, section Proposed TSCA reporting and recordkeeping requirements for chemical substances when manufactured or processed as nanoscale materials.
[130] *Breggin et al.* 2009, p. 35.

Code (HSC, 37:57018-57020 §, 1.1.2007) requires manufacturers and importers to provide the state agency information on any requested chemical regarding analytical test methods, fate and transport in the environment, and other relevant information. Department of Toxic Substances Control (DTSC) has conducted two chemical information call-ins concerning CNTs, quantum dots, nano silver, nano zero valent iron, nano cerium oxide, nano titanium dioxide, and nano zinc oxide to make information on chemicals more available.[131]

Also, the 'Green chemistry' section of the HSC (HSC 20:25251-25257.1 §, 1.1.2009) includes provisions that relate to nanomaterials. HSC 20:25256 § mandates the DTSC to establish the Toxics information clearinghouse, which shall provide a decentralized web-platform for the collection, maintenance, and distribution of specific chemical hazard trait[132] and toxicological end-point data. HSC 20:25256.1 § requires the Office of Environmental Health Hazard Assessment (OEHHA) to evaluate and specify the hazards traits and other relevant data that are to be included in the clearinghouse. Furthermore, according to HSC 20:25252 § the DTSC shall adopt regulations to establish a process to identify and prioritize chemicals or chemical ingredients in consumer products[133] that may be considered as being a chemical of concern. A 'Chemical of concern' means a 'candidate chemical' that has been identified and designated as a chemical of concern according to the 'Safer consumer products' section in the California Code of Regulations (CCR 22:69501-69510 §, 1.10.2013). In adopting the regulations, the DTSC shall develop criteria by which chemicals and their alternatives may be evaluated. These criteria shall include but are not limited to, the traits, characteristics, and endpoints that are included in the clearinghouse data. The CCR section 22:69401-69407.2 § (29.1.2012) 'Green chemistry hazard traits, toxicological and environmental endpoints and other relevant data' includes a hazard trait that has a reference to particle size 'Particle size or fiber dimension' (CCR 22:69405.7 §). The pre-regulatory draft published by the OEHHA included the 'Nanomaterial hazard trait' and references to nanoparticles in the 'Particle size or fiber dimension' hazard strait.[134] Accordingly, the first draft of the Safer consumer products regulation included references to nanomaterials.[135] Although the explicit references

[131] *DTSC* 2016, section Chemical information call-in.
[132] 'Hazard traits' are properties of chemicals that fall into broad categories of toxicological, environmental, exposure potential, and physical hazards that may contribute to adverse effects in exposed humans, domesticated animals, wildlife, or in ecological communities, populations or ecosystems (CCR 22:69401.2(e)).
[133] 'Consumer product' means a product or part of the product that is used, brought, or leased for use by a person for any purposes. The term does not include food and pesticides, among others (HSC 20:25251(e) §).
[134] *OEHHA 2010*, p. 19, 21.
[135] *DTSC* 2010, p. 1-110.

have been removed, both regulations apply to nanomaterials. The list of candidate substances contains nanomaterials, e.g. carbon black, CNTs, titanium dioxide, and silicon carbide whiskers.[136]

In addition, the Safe Drinking Water and Toxic Enforcement Act (HSC, 20:25249.5-25249.13 §, 1.1.1987) (also designated as Proposition 65) requires warning labels for chemicals that are known to cause cancer or reproductive toxicity and are listed in the Proposition 65 list (27 CCR § 27001). The listed chemicals include, e.g., titanium dioxide and carbon black. The OEHHA is currently proposing amendments to warning and labelling requirements but the proposed text does not explicitly mention nanomaterials or require 'nano' labelling.[137]

Case law. At this time, there are not any federal or state cases in chemicals sector regarding nanomaterials or nanoscale substances in which the EPA or the state of California is a party.[138]

Soft regulation. Guidelines, recommendations, communications, and codes of conduct. Regulatory authorities in the US have not generated guidelines, recommendations, communications, and code of conducts with reference to nanotechnology and nanomaterials as eagerly as their counterparts in the EU. The policy principles published by the Executive office of the US President in 2011 has been already mentioned above.[139] The EPA released in 2007 Nanotechnology White Paper to 'inform EPA management of the science needs associated with nanotechnology, to support related EPA program office needs, and to communicate the nanotechnology science issues to stakeholders and the public'.[140] More importantly, in 2008 the EPA published a guidance to determine whether a nanoscale substance is a new chemical for the purposes of the TSCA inventory that has been the basis for the EPA's approach to determine nanomaterial under the TSCA since then.[141]

[136] *DTSC* 2016, section DTSC Candidate chemical database.
[137] *OEHHA* 2016, p. 1-27.
[138] *Westlaw* 2016, section Cases.
[139] *Executive office of the US President* 2011, p. 1-5.
[140] *EPA* 2007, p. 15.
[141] *EPA* 2008, p. 1-7.

Self-regulation. Environmental Defense Fund (EDF) and DuPont launched in 2007 a Nano Risk Framework that is a NGO-industry partnership targeted to companies working with nanomaterials to evaluate and address the potential risks the nanomaterials pose.[142] Several companies have implemented, incorporated, or benchmarked the framework since 2007.[143] The ISO has integrated the framework into its technical report on nanomaterial risk evaluation (ISO/TR 13121:2011). In 2008, the EPA introduced a voluntary industry-government reporting initiative, the Nanoscale Materials Stewardship Program (NMSP), which invited producers of nanomaterials to report to the EPA safety-relevant information. The aim of the program was to provide a firmer scientific foundation for regulatory decisions by voluntary submission and development of information for nanoscale materials.[144]

The Responsible Care ® has been adopted also in the US chemicals sector. For example, DuPont has established an internal, mandatory stewardship process for any products containing new nanomaterials.[145] The American Chemistry Council (ACC) states in its position on nanotechnology that the product stewardship principles in programs such as the ACC's Global Chemicals Management Policy and the Responsible Care® apply to nanotechnology-related activities.[146] Analogous to the EU, some producers associations in the US have taken actions to address the global regulatory and EHS issues associated to their products. One such example is the NanoSafety Consortium for Carbon (NCC) that twelve leading companies involved in the commercialization of carbon nanomaterials founded in 2010 to strengthen industry-government collaboration.

Standards. There are three standardization organizations in the US that have dealt with the nanotechnology issues besides the above described the OECD and the ISO. At the federal level, the Center for Nanoscale Science and Technology in the National Institute of Standards and Technology (NIST) develops measurement methods, instrumentation and standards to support nanotechnology progress and marketing efforts.[147] Additionally, the American National Standards Institute (ANSI), which is a NGO and coordinates voluntary standardization activities in the US and internationally, has formed a Nanotechnology Standards Panel

[142] *Environmental Defense – DuPont* 2007, p. 7.
[143] *DuPont* 2016, section DuPont Nanotech Project: Endorsement and Public Impact.
[144] *EPA* 2009, p. 3.
[145] *DuPont* 2012, section Position statements.
[146] *ACC* 2016, section Nanotechnology.
[147] *NIST* 2016, section Center for Nanoscale Science and Technology.

that participate for instance in the development of the ISO standards.[148] A different NGO, the ASTM International has established the Committee E56 on Nanotechnology which generates standards and guidance related to nanotechnology as well.[149]

Information measures. Information measures applied are practically corresponding in the EU and the US. Analogous to the chemical database maintained by the ECHA, the access to the EPA's TSCA inventory is free online. The database is updated approximately every six months. In addition, the DTSC of California maintains Toxics information clearinghouse accredited by the above mentioned mandate.[150] Public consultations during, for example, the EPA's rulemaking as determined in 5 U.S.C. § 553 of the Administrative Procedure Act (5 U.S.C. § 551 et seq., 1946) are one principal method to increase transparency and public awareness, too.

Web-platforms have been created, too. One of them, www.nano.gov, is maintained by the National Nanotechnology Coordination Office (NNCO) that provides public outreach on behalf of the NNI.[151] In addition, the NNCO organizes NNI-sponsored workshops and coordinates development of information on the NNI and its activities.

The EPA conducts its own nanomaterial research, funds chemical research and participates in collaborative research projects on nanomaterials.[152] In addition, the EPA participates actively in the work of the WPMN of the OECD.[153] What regards to the industry, for instance DuPont is also engaged in the WPMN, and provides expertise and support for the NNI and nano-related research programs.[154] The Nanotechnology panel of the ACC co-sponsors the nano-research projects to advance knowledge of good product stewardship practices among nanomaterial producers and users.[155]

[148] *ANSI* 2016, section Nanotechnology Standards Panel.
[149] *ASTM International* 2016, section Committee E56 on Nanotechnology.
[150] *DTSC* 2016, section Toxics Information Clearinghouse.
[151] *NNI* 2016, section National nanotechnology coordination office (NNCO).
[152] For EPA's activities on nanomaterial research, see *EPA* 2016, section Research on nanomaterials.
[153] *EPA* 2015, section Control of nanoscale materials under the Toxic substances control act.
[154] *DuPont* 2012, section Position statements.
[155] *ACC* 2016, section Nanotechnology panel activities.

3.4 Food and pesticides/biocides

3.4.1 The EU – legal provisions for nanomaterials incorporated in specific regulations

Hard regulation. In the EU, nanomaterials are increasingly regulated by vertical, sector specific regulations. The regulations concerning food, food packaging and pesticides/biocides are in the scope of this study.[156] The regulations that unequivocally address nanomaterials in these areas are the Regulation (EU) 2015/2283 on novel foods (Novel Food Law)[157] the Regulation (EU) No 1169/2011 on the provision of food information to consumers (FIC)[158], the Regulation (EU) No 10/2011 on plastic materials and articles intended to come into contact with food[159], the Regulation (EC) No 450/2009 on active and intelligent materials and articles intended to come into contact with food[160], and the Regulation (EU) No 528/2012 concerning the making available on the market and use of biocidal products (BPR)[161]. In addition, the General Food Law, the Regulation (EC) 1935/2004 on materials and articles intended to come into contact with food[162], the Regulation (EC) 1332/2008 on food enzymes[163], Regulation (EC) 1333/2008 on food additives[164], Regulation (EC) 1334/2008 on flavourings and certain food ingredients with flavouring properties[165], and the Regulation (EC) No 1107/2009 concerning the placing of plant protection products on the market (PPP)[166] are applicable even though nanomaterials are not mentioned.

The basis for high level of protection of human health and consumers' interest in the food sector is the General Food Law and the precautionary principle defined in it. Furthermore, the FIC apply to food business operators at all stages of the food chain, where their activities concern the provision of food information to consumers (Article 1(3)). Article 18(3) of the FIC contains labelling requirement. The requirement is connected to the definition of engineered nanomaterials and states that all ingredients present in the form of engineered nanomaterials shall be clearly indicated in the list of ingredients. The names of such ingredients

[156] As an overview of the nanotechnology applications in the food and pesticides/biocides sectors see *Amenta et al.* Reg. Toxicol. Pharmacol. 2015, p. 464-465.
[157] OJ, N:o L 327, 11.12.2015, p. 1-22.
[158] OJ, N:o L 304, 22.11.2011, p. 18-63.
[159] OJ, N:o L 12, 15.1.2011, p. 1-89.
[160] OJ, N:o L 135, 30.5.2009, p. 3-11.
[161] OJ, N:o L 167, 27.6.2012, p. 1-123.
[162] OJ, N:o L 338, 13.11.2004, p. 4-17.
[163] OJ, N:o L 354, 31.12.2008, p. 7-15.
[164] OJ, N:o L 354, 31.12.2008, p. 16-33.
[165] OJ, N:o L 354, 31.12.2008, p. 34-50.
[166] OJ, N:o L 309, 24.11.2009, p. 1-50.

shall be followed by the word 'nano' in brackets. The new Novel Food Law defines 'engineered nanomaterials' (Article 3(2)(f)), and the FIC is consequently amended to refer this revised definition. The definition in the Novel Food Law differs from the EC recommendation on the definition of nanomaterial but the EC can, by means of delegated acts, adjust and adapt the definition to technical and scientific progress or to definitions agreed at international level (Article 31). An option to amend nanomaterial definitions by delegated acts has been incorporated in the most recent regulations in the EU, with the intention to harmonize the definition of nanomaterial. The food consisting of engineered nanomaterials is 'novel food' (Article 3(2)(a)) and may entry on the market only if authorized and included in the EU's list of novel foods (Article 6(2)). Novel foods are subject to the general labelling requirements laid down in the FIC and other relevant labelling requirements in the EU food law.[167]

Food enzymes, additives and flavourings are assessed under the Regulation (EC) 1332/2008, Regulation (EC) 1333/2008, and Regulation (EC) 1334/2008, respectively, via pre-marketing procedure established in the Regulation (EC) 1331/2008[168]. The framework Regulation (EC) 1935/2004 on materials and articles intended to come into contact with food does not mention nanomaterials but the Regulation (EC) No 450/2009 on active and intelligent materials and articles intended to come into contact with food and the Regulation (EU) No 10/2011 on plastic materials and articles intended to come into contact with food that are detailed measures to implement the framework regulation, refer to nanoparticles/nanoform substances although do not contain any definition for nanomaterial. The former requires a case-by-case risk assessment of nanoparticles in intelligent packaging systems until more information is known[169], and the latter states that substances in nanoform shall only be used if explicitly authorized and mentioned in the specifications in the Annex 1 (Article 9(2)). According to Article 4(1)(b) of the Regulation (EU) No 10/2011, the plastic materials and articles intended to come into contact with food have to comply with the labelling requirements set out in Article 15 of the Regulation (EC) 1935/2004. Article 15(1)(c) of the Regulation (EC) 1935/2004 states that relevant information on active components such as substances released has to be provided to enable food business operators to comply with any

[167] *Supra note* 157, p. 6 recital (33).
[168] OJ, N:o L 354, 31.12.2008, p. 1-6.
[169] *Supra note* 160, p. 4 recital (14).

other relevant EC or national provisions applicable to food, including the provisions on food labelling.

With regard to pesticides, the PPP does not mention nanomaterials but requires a pre-market authorization at the EU level (Article 4(1), Article 13) for active substances in pesticides used as plant protection products.[170] The plant protection products are authorized at the member state level (Article 28(1)). The provisions of the PPP are grounded on the precautionary principle (Article 1(4)). A case-by-case assessment of the active substances technically allows considering nanomaterials under the PPP. Nevertheless, the EFSA has stated that there is not any nano-specific risk assessment of active substances yet.[171] This stems in part from the absence of the nano-specific guidance. In the very recent opinion, the EFSA's Scientific committee has identified nanotechnology to be among the three priority topics for the development of risk assessment guidance in 2016-2018.[172]

The BPR includes specific, relatively detailed provisions for nanomaterials applied as active substances in the biocides or in the biocidal products[173] if the nanomaterial meets the criteria defined in the Article 3(1)(z) of the regulation. The definition is based on the EC recommendation on the definition of nanomaterials and can be amended by the delegated acts (Article 3(4)). According to Article 4(4) of the BPR, the approval of an active substance shall not cover nanomaterials except where they are explicitly mentioned. Active substances in the biocides require an authorization at the EU level (Article 9), and the biocidal products at the EU or the member state level (Article 17(2), Articles 42-43). A competent authority in a chosen member state will evaluate an application. Biocidal products that contain nanomaterials are not acceptable in a simplified authorization procedure (Article 25(1)(c).

A separate dossier will be usually needed for nanoforms of active substances. The information requirements to be included in the dossier are listed in the Annex II of the BPR. When test methods are applied to nanomaterials, an explanation shall be provided of their

[170] A 'pesticide' is something that prevents, destroys, or controls a harmful organism or disease, or protects plants or plant products during production, storage and transport. Pesticides are typically used in the form of plant protection products but the term 'pesticide' covers also non plant/crop uses, for example biocides, see *EC* 2016, section Pesticides.
[171] *EFSA* 2016, p. 15.
[172] *EFSA Scientific committee* EFSA J. 2016, p. 4508-4509.
[173] Annex V of the BPR describes biocidal product-types that include, e.g., different disinfectants, preservatives, pest controllers, and antifouling products.

scientific appropriateness for nanomaterials, and where applicable, of the adjustments that have been made in order to respond to the specific characteristics of nanomaterials (paragraph 5 of the Annex II). Furthermore, a nano-specific risk assessment is required if nanomaterials are used in the biocidal product (Article 19(1)(f)). Information requirements for the biocidal products are listed in the Annex III of the BPR. In addition, a biocidal product and a treated article placed on the market shall be labelled with the names of all nanomaterials followed by the word 'nano' in brackets (Article 69 (2)(b), Article 58(2),(3)(d), respectively). A label of the biocidal product must inform about any specific risks related to the nanomaterials it contains.

Soft regulation. Although nano-specific information requirements in the BPR, the ECHA has not published guidance on, e.g., appropriate test methods which makes it difficult for companies and competent authorities to fulfill the purpose of the regulation regarding nanobiocides.[174] However, according to the ECHA's general guidance document for the BPR, 'the REACH guidance should be taken into account for the evaluation of biocides, where relevant and indicated'.[175] Consequently, the upcoming amendment of the REACH Annexes will most likely affect the interpretation of the BPR, too.

Generally, soft regulation measures in the food and pesticides/biocides sectors are not as eagerly applied than in the chemicals sector in the EU, partly perhaps due to the fact that legal provisions are increasingly incorporated in the specific regulations. The EFSA has published a "Guidance on the risk assessment of the application of nanoscience and nanotechnologies in the food and feed chain".[176] However, according to the new opinion of the EFSA's Scientific committee, the guidance needs updating to cover also nanopesticides and nanoformulations, food contact materials, food and feed additives, and novel foods; as well as an update of the physicochemical property measurements and other data needed for food/feed assessment. In addition, a second guidance document should be produced on the environmental risk assessment for nanoparticles used in the food chain.[177]

[174] *Brinch – Hansen – Hartmann – Baun* Nanomaterials 2016, p. 10-11.
[175] *ECHA* 2014, p. 27.
[176] *EFSA Scientific committee* EFSA J. 2011, p. 2140-2176.
[177] *EFSA Scientific committee* EFSA J. 2016, p. 4509.

On the other hand, the WPMN of the OECD with the EU's representatives and national authorities/stakeholders involved, work hard to harmonize testing methods for nanomaterials. The WPMN has published several documents on, for example, sample preparation and dosimetry, as well as environmental fate and ecotoxicity testing of nanomaterials in the Series on the safety of manufactured nanomaterials.[178]

3.4.2 The US – emerging case law on nano-regulation

Federal regulation. The FDA considers the risks of nanomaterials used in food, food additives and packaging under the Federal Food, Drug, and Cosmetic Act (FFDCA, 21 U.S.C. § 301 et seq., 1938) and Public Health Service Act (PHSA, 42 U.S.C. § 201 et seq., 1944). Precise legal authorities differ by product category and may include both pre-market authorization[179] of new products and post-market reviews of products sold to consumers. Products subject to pre-market authorization include biological products, devices, food additives, and color additives. The Code of Federal Regulations (CFR) amplifies that food additives include substances that may migrate to food from food contact substances (21 CFR § 170.3(e)(1)). The products that are not subject to pre-market authorization include food ingredients that are generally recognized as safe (GRAS).[180]

Neither the FFDCA nor the PHSA does specify nanotechnology-based product and the FDA has not defined nanomaterial. Instead, a broad approach to consider whether FDA-regulated products contain nanomaterials or involve nanotechnology has been applied.[181] The FDA has stated that the assessments will continue to be product-specific, taking into account the effects of nanomaterials in the particular biological and mechanical context of each product and its intended use.[182]

The EPA regulates nanomaterials used in pesticides/biocides under the Federal Insecticide, Fungicide and Rodenticide Act (FIFRA, 7 U.S.C. § 136 et seq., 1947). No person in any state may distribute or sell to any person any pesticide[183] that is not registered under the

[178] *OECD* 2016, section Publications in the Series on the Safety of Manufactured Nanomaterials.
[179] Term 'pre-market authorization' refer to a number of regulatory actions under the FFDCA, the PHSA, and related FDA regulations, see *FDA* 2007, p. 19.
[180] *Ibid.*, p. 20, 25.
[181] *Hamburg* Science 2012, p. 299-300.
[182] *FDA* 2014a, p. 4.
[183] 'Pesticide' means any substance or mixture of substances intended for pesticidal purpose, i.e., preventing, destroying, repelling, or mitigating any pest, or intended for use as a plant regulator, defoliant, or desiccant (40

FIFRA (7 U.S.C. § 136a(a)). The applicant must provide the EPA with data demonstrating that the proposed registration fulfill the requirements (7 U.S.C. 136a(c)(1)(F)). The FIFRA has not specific provisions for nanomaterials but the EPA has indicated that if a pesticide product[184] contains active or inert, intentionally produced nanoscale ingredients it has to be registered.[185]

The FIFRA contains two provisions for registration: 'unconditional' and 'conditional' (7 U.S.C. 136a(c)(5) and 7 U.S.C. 136a(c)(7), respectively. Relevant to nanomaterials, conditional registration is possible according as the 7 U.S.C. 136a(c)(7)(C) if: 1) the pesticide contains an active ingredient not contained in any currently registered pesticide; 2) a period reasonably sufficient for generation of required data has not elapsed since the EPA first imposed the data requirement; 3) use of the pesticide during such period will not cause any unreasonable adverse effect on the environment; and 4) use of the pesticide is in the public interest. If the data provided is not satisfactory for unconditional registration, the EPA may register the pesticide product on the condition that the applicant provides additional data. The data shall be submitted within a reasonable period of time determined by the EPA, commonly not more than four years (7 U.S.C. § 136a-1(d)(4)(B)). Conditional registration shall be cancelled if the data is not provided (7 U.S.C. § 136a-1(d)(5)(B)). In addition, the FIFRA allows the EPA to require pesticide registrants to develop information that is needed in order to review or maintain the registration (7 U.S.C. § 136a(g)). When developing data requirements, the EPA must consider economic factors (7 U.S.C. § 136a(c)(2)(A)).

State regulation. There are currently no explicit regulations in California concerning nanomaterials in the food or pesticides/biocides sectors. However, the DTSC and Department of Pesticide Regulation have signed a Memorandum of Understanding (MeU) in 2010 concerning nanosilver.[186] The MeU allows the DTSC to review pesticide registration documents to identify potential nanosilver manufacturers/importers with the intention to possibly contact them in the future call-ins.

CFR § 152.3; 40 CFR § 152.15). Pests include, among other, any fungus, virus, prion, or other microorganism, except those on or in living man or other living animals and those on or in processed food or processed animal feed, beverages, drugs and cosmetics (40 CFR § 152.5(d)).

[184] 'Pesticide product' means a pesticide in the particular form (including composition, packaging and labelling) in which the pesticide is, or is intended to be, distributed or sold. The term includes any physical apparatus used to deliver or apply the pesticide if distributed or sold with the pesticide (40 CFR § 152.3).

[185] *EPA 2011, 76 FR*, p. 35387.

[186] *DTSC* 2016, section Partnerships and collaborations.

Case law. A number of NGOs have filed lawsuits against the EPA as a result of registration decisions under the FIFRA concerning nanosilver pesticides and due to failure to answer the petition about rulemaking for nanosilver pesticides.

The Natural Resources Defense Council (NRDC) challenged in 2012 the EPA's conditional registration of two nanosilver pesticides, AGS-20 and AGS-20U (collectively referred AGS-20 hereafter). The intended use of the AGS-20 according to the manufacturer will be in textiles to suppress the growth of microbes.

> The NRDC claimed that the AGS-20 was allowed to be used in baby blankets, clothing, and other textiles without the data about its potential adverse effects on humans and wildlife. In addition, the NRDC argued that the EPA should have been considered exposure by infants in the risk assessment, as well as the risk from aggregate exposure to the AGS-20 from multiple sources.

After several briefs, the US Court of Appeals for the 9th Circuit gave in 2013 a decision in which it partly granted and partly denied the petitioner's claims.[187]

> The court held that substantial evidence supported the EPA's decision to use the characteristics of toddlers rather than infants in the risk assessment, and stated that an aggregate risk assessment is required only for the unconditional registration. The court vacated the EPA's decision only in so far as it concluded that there is no risk concern requiring mitigation for short- and intermediate-term aggregate oral and dermal exposure to textiles that are surface coated with the AGS-20 because the EPA failed to follow its own rule for the risk assessment.[188]

The EPA amended the registration decision of the AGS-20 because of court's decision by reducing the maximum application rate in the coating and limiting the scope of textiles and fibers that can be treated.[189]

In 2014, six NGOs filed an administrative procedure lawsuit[190] against the EPA due to EPA's failure to answer plaintiffs' 2008 legal petition[191].

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[187] *NRDC v. EPA* (2013).
[188] *NRDC v. EPA* (2013), holdings 2-4. The EPA has set out a rule that there is a risk concern requiring mitigation if the 'margin of exposure' in the short- or intermediate-term exposure is less than or equal to 1,000. In one exposure scenario, EPA calculated a margin of exposure of 1,000. The finding presents a risk concern but the EPA omitted it.
[189] *EPA* 2013, p. 1-3.
[190] *CFS and others v. McCarthy and EPA* (2014).
[191] *ICTA* 2008, p. 1-116.

The petitioners requested that the EPA should undertake the following actions among others:

- classify nanoscale silver as a pesticide and require the registration of the products that contain nanosilver as pesticides
- determine that nanosilver is a new pesticide that requires a new pesticide registration
- analyze the potential human health and environmental risks of nanoscale silver
- amend the FIFRA pesticide requirements to specifically apply to the nanosilver pesticides, including post-registration notification of adverse effects, post-registration testing and new data development
- take actions for adequate oversight of nanosilver pesticides, including amending FIFRA regulations to require nano-specific data, and set a pesticide tolerance for nanosilver.

In March 2015, the EPA published a response to the petition.[192]

The EPA granted the petitioners' request to treat products that contain nanoscale silver and are found to have a pesticidal purpose as pesticides under the FIFRA. However, the EPA denied to classify nanosilver as such or all products that contain nanosilver as pesticides. Considering the effects of nanosilver on human health and environment, the EPA admitted that the existing information requirements may need to be adapted. The EPA stated that it will identify products containing nanosilver and evaluate them in the registration review. The EPA denied the petitioners' request that all forms and all pesticidal uses of nanosilver generally pose an unreasonable human health or environmental risk.

Regarding post-registration notification and post-registration testing the EPA stated that the statute and the regulations already bind the registrant to submit additional information regarding unreasonable adverse effects to the EPA, and the EPA has authority to require additional data to determine whether the registered pesticides continue to meet the standards for registration. About nano-specific data requirements the EPA stated that the FIFRA authorizes the agency to require additional data and there is no need to initiate rulemaking this time. Finally, the EPA told that there is currently no registered nanosilver pesticides with food or feed uses but if the EPA receives an application for such use and determines that a tolerance or exemption from the requirement of a tolerance could be needed, the EPA will not register the product until appropriate action has been taken under the FFDCA.

[192] *EPA* 2015, p. 1-23.

In July 2015, the NRDC, the Center for Food Safety (CFS), and International Center for Technology Assessment (ICTA) filed two separate petitions for review the EPA's conditional registration of the NSPW-L30SS for use as a non-food-contact preservative for plastics and textiles.[193]

> The petitioners opposed the EPA's risk assessment conclusion that the use of the NSPW-L30SS would not cause unreasonable adverse health effects during the conditional registration period. In addition, the petitioners stated that data requirements were in place well before 2015 and therefore the applicant should not get more time to submit data. Furthermore, the petitioners disagreed with the EPA's public-interest finding.

In March 2016, the EPA submitted an answering brief for the consolidated case.[194]

> The EPA stated that during the public consultation the petitioners did not raise the issues brought before the court and thus denied the EPA's opportunity to address these issues. The EPA argued that it has properly determined that the applicant had insufficient time to generate data because the EPA imposed new data requirements simultaneously with the registration decision. According to the EPA, the use of the NSPW-L30SS is in the public interest because it could reduce the environmental silver load and risks associated with silver. The NSPW-L30SS is applied at much lower rates than conventional silver, expected to release silver ions at a controlled rate, and the amount of silver that leaches from materials into the environment is so low that it cannot be detected by the measuring instruments. The EPA inquires the court to deny the petitions.

The cases show that the NGOs in the US are active and follow prudently the decisions of the agencies. However, thus far only the case *NRDC v. EPA*[195] provides some support from the court to the agencies in developing the approaches to regulate nanomaterials. The court predominantly confirmed the EPA's approach to nanopesticides and addressed critique only to technical aspects of EPA's risk assessment procedure.

Soft regulation. The EPA has not been very active to release guidance documents in the pesticides sector. It has published the above referred policy document in relation to pesticide products containing nanoscale materials[196], and 'Preliminary work plan: Nanosilver', which

[193] *NRDC v. EPA* (2015); *CFS and ICTA v. EPA* (2015).
[194] *EPA* 2016a, p. 2-3, 23-25.
[195] *NRDC v. EPA* (2013), holdings 2-4.
[196] *EPA 2011, 76 FR*, p. 35383-35395.

contains a summary of the anticipated data requirements to guide the applicants in the nanosilver registration review.[197]

In contrast, the FDA has produced two guidance documents for industry in relation to food: 1) Considering whether an FDA-regulated product involves the application of nanotechnology[198], 2) Assessing the effects of significant manufacturing process changes, including emerging technologies, on the safety and regulatory status of food ingredients and food contact substances, including food ingredients that are color additives[199]. The former elaborates two points that should be applied in the consideration: the size, or the nano-related properties.[200] In another guidance document the FDA states that when a food substance is manufactured to include particle size distribution shifted more fully into the nanometer range, safety assessments should be based on data relevant to the nanometer version of the food substance, and if nano-engineered food substances have new properties, additional or different test methods may be necessary to determine their safety. Studies to establish the safety of food substances manufactured using nanotechnology should have been appropriately validated for these materials.[201]

In addition, both the EPA and the FDA conduct nano-related research in the pesticides and food sectors. The FDA, for example, focuses on the development of testing methods to assess the safety of products that use nanomaterials through its six nanotechnology programs.[202]

[197] *EPA* 2012, p. 1-32.
[198] *FDA* 2014a, p. 1-14.
[199] *FDA* 2014b, p. 1-29.
[200] *FDA* 2014a, p. 6.
[201] *FDA* 2014b, p. 14-15.
[202] *FDA* 2016, section Current nanotechnology programs at FDA.

4 ABILITY OF THE CURRENT POLICY INSTRUMENTS TO CORRESPOND TO THE DESIRED GOALS

4.1 Information gathering

Up to the end of year 2015, the ECHA had received 13 registrations for substances where the registrants voluntarily flagged that the scope of the registration dossier is also containing nanomaterials.[203] These included for example carbon black, CNTs, silver, zinc-, cerium-, and titanium oxides, organometallic, and organic compounds. During years 2014-2015 the ECHA has issued 14 compliance check decisions covering 8 different substances in nano-form.[204] In 2016, the ECHA has issued at least one compliance check decision on nanoforms of a substance. Until now, eight announcements have been appealed to the Board of Appeal[205].[206] The appellants stated that ECHA exceeds the limits of its authority by requesting information at a level of detail that is not provided for in the REACH, and breaches the principle of legal certainty by requesting information related to undefined terms, such as 'forms', 'grades', and 'nanoforms'. In addition, one appellant claims that inclusion of silicon dioxide on the CoRAP due to grounds for concern related to "the substance characterization, nanoparticles and toxicity of different forms of the substance" breach of Article 44 (Criteria for substance evaluation) of the REACH. The appeals have challenged the ECHA's legal grounds to request information on nanomaterials, in the absence of specific provisions on nanomaterials in the REACH.[207] The Board of Appeal has not published final decisions for any of these announcements, thus the ECHA still waits for the outcome of the appeals to conclude whether there is a need to alter the approach to assess nanomaterials under the REACH.

Under the BPR the ECHA has approved one nanomaterial, synthetic amorphous silicon dioxide, as an active substance.[208] However, the dossier submitted for that material did not include nano-specific testing because it was submitted and evaluated before September 2013 when no nano-specific provisions were effective. In addition, because the manufacturers claimed that the material is present as stable micron-size aggregates in the active substance,

[203] *ECHA* 2015a, section Registered substances. See also *EFSA* 2016, p. 12.
[204] *ECHA* 2015b, Annex 3.
[205] The Board of Appeal is responsible for deciding on appeals against certain decisions of the ECHA taken under the REACH and the BPR. It is a part of the ECHA but makes its decisions independently.
[206] *ECHA* 2016, section Announcements.
[207] *ECHA* 2015b, Annex 1, p. 2.
[208] *ECHA* 2016, section Biocidal active substances.

the exposure to primary nanoparticles was not expected during the intended uses.[209] Currently two nanomaterials: 'Silicon dioxide as a nanomaterial formed by aggregates and agglomerates' and 'Silver adsorbed on silicon dioxide as a nanomaterial in the form of a stable aggregate with primary particles in the nanoscale' have been included in the review programme of the existing substances[210] and are still under review.

According to the annual report for year 2015, the EFSA has not received applications for a novel food explicitly comprising a nanoform, or nanoforms as flavourings. The EFSA is currently carrying out a re-evaluation of the food additives and some of them may comprise nanofraction, e.g., silver (E174) and titanium dioxide (E171).[211] Considering food contact materials the EFSA has received and evaluated/evaluating applications covering engineered nanomaterials. Up to the end of year 2015, there has been no demonstration of migration of nanomaterials into the food. The EFSA have stated that under the Regulation (EU) No 10/2011 on plastic materials and articles intended to come into contact with food the following substances have authorizations relating to nano-form: titanium nitride nanoparticles, silicon dioxide, carbon black, (butadiene, ethyl acrylate, methyl methacrylate, styrene) copolymer in nanoform crosslinked with divinylbenzene, crosslinked with 1,3-butanediol dimethacrylate or not crosslinked, Kaolin.[212]

In the US, the companies were reluctant to participate the voluntary NMSP scheme introduced by the EPA. Although 31 companies provided data of altogether 132 nanomaterials, only 4 companies were willing to participate in the development of additional test data.[213] The EPA concluded that a number of the EHS data gaps the agency hoped to fill through the NMSP still exist. The EPA discontinued the NMSP in 2009 and began to develop regulatory approaches under the TSCA to collect nanomaterial-related data from the manufacturers of chemicals.[214]

[209] See *Brinch – Hansen – Hartmann – Baun* Nanomaterials 2016, p. 10-11. The authors state that the approval of nanomaterials in the aggregates may create a loophole for not needing to provide hazard data on individual particles if data showing that the particles form stable aggregates can be provided.
[210] OJ, N:o L 294, 10.10.2014, p. 1-34.
[211] *EFSA* 2016, p. 14.
[212] *EFSA* 2016, p. 14-15.
[213] *EPA* 2011, p. 18. See also *EPA* 2009, p. 3.
[214] *EPA* 2011, p. 4.

Since 2005 the EPA has reviewed over 200 nanoscale chemical substances in the NMSP and under the TSCA.[215] At least 170 of the chemical substances manufactured at the nanoscale had reported or estimated production volumes less than 10 000 kg. Based on that, the proposed alteration for the low volume exemption in the new reporting and recordkeeping rule is reasonable. However, the EPA has received 69 comments about the proposed rule. The comments make clear that the industry does not support the new rule and raise several points that have to be further clarified, including legal, technical, and practical aspects. The arguments include, for example, that discrete physical forms are not chemical substances because molecular identity is the basis for identification of all substances under the TSCA, and that proposed information requests are outside of the statute because 15 U.S.C. § 2607(a)(2) sets out a closed list of information.[216] Because material characteristics such as particle size and morphology or other proposed properties (zeta potential, specific surface area, dispersion stability) are not explicitly listed, they cannot be considered as part of the statutory definition of chemical identify. The closed list claim is not well-grounded because the House conference report reveals that the intent of Congress was that the list in 15 U.S.C. § 2607(a)(2) is *illustrative*, not comprehensive.[217] However, the EPA admits in the proposal that it does not have the authority under 15 U.S.C. § 2607(a) to require manufacturers to produce and submit test data that is not available.[218] This raises the question: What it the meaning of this exercise? The recent amendment of the TSCA did not increase the EPA's authority under 15 U.S.C. § 2607(a).

At state level the DTSC of California has conducted two chemical call-ins and received at least some information on CNTs from 13 different respondents in the first call-in, and on six chemical substances: quantum dots, nano silver, nano zero valent iron, nano cerium oxide, nano titanium dioxide, and nano zinc oxide from 14 different respondents in the second call-in.

[215] *EPA 2015, 80 FR*, p. 18335-18336, see also *EPA* 2015, section Control of nanoscale materials under the Toxic substances control act.
[216] *NanoManufacturing Association* 2015, p. 3-6.
[217] *House conference report No. 94-1679*, section 8.
[218] *EPA 2015, 80 FR*, p. 18337.

In relation to the pesticides, the EPA has conditionally registered two pesticide products containing silver nanoparticles, AGS-20 and NSPW-L30SS under the FIFRA.[219] The additional information required include particle size distribution, surface area, solubility, zeta-potential, and several toxicity/ecotoxicity studies. In addition, the EPA has initiated a registration review of nanosilver.[220]

In the food sector the FDA has received at least one pre-market notification of food contact substance that has included information describing the use of the substance with particle sizes in a nanometer range (i.e., titanium nitride as an additive in food-contact bottles).[221] To date, the FDA has not received food or color additive petitions for nano-based food substances.[222] Synthetic amorphous silica has been noticed to be a GRAS substance for use as an anticaking or defoaming agent, stabilizer, adsorbent, carrier, conditioning agent, chill proofing agent, filter aid, emulsifying agent, viscosity control agent, and anti-settling agent in various food categories including dairy-based drinks and desserts, milk and cream powder, processed fruits and vegetables, breakfast cereals, pre-cooked pastas, noodles, or rice products, sport and energy drinks, and alcoholic/non-alcoholic beverages.[223] In the GRAS notice, the registrant stated that the substance exists mostly in particle size range 0.1-1 μm and does not exist as easily dispersible nanoparticles. The FDA has not made its own determination regarding the GRAS status of the subject use of the synthetic amorphous silica.

The number of nanomaterials on which the regulatory authorities in the EU and the US have received or requested information under different regulations/information gathering schemes are summarized in Table 1. It has to be noticed that the same nanomaterial may be registered/evaluated under different regulations.

[219] *EPA* 2016b, p. 2.
[220] *EPA* 2012, section Nanosilver registration review docket.
[221] *FDA* 2014b, p. 15; *FDA* 2016, section Inventory of effective food contact substances (FCS) notifications.
[222] *FDA* 2016, section Food & color additive petitions.
[223] *FDA* 2016, section GRAS notices.

Table 1. Summary of the number of nanomaterials on which the regulatory authorities have received or requested information under different regulations/schemes in the EU and the US.

Regulation/Scheme	Authority	Number of nanomaterials*
REACH	ECHA	21
BPR	ECHA	3**
Regulation (EU) No 10/2011	EFSA	5
Regulation (EC) 1333/2008	EFSA	2
NMSP + TSCA	EPA	>200
FIFRA	EPA	2
FFDCA	FDA	2
Chemical Information Call-in Statute	DTSC	27

*Reported by the registrants/other applied entities, or identified by the authority
**Of which one substance is registered without nano-specific information requirements

Today, the US authorities have received information on more nanomaterials/new uses of nanomaterials than the EU authorities. The main reason is that the EPA and the DTSC in California started several years ago regulatory approaches to collect information on nanomaterials under the TSCA and the Chemical Information Call-in Statute, respectively. However, the situation may change in the future if a revision of the REACH Annexes with explicit requirements for nanoforms of substances come to pass. The revision is expected to take place in early 2017.

A clear problem that the regulatory authorities have faced is the absence of specific provisions in the regulations (e.g., REACH, TSCA) to request information on nanomaterials and their characteristics. Even if the provisions exist (e.g., BPR) or some regulations are applicable to nanomaterials without them (e.g., PPP), the absence of nano-specific guidance on methods to measure physicochemical properties and to conduct risk assessment hinders the proper compliance. On the other hand, the industry in the EU and the US has been reluctant to report nanomaterials or conduct nano-specific tests voluntarily, though some industry-government collaboration initiatives have arisen. Altogether, the information received by the regulatory authorities is very incomplete compared, e.g., to the amount of consumer products that contain nanomaterials.

4.2 Consistency in risk assessment and risk management

Effective risk assessment of nanomaterials demands a well-defined trigger for nano-specific measures. The EC has recommended a definition for nanomaterial, and an intention to harmonize different definitions existing in sector specific regulations can be seen. A common

definition supports the consistent identification of hazard, though the definition will certainly change in time when the scientific knowledge increases.

However, next steps of risk assessment: hazard characterization, exposure assessment, and risk characterization are still premature. In the new REACH guidance drafts the ECHA refers to ISO standards and the OECD's guidance in carrying out characterization and exposure assessment of nanomaterials but states that many of the methods are still under development and further validation is needed.[224] The EFSA's "Guidance on the risk assessment of the application of nanoscience and nanotechnologies in the food and feed chain" includes references to OECD guidance but as mentioned earlier the guidance needs updating.[225] Anyway, attempts towards consistent risk assessment have been taken in the EU. For example, to facilitate harmonization of risk assessment practices and methodologies, to enhance exchange of information and data between the EFSA and the member states, and to achieve synergies in risk assessment activities, the EFSA formed in 2011 'Scientific network of risk assessment of nanotechnologies in food and feed'.[226]

In the US, the EPA has referred/required tests according to the OECD's guidelines for example in the conditional registration decisions of nanosilver pesticides.[227] Though, the international standards and guidelines are not as frequently referred by the US authorities than in the EU. For example, the new reporting and recordkeeping rule proposed by the EPA does not contain references to specific OECD guidelines or ISO standards but encourages persons who intend to conduct testing to consult the EPA before selecting a protocol.[228] In order to develop testing strategies, the EPA has conducted case studies that are based on a comprehensive environmental assessment approach of the selected nanomaterials.[229] The aim is to use the case studies as a starting point to identify what is known and to prioritize possible research directions to support future assessments of the nanomaterials. Also the FDA develops testing methods to assess the safety of products that use nanomaterials. Furthermore, the industry has contributed on harmonization of risk assessment of nanomaterials, for example

[224] See for example *ECHA* 2016b, p. 6-7, 18; *ECHA* 2016c, p. 7-9, 13.
[225] *EFSA Scientific committee* EFSA J. 2011, p. 2151-2168.
[226] *EFSA* 2016, section Cross-cutting networks.
[227] *EPA* 2011, Appendix A; *EPA* 2015, Appendix B.
[228] *EPA 2015, 80 FR*, p. 18337.
[229] As an example of such a case study see *EPA* 2012, p. 1-432.

through Nano Risk Framework. As another example, the NCC has proposed a testing agreement on carbon nanomaterials to the EPA in 2011.[230]

Many technical comments for the EPA's reporting and recordkeeping rule underlined that if the aim is to get comparable data, more guidance on characterization methods and parameters relevant to real exposure conditions is needed.[231] It was notified that standardized measurement methods for all the proposed physicochemical characteristics do not exist yet. In addition, terminology used in the proposal creates uncertainty among manufacturers and processors and may result in noncompliance.[232] For example a phrase "unique and novel characteristics" is used as a trigger for a reportable chemical substance. Furthermore, the proposed exclusions, for example chemical substances manufactured at the nanoscale as part of a film on a surface, were considered inconsistent without justification. In the proposed rule, nanoscale substances coated with different chemical substances are considered discrete forms that require reporting but the films do not. However, the films can be considered to be coatings, or vice versa.[233] In the US, the regulatory authorities both in the federal and state level are reluctant to set consistent definition for a nanomaterial, and the above described problems arise from that approach. The ACC's Nanotechnology Panel has stated that the lack of clear triggers to identify nanomaterials that may be of regulatory interest creates ambiguity and confusion among stakeholders.[234]

Many regulations in the EU are underpinned by the precautionary principle as risk management tool. However, "no data, no market" rule does not currently apply to nanomaterials in reality due to lack of explicit provisions in the regulations and/or lack of nano-specific guidance. A limited number of nanomaterials evaluated makes it difficult to conclude if there is any consistency in the risk management of nanomaterials in the EU yet. In my opinion, for example mandatory 'nano' labelling recently included in the FIC (Article 18(3)) and the BPR (Article 69 (2)(b), Article 58(2),(3)(d)) cannot be considered to be a consistent risk management tool at this stage.

[230] *NCC* 2016, section Home.
[231] *NanoManufacturing Association* 2015, p. 22-23; *NIA* 2015, p. 2; *UC CEIN* 2015, p. 3-5.
[232] *NanoManufacturing Association* 2015, p. 22; *NIA* 2015, p. 2; *EDF* 2015, p. 12.
[233] *UC CEIN* 2015, p. 6.
[234] *ACC* 2016, section Nanotechnology definitions.

In the US, the EPA has permitted a restricted manufacturing of new nanomaterials through the use of consent orders or SNURs under the TSCA. The EPA has also allowed the manufacturing of new nanomaterials based on regulatory exemptions but only in circumstances where exposures were tightly controlled to protect against unreasonable risks.[235] In addition, under the FIFRA the EPA has conditionally registered two nanosilver pesticides, and taken actions against companies that have used nanosilver in their products as antimicrobial agent without registration.[236] It can be stated that a case-by-case risk management approach with product specific restrictions/additional information requirements has been adopted in the US. The emerged case law on nano-regulation reveals that the courts predominantly support the approach taken by the EPA.

In the industry, different risk management tools have been launched but it is not known how widely they are currently applied in the EU and the US. The general view of the industry in both the EU and the US is that the current regulatory framework is adequate to cover nanomaterials. The industry also seems to wait how the regulatory framework evolves with the increasing nano-specific regulations which may hamper the development of self-regulation procedures.

Overall, the consistency in the risk assessment and the risk management is still in the early development phase in the EU and the US. Research projects involving regulatory authorities, industry representatives, or both have been eagerly launched with the aim to contribute the harmonization of the risk assessment and management methods.

4.3 Establishment of open, flexible, and proactive approach

To respond the demand of flexibility, framework governance instruments have been used more and more commonly in the EU during the last decade. The REACH is an example of a framework regulation. The aim is that the executive branch fill in the technical details of the legislation via implementing secondary rules, such as guidance documents.[237] However, as is the case with the nanomaterials under the REACH, if the explicit provisions do not exist in the framework regulation, the legal grounds of the regulatory authorities to rely on the secondary rules may be and have been challenged.

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[235] *EPA* 2015, section Control of nanoscale materials under the Toxic substances control act.
[236] *EPA* 2014, section Newsroom; *EPA* 2015, section Newsroom.
[237] *Korkea-aho* Legisprudence 2012, p. 404.

On the contrary, in the US the executive branch promulgates legally binding rules and orders to apply the primary statutes for example on different nanomaterials. In addition, the regulatory authorities in the US may produce nonbinding guidance for industry to assist in the compliance of the regulations. The rule-making is a slow and non-flexible process, definitely not suitable for regulating rapidly evolving emerging technologies. In the recent amendment of the TSCA, a chemical testing procedure is expedited with new order and consent agreement authorities instead of rule-making (15 U.S.C. § 2603(a),(b)). This will enhance the flexibility of the TSCA in the future.

Consultations during law-making and guidance or rule drafting are means of more open approach. For example, the REACH guidance writing process lead by the ECHA includes a consultation procedure to ensure the broadest possible acceptance for guidance amongst stakeholders. Another measure to share information are public, freely accessible databases such as databases on chemicals and active substances in pesticides/biocides hosted by the ECHA and the EPA. However, cooperation between different regulatory authorities appears to be quite modest nationally and internationally in comparing/sharing the information on nanomaterials in the existing databases. Same is true for different web-platforms created to provide public information on nanomaterials in the EU and the US. The need for improved regulatory coherence and cooperation has been an issue during the ongoing TTIP negotiations, and at the 14th round the EU published a proposal for a future framework for transatlantic regulatory cooperation.[238]

Several ongoing research projects may also support more open approach if the results are published in the open databases. In the industry, product stewardship programs have been adopted for example under the Responsible Care® to communicate with the stakeholders. In the US, an opportunity to challenge laws and secondary regulations in the court is one tool for open and proactive approach, too.

Different standards and recommendations published in the EU, in the US, and via international standardization organizations are one way to enhance proactivity. The EC's definition for nanomaterial will enhance proactivity if it is harmonized across the sectoral regulations

[238] *EC* 2016, p. 7.

and guidance. Standardized methods and procedures for the physicochemical characterization of nanomaterials and for exposure assessment studies will reduce the uncertainty if the methods are explicitly referred in the regulations/rules/orders/guidance. However, the current stage of guidance and standards is not adequate to provide solid base for proactive legislation in either jurisdiction.

Thus, achieving the goal of open, flexible and proactive approach relies heavily on soft regulation instruments in the EU but includes legally binding measures in the US. The problems directly related to soft regulation instruments include the challenging the legal grounds of the regulatory authorities and the inadequacy of the existing standards and guidance. On the other hand, the rule-making procedure in the US is far from flexible, and the proactivity can be questioned if the information requirements change due to inconsistency in the definitions for nanomaterials, their properties, and related measurement methods, as elaborated in the previous sections.

5 DISCREPANCIES BETWEEN THE REGULATORY APPROACHES FOR NANOMATERIALS IN THE EU AND THE US

5.1 Chemicals

A case-by-case risk assessment approach prevails in both regulatory frameworks. Both the EU and the US have rejected calls for entirely new and/or technology-based regulations. However, the REACH and the TSCA have some discrepancies that should be taken into account by the companies, regulatory authorities, and the policymakers.

The REACH requires the registration of all chemical substances, new and existing, that are produced over 1 tonne per year (Article 6(1)). When a registrant manufactures of imports the substance in the nanoform as well as in the bulk form, the registration dossier should include the information of the substance in both the bulk form and the nanoform.[239] Burden of proof to generate data, assess chemical safety, and provide information is on the industry (Articles 10-14). The industry has to generate new data if necessary without action by the regulator. The ECHA may also request additional information not required in the minimum data set described in the Annexes VII to X (Article 46). In addition, Article 22 of the REACH requires the registrants to update the registration dossier if the composition, use, knowledge of risks or classification and labelling of a substance changes, among others. However, the registrant may start or continue the manufacture or import a substance even if the registration has not been evaluated if there is no indication to the contrary from the ECHA (Article 21).

In contrast, the TSCA requires a PMN or SNUN only for new chemicals or significant new uses of chemicals if the EPA has issued a SNUR for that chemical (15 U.S.C. § 2604(a)). Information requirements in the PMN and the SNUN are restricted to the existing and reasonable ascertainable information on properties and health and environmental effects of the chemical (15 U.S.C. § 2604(d)). According to the amended statute, the burden of proof is still predominantly on the EPA but the authority to require the development of new information on chemicals is expanded (15 U.S.C. § 2603(a)).

In addition, the EPA must, before a new chemical can enter on the market or significant new use of the existing chemical start, determine that the chemical: 1) is “not likely to present

[239] *EC* 2012, p. 26-27.

and unreasonable risk" and publish the finding, 2) "presents an unreasonable risk" and issue an order to address such risk, 3) "information available…is insufficient to permit a reasoned evaluation" and issue an order to obtain information (15 U.S.C. § 2604(a)(3)). 15 U.S.C. § 2605(a) provides different regulatory options after the EPA has identified the possibility for unreasonable risk, for example requirement of warnings or instructions labels, regulating the commercial use, requirement for the manufacturers to notify distributors of the unreasonable risk, production volume limitations or production prohibition. Costs and availability of alternatives has to be considered when selecting among risk management options. On the contrary, the 15 U.S.C. § 2604(e) states that the EPA shall issue an order that may contain for example testing requirements for toxicity or environmental fate, and restrictions for distribution and use without consideration of costs or other non-risk factors, if the information provided is insufficient to perform evaluation or the substance may present an unreasonable risk. However, the order can be issued only on a temporary basis pending development of information.

The burden of proof is the most significant discrepancy between the REACH and the TSCA, though the EPA's authority to require development of new information is expanding. However, only voluntary reporting of nanomaterials or nanoscale forms of bulk substances exists today under the REACH. If the revision of the REACH Annexes makes the reporting of nanoforms of substances mandatory, it will increase compliance costs and may result in trade irritation between the EU and the US because the REACH registration is required for all substances, not just for new substances or significant new uses of the existing substances as is the registration under the TSCA. Another, smaller discrepancy is that the REACH allows the entry on the market before the evaluation is complete but the TSCA requires the EPA to make an affirmative finding about the safety of the chemical and to complete the evaluation before the entry on the market is allowed.

Dissimilar labelling requirements may also introduce trade irritants between the EU and the US. The TSCA enables the EPA to require warning or instruction label as a risk management measure (15 U.S.C. § 2605(a)). However, no mandatory 'nano' labelling exists under the TSCA. In California, the Safe Drinking Water and Toxic Enforcement Act requires warning labels for chemicals known to cause cancer or reproductive toxicity (27 CCR § 27001), including for example titanium dioxide and carbon black, but does not require 'nano' labelling.

In the EU, nanomaterials that fulfill the criteria for classification as hazardous under the CLP must be labelled, independently of the tonnage in which the substances are manufactured or imported. However, as explained in the section 3.3.1, the materials and test methods are currently inadequately reported to enable performing the evaluation. The ongoing revision of the GHS that the CLP labelling requirements rely on, may improve its applicability to the classification and labelling of nanomaterials under the CPL. However, it can be concluded that currently the labelling requirements in the chemicals sector do not generate discrepancies between the EU and the US.

5.2 Food and pesticides/biocides

Regulation in food sector is based on product categories in both the EU and the US but the content of the product categories and definitions differs a little bit. The US does not separately regulate for example novel foods or food enzymes, and food contact materials are included in food additives.

Recently, the approaches to regulate nanomaterials in the food sector have diverged in the EU and the US. A case-by-case assessment under the existing regulations without explicit provisions for nanomaterials has been adopted by the FDA in the US. In contrast, new nano-specific provisions have been included in several regulations in the EU. Consequently, any food consisting of engineered nanomaterials shall not entry on the EU market after 1.1.2018 if not authorized and included in the EU's list of novel foods (Novel Food Law Article 6(2)). In addition, the Regulation (EU) No 10/2011 on plastic materials and articles intended to come into contact with food requires that use of nanoform is acceptable only if explicitly authorized and mentioned in the specifications of Annex 1 (Article 9(2)).

Furthermore, there are more extensive labelling requirements in the food sector in the EU than in the US. The FDA's Nanotechnology Task Force recommended in 2007 that the FDA should address case-by-case whether labelling must or may contain information on the use of nanoscale materials and the FDA has adopted this approach.[240] In the EU, the FIC requires that all ingredients present in the form of engineered nanomaterials shall be clearly indicated in the list of ingredients, followed by the word 'nano' in brackets (Article 18(3)). The labels of plastic materials and articles intended to come into contact with food have to include

[240] *FDA* 2007, p. 35.

relevant information on active components such as substances released to enable food business operators to comply with any other relevant EC or national provisions applicable to food, including the provisions on food labelling (Article 15(1)(c) of the Regulation (EC) 1935/2004). In addition, novel foods are subject to the labelling requirements in the FIC (Article 18(3)) and other relevant labelling requirements in the EU food law.

The explicit requirements for nanomaterials in the EU result in a clear discrepancy between the regulatory approaches for nanomaterials in the EU and the US in the food sector, and will most likely create trade irritants in the future.

In regard to pesticides/biocides, a case-by-case assessment of active substances enables considering the nanomaterials under the PPP in the EU (Article 4(1), Article 13) but the EFSA has stated that there is no nano-specific risk assessment of active substances yet. The BPR has specific provisions, including information requirements (Annexes II and III), for nanomaterials as active substances in biocides or biocidal products. The approval of the active substance shall not cover nanomaterials except where explicitly mentioned (Article 4(4)). A nano-specific risk assessment is required if nanomaterials are used in the biocidal product (Article 19(1)(f)). When test methods are applied to nanomaterials, an explanation shall be provided of their scientific appropriateness for nanomaterials, and where applicable, of the adjustments that have been made in order to respond to the specific characteristics of nanomaterials (paragraph 5 of Annex II). A biocidal product and treated article placed on the market shall be labelled with the names of all nanomaterials followed by the word ‘nano’ in brackets (Article 69 (2)(b), Article 58(2),(3)(d), respectively). In addition, a label of the biocidal product must inform about any specific risks related to the nanomaterials it contains.

In the US, no person in any state may distribute or sell to any person any pesticide that is not registered under the FIFRA (7 U.S.C. § 136a(a)). The FIFRA has not specific provisions for nanomaterials but the EPA has indicated that if a pesticide product contains active or inert, intentionally produced nanoscale ingredients it has to be registered. So far, the EPA has registered nanosilver pesticides on the condition that the applicants provide additional data within four years. Conditional registration shall be cancelled if the data is not provided. In addition, the FIFRA allows the EPA to require registrants to develop information that is needed in order to review or maintain the registration (7 U.S.C. § 136a(g)). The FIFRA does not contain mandatory ‘nano’ labelling.

The BPR includes rather strict requirements for nanomaterials that may affect larger group of materials than a case-by-case approach of the EPA. However, the BPR has been into force since 1.9.2013 but none nanomaterial with nano-specific information has been approved. Time will tell if the BPR creates trade irritation between the EU and the US. The mandatory 'nano' labelling that it contains may be one item which requires special attention. In contrast, the active regulatory approach adopted by the EPA, especially if expanded to larger number of nanomaterials, will definitely have an effect on any entity who distributes or sells in the US pesticides/pesticide products that contain nanomaterials.

5.3 Comparison with the strategies adopted for the GM crops and food

A short survey to the regulatory strategies adopted earlier for the genetically modified (GM) crops and food in the EU and the US may perhaps assist to understand the present approaches applied to regulate nanomaterials, and to serve as an example of problems that may arise from discrepancies in the regulatory approaches. The analysis is not aimed to be comprehensive but explanatory with only few references. Individual regulations or agreements are not studied.

The polarization between the EU and the US in how to regulate GM crops and food traces back to choices made in the 1980s. The "products approach" adopted in the US assumes that no risk arises from applying the GM technology to agricultural production. The GM products should be an object of more stringent rules only when the end products are not substantially equivalent to their conventional counterparts. In contrary, the "process approach" adopted in the EU and in its member states is based on the assumption that GM technology itself may entail novel and unique EHS risks.[241]

The tensions between the divergent approaches have produced conflicts since the 1990s when the US started to grow Monsanto's GM soybeans and the EU authorized their import without any segregation or labelling requirements. Almost immediately public opposition to the GM crops and food arose in the Europe. A number of the EU member states expressed concern at the levels of uncertainty surrounding the GM products and the potential harmful

[241] *Winickoff et al.* Yale J. Int'l L. 2005, p. 86-89.

effects of the GM crops. As a result, the member states granted no new approvals of genetically modified organisms (GMO) after 1998. The EU established a legal framework, based on the precautionary principle, to ensure that the development of the GMOs takes place in safe conditions.[242] The framework requires full traceability and clear labelling of all GM-derived products. The approach was justified by the need to reassure a skeptical European public without providing references to the presence of actual risks. It has been stated that these are the toughest GMO rules in the world, have departed from the general risk management principles, and have increased regulatory burden, blocked innovation, decreased competitiveness, and discouraged research.[243]

In 2003, the US with other countries initiated dispute at the World Trade Organization (WTO) against the EC for delaying approvals of the GM crops and food. In addition, the US complained about safeguard measures taken by the member states of the EU to prohibit the import of the GMO products. A dispute settlement panel of the WTO found in 2006 that a general *de facto* moratorium on approvals prevailed in the EU at the time of the complaint which induced undue delay in the approval process. The moratorium was not justified under the international trade agreements, as were not the safeguard measures of the member states. By maintaining these measures the EC was acted against the international trade agreements.[244] The EU has subsequently moved products through the approval process but has recently adopted the Directive (EU) 2015/412 regarding the possibility for the member states to restrict or prohibit the cultivation of GMOs in their territory[245] that allows a member state to prohibit or restrict the cultivation of GMOs based on environmental or agricultural policy objectives, among others. In addition, the EC has published a proposal regarding the possibility for the member states to restrict or prohibit the use of GM food and feed on their territory.[246]

It can be recognized that in the EU a strong political and public pressure to set strict regulations and mandatory labelling for import and cultivation of the GM crops and feed exists. The same phenomenon can be observed with the nanomaterials, the nano-specific provisions

[242] *EC* 2016, section GMO legislation.
[243] *Cantley – Lex* 2011, p. 49, 56.
[244] *WTO* 2006, section Dispute DS291. European Communities – Measures affecting the approval and marketing of biotech products.
[245] OJ, N:o L 68, 13.3.2015, p. 1-8.
[246] *COM (2015) 177*, final, p. 1-13.

in the sectoral legislation follow the precautionary approach adopted for the GMOs. However, it is also evident that the EC does not want to repeat the mistakes done with the GMOs, and has rejected calls for totally new nanomaterial legislation. The ongoing TTIP negotiations could defuse regulatory tensions and prevent future trade conflicts between the EU and the US in the GMO and nanomaterial topics.

6 SUMMARY AND CONCLUDING REMARKS

The primary policy goals for the regulation of the EHS risks of nanomaterials at this stage in the EU and the US are: 1) information gathering, 2) consistency in risk assessment and risk management, and 3) establishment of open, flexible, and proactive approach. Currently the approaches to regulate EHS risks of nanomaterials in the chemicals, food, and pesticides/biocides sectors rely mainly on the existing governmental, mandatory regulations. Some self-regulation schemes have been established in the past but new ones have not been formulated recently and the industry generally states that the current regulatory frameworks in the EU and the US adequately cover nanomaterials.

However, this study shows that information on nanomaterials received by the regulatory authorities under the applied regulatory instruments is very incomplete. A clear problem is the absence of specific provisions in the regulations (e.g., REACH, TSCA) to request information on nanomaterials and their characteristics. Even if the provisions exist (e.g., BPR) or regulations are applicable to nanomaterials without them (e.g., PPP), the absence of nano-specific guidance on methods to measure physicochemical properties and to conduct risk assessment hinders the proper compliance. On the other hand, the industry has been reluctant to report nanomaterials or conduct nano-specific tests voluntarily.

Furthermore, the consistency in the risk assessment and the risk management is in the early development phase in the both jurisdictions. There are differences between the approaches of the EU and the US that may hinder harmonization of the risk assessment. Effective risk assessment of nanomaterials demands a well-defined trigger for nano-specific measures but the regulatory authorities in the US are reluctant to set consistent, if any, definition for nanomaterial. The EC has recommended a definition, and an intention to harmonize different definitions existing in sectoral regulations can be seen. In addition, the regulatory authorities in the EU refer by rule to ISO standards and the OECD's guidance to carry out characterization and exposure assessment of nanomaterials but in the US the international standards and guidelines are not as frequently referred. Though, the regulatory authorities in both jurisdictions participate actively in the work of the WPMN and ISO TC 229 and recognize that international standardization is important for the harmonization of the risk assessment of nanomaterials.

A limited number of nanomaterials evaluated in the EU makes it difficult to determine if there is any consistency in the risk management of nanomaterials yet. However, the nano-specific provisions incorporated recently in the sectoral regulations follow the precautionary approach adopted for the GMOs previously. In the US, a case-by-case risk management approach with product specific restrictions/additional information requirements has been adopted. The emerged case law on nano-regulation reveals that the US courts predominantly support the approach taken.

Methods to achieve open, flexible and proactive regulation framework differ between the EU and the US. The EU relies on soft regulation instruments whereas legally binding measures have been established in the US. The problems related to soft regulation instruments include the challenging of the legal grounds of the regulatory authorities and the inadequacy of the existing standards and guidance. On the other hand, the rule-making procedure in the US is far from flexible, and the proactivity can be questioned if the information requirements change due to inconsistency in the definitions for nanomaterials, their properties, and related measurement methods.

This study also identified discrepancies between the regulatory approaches that may create for example trade irritants in the future. In chemicals sector, the burden of proof is the most significant discrepancy between the REACH and the TSCA. If the upcoming revision of the REACH Annexes makes the reporting of nanoforms of substances mandatory, it may result in trade irritation between the EU and the US because the REACH registration is required for all substances, not just for new substances or significant new uses of the existing substances as is registration under the TSCA.

In the food sector, the approaches to regulate nanomaterials have diverged in the EU and the US recently. A case-by-case assessment without explicit provisions for nanomaterials has been adopted in the US. In contrast, new nano-specific provisions have been included in the regulations in the EU. Furthermore, there are more extensive labelling requirements in the EU than in the US. These requirements for nanomaterials in the EU will most likely create trade irritants in the food sector.

In regard to pesticides/biocides, the mandatory nano-specific information requirements that the BPR includes may be one item which requires special attention in the future. In addition,

the active regulatory approach for nanopesticides adopted by the EPA, especially if expanded to larger number of nanomaterials, will certainly have an effect on any entity who distributes or sells in the US pesticides/pesticide products that contain nanomaterials.

To conclude, the ability of the current policy instruments to correspond to the desired goals is limited which should be recognized by the policymakers. The focus of the approaches to regulate EHS aspects of nanomaterials in the chemicals, food, and pesticides/biocides sectors is still on the risk assessment rather than the risk management, mainly due to yet prevailing scientific uncertainties and a lack of appropriate guidance. The approaches to regulate nanomaterials in the EU and the US are right now diverging more due to the recent and forthcoming regulatory activities. The tendency in the EU is towards more precautionary approach with the new nano-specific provisions in the sectoral regulations and burden of proof on the industry. In the US, a case-by-case assessment without explicit provisions for nanomaterials has been retained. The implications of these trends on the transatlantic trade should be taken into account by the companies, regulatory authorities, legislators, and policymakers.