

Linda Breggin, [Robert Falkner](#), Nico Jaspers, John Pendergrass and Read Porter

Securing the promise of nanotechnologies: towards transatlantic regulatory cooperation Report

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Securing the Promise of Nanotechnologies

Towards Transatlantic Regulatory Cooperation

Linda Breggin, Robert Falkner, Nico Jaspers,
John Pendergrass and Read Porter

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OF ECONOMICS AND
POLITICAL SCIENCE ■



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Acronyms

ABA	American Bar Association
ACHS	Advisory Committee on Hazardous Substances
ANF HQ	Thailand Science Park Project
ANSI	American National Standards Institute
APNF	Asia Pacific Nanotechnology Forum
ASTM	American Society for Testing and Materials
BAuA	German Federal Institute for Occupational Safety and Health
BIAC	Business and Industry Advisory Committee
BIPM	International Bureau of Weights and Measures
BSE	Bovine Spongiform Encephalopathy
CAA	Clean Air Act
CAS	Chemical Abstracts Service
CASG Nano	REACH Competent Authorities subgroup on Nanomaterials
CBEN	Center for Biological and Environmental Nanotechnology
CBI	Confidential Business Information
CC	Chemicals Committee
CDC	Center for Disease Control and Prevention
CEN	European Committee for Standardisation
CEN/TC	European Committee for Standardisation, Technical Committee
CERCLA	Comprehensive Environmental Response, Compensation, and Liability Act
C.F.R.	Code of Federal Regulations (US)
CFSAN	Center for Food Safety and Applied Nutrition
cGMP	Current Good Manufacturing Practice
CIR	Cosmetic Ingredient Review
CMR	Carcinogenic, Mutagenic, Toxic for Reproduction
CNT	Carbon Nanotubes
COM	Communication (EU)
CPIS	Cosmetic Product Ingredient Statement
CPSA	Consumer Product Safety Act
CPSC	Consumer Product Safety Commission

CSREES	Cooperative State Research, Education, and Extension Service
CWA	Clean Water Act
DEFRA	UK Department for Environment, Food, and Rural Affairs
DG	Directorate-General
DG EMPL	Directorate-General Employment, Social Affairs and Equal Opportunities
DG ENTR	Directorate-General Enterprise and Industry
DG ENV	Directorate-General Environment
DG INFSO	Directorate-General Information Society and Media
DG JRC	Directorate-General Joint Research Centre
DG RTD	Directorate-General Research
DG SANCO	Directorate-General Health and Consumers
DSHEA	Dietary Supplement Health and Education Act
DSNDCPA	Dietary Supplement and Non-prescription Drug Consumer Protection Act
ECHA	European Chemicals Agency
ECOS	European Environmental Citizens Organisation for Standardisation
EEA	European Environment Agency
EEC	European Economic Community
EFSA	European Food Safety Authority
EFTA	European Free Trade Association
EHS	Environment, Health and Safety
EINECS	European Inventory of Existing Commercial chemical Substances
ELI	Environmental Law Institute
ELINCS	European List of Notified Chemical Substances
ELR	Environmental Law Reporter
EMEA	European Medicines Agency
EPA	US Environmental Protection Agency
ESIS	European Chemical Substances Information System
EU	European Union
EU-OSHA	European Agency for Safety and Health at Work
EUP	Experimental Use Permit (US EPA)
FCN	Food Contact Notification
FCM	Food Contact Material
FDA	US Food and Drug Administration
FDF	Food and Drink Federation (UK)
FFDCA	Federal Food, Drug, and Cosmetic Act
FHSA	Federal Hazardous Substances Act
FIFRA	Federal Insecticide, Fungicide, and Rodenticide Act

FOIA	Freedom of Information Act	NGO	Non-Governmental Organization
FPLA	Fair Product Labeling Act	NMSP	Nanoscale Materials Stewardship Program
FP7	Seventh Framework Programme (EU)	NNI	National Nanotechnology Initiative
FSA	UK Food Standards Agency	NRP	National Residue Program
FSIS	Food Safety and Inspection Service	NSET	Nanoscale Science, Engineering and Technology
GAO	Government Accountability Office (US)	NSTC	National Science and Technology Council
GHS	Globally Harmonized System of Classification and Labelling of Chemicals	OECD	Organization for Economic Co-operation and Development
GRAS	Generally Recognized As Safe	OEL	Occupational Exposure Limit
HPV	High Production Volume	OSHA	Occupational Safety and Health Administration
IANH	International Alliance for NanoEHS Harmonization	OSH Act	Occupational Safety and Health Act
ICCM	International Conference on Chemicals Management	OTC	Over-the-Counter
ICCR	International Cooperation on Cosmetic Regulations	PBT	Persistent, Bioaccumulative, Toxic
ICON	International Council on Nanotechnology	PCPC	Personal Care Products Council
ICS UNIDO	International Centre for Science and High Technology, United Nations Industrial Development Organization	PEN	Project on Emerging Nanotechnologies
ICTA	International Center for Technology Assessment	PET	Polyethylene Terephthalate
IEC	International Electrotechnical Commission	PHSA	Public Health Service Act
IFCS	Intergovernmental Forum on Chemical Safety	PMN	Pre-Manufacture Notice
IRGC	International Risk Governance Council	ppb/ppm	Parts per billion/million
IRMM	Institute for Reference Materials and Measurements	PPORD	Product and Process Oriented R&D
ISO	International Organization for Standardization	PPP	Plant Protection Products
ITC	Interagency Testing Committee (US EPA)	PPPA	Poison Prevention Packaging Act
IUPAC	International Union of Pure and Applied Chemistry	RCEP	UK Royal Commission on Environmental Protection
IUR	Inventory Update Rule (US EPA)	RCRA	Resource Conservation Recovery Act
LSE	London School of Economics and Political Science	R&D	Research and Development
MN	Manufactured Nanomaterials	REACH	Registration, Evaluation, Authorisation, and Restriction of Chemical Substances
MRL	Maximum Residue Levels	SAICM	Strategic Approach to International Chemicals Management
MWCNT	Multiwalled Carbon Nanotubes	SCCNFP	Scientific Committee on Cosmetic Products and Non-Food Products (until 2004)
NDI	New Dietary Ingredient	SCCP	Scientific Committee on Consumer Products
NIOSH	National Institute for Occupational Safety and Health	SCCS	Scientific Committee on Consumer Safety
NIST	National Institute of Standards and Technology	SCENIHR	Scientific Committee on Emerging and Newly Identified Health Risks
		SCOEL	Scientific Committee on Occupational Exposure Limits
		SIEF	Substance Information Exchange Forum
		SiO ₂	Silicon Dioxide
		SNUN	Significant New Use Notice
		SNUR	Significant New Use Rule
		SVHC	Substances of Very High Concern

TABD	Transatlantic Business Dialogue	VAMAS	Versailles Project on Advanced
TACD	Transatlantic Consumers Dialogue		Materials and Standards
TiN	Titanium Nitride	VCI	German Chemical Industry
TiO ₂	Titanium Dioxide		Association
TSCA	Toxic Substances Control Act	VCRP	Voluntary Cosmetic Registration
TUAC	Trade Union Advisory Committee		Program
		vPvB	Very Persistent and Very
UNEP	United Nations Environment		Bioaccumulative
	Programme	VRS	Voluntary Reporting Scheme
UK	United Kingdom	WHO	World Health Organization
US	United States	WPMN	Working Party on Manufactured
U.S.C.	United States Code		Nanomaterials
USDA	United States Department of	WPN	Working Party on Nanotechnology
	Agriculture	WTO	World Trade Organization
USPTO	U.S. Patent and Trademark Office		
UV	Ultraviolet	ZnO	Zinc Oxide

Executive Summary

Nanotechnologies are set to transform industrial society. Nanotechnologies allow for the manipulation of matter or creation of structures down to the molecular level (typically at a scale of approximately 100 nanometres or less, a nanometre being one- billionth of a metre). They promise benefits in a wide range of applications, from health care to food, cosmetics, chemicals, information technology and energy storage.

Nanomaterials are already being used in numerous consumer products, and more commercial applications can be expected in coming years. At the same time, a gap has emerged between the development of nanotechnologies and our understanding of how nanomaterials interact with the environment and the human body. Early results of research suggest that the safety of all nanomaterials cannot be taken for granted. The ongoing expansion of nanotechnologies may produce novel nanostructures that cause currently unknown forms of hazard. Developing nanomaterials governance that is both effective and proportional to potential risks is critical to the future success of existing and emerging nanotechnologies.

The European Union and the United States are worldwide leaders in the scientific and commercial development of nanotechnologies. Their regulatory responses to potential risks will send an important signal worldwide. In the past, they have cooperated in international efforts to harmonize their respective risk regulation, through the Organization for Economic Cooperation and Development (OECD) and the World Trade Organization (WTO). Where successful, such efforts have promoted high levels of protection while enabling scientists and industries to operate freely in the transatlantic economic space.

In some cases, however, transatlantic coordination and cooperation have proved difficult. Differences in legislative frameworks, regulatory cultures and societal risk perceptions can contribute to a divergence of regulatory responses. This was the case, for example, with high-profile transatlantic disputes over hormone-treated beef and genetically modified food, which have had a negative impact on transatlantic relations and trade. These experiences have shown the importance of identifying technological risks and promoting international cooperation at an early stage in the policy process.

This report aims to contribute to the debate on how best to address the risks of emerging nanotechnologies and how to promote coordinated and convergent approaches in the EU and US. It presents the main findings of a project that was carried out by a consortium of research institutions from both sides of the Atlantic: the London School of Economics and Political Science (LSE) and Chatham House (the Royal Institute of International Affairs) in the UK, and the Environmental Law Institute (ELI) and the Project on Emerging Nanotechnologies (PEN) at the Woodrow Wilson International Center for Scholars in the United States.

The project was funded by a research grant from the European Commission, and is based on extensive consultation with experts and stakeholders in nanomaterials regulation on both sides of the Atlantic. It provides a detailed comparative analysis of EU and US regulatory frameworks in the key areas of chemicals, food and cosmetics, and identifies options and challenges for policy-makers and regulators in promoting greater transatlantic cooperation and convergence in nanomaterials regulation.

Regulatory challenges of nanomaterials

Governments in leading industrialized countries are currently relying on existing frameworks for environmental, health, and safety (EHS) regulation to deal with nanotechnology risks, making minor adjustments to specific regulations and their implementation in order to close any potential gaps or eliminate uncertainties. Regulators face a number of challenges in dealing with the potential risks of nanomaterials. These challenges are related to a series of uncertainties, with regard to the development and commercial application of nanomaterials, hazards and exposure pathways, the direction and speed of technological change, and the suitability and effectiveness of existing regulatory frameworks.

Rapid technological change. While the current regulatory focus is on passive nanomaterials, future developments will include active nanomaterials and are likely to converge with other technologies such as information, bio- and cognitive technologies. These future-generation nanomaterials will develop in ways that are difficult to foresee. Regulators will need to constantly expand their knowledge base covering multiple areas of scientific and engineering inquiry and develop flexible responses to a constantly changing technological environment.

Uncertainty of commercialization paths. While the number of existing commercial products using nanomaterials keeps growing, uncertainty exists regarding future commercialization paths. As the range of commercial applications expands, governments will have to address potential risks of nanomaterials in diverse regulatory contexts covering different industries and commercial applications, potentially adding to existing uncertainty about the regulatory coverage of nanomaterials risks.

Uncertainty regarding nanomaterials risks. A lack of data on hazards and exposure pathways of certain nanomaterials, combined with uncertainty about the applicability of some existing testing methods, are widely recognized impediments to the effective implementation of regulations. It is, therefore, too early to establish whether existing regulatory frameworks can and will be effective in the face of potential risks.

Uncertainty regarding the suitability of regulatory frameworks. Whether current laws provide adequate oversight for certain applications of nanotechnologies or whether new legislative instruments are needed depends very much on how existing statutes and regulations are implemented. Adequate guidance for implementation and the provision of the necessary resources for regulatory oversight thus become critical factors in developing effective regulatory responses.

Uncertainty regarding regulatory and scientific resources. The challenges that novel technologies such as nanotechnology present require significant investment in human resources. Statutes are a necessary but insufficient condition for success if the regulators lack enforcement capacity, scientific expertise and foresight. The public sector will increasingly have to compete with industry for talent in these emerging technology areas.

Towards regulatory effectiveness and convergence: policy recommendations

What should the EU and US do to promote more effective and convergent regulation of nanomaterials? Below we present key policy-relevant findings of this project, based on our own research and consultations with relevant experts and stakeholders. We focus on three clusters of issues that we identified as the most important areas: the creation of the scientific building blocks that are necessary for risk assessment; the closure of existing knowledge gaps with regard to the commercialization of nanomaterials and potential EHS risks; and questions of societal and ethical perspectives and how they are addressed in risk management. We conclude with an outlook on the global challenges of developing nanomaterials regulation in a world of internationally integrated markets and new nanotechnology producers in emerging economies

Creation of scientific building blocks

Nearly all experts whom we consulted agreed on the need to establish a firm scientific basis for risk assessment. Many of the scientific building blocks, with regard to definition and characterization of nanomaterials, metrology and testing methods, are as yet missing or have not been internationally standardized. Developing common practices in these areas is a critical step towards more effective regulation; they are key building blocks of risk assessment. Regulators and experts in the US, Europe and elsewhere are currently seeking to fill existing gaps by working together in various international forums. Our research suggests that ongoing work on creating scientific building blocks for risk assessment needs to be stepped up and expanded if it is to produce results in a timely fashion. The rapid pace of commercialization of nanomaterials demands a greater sense of urgency in this area.

The OECD enjoys broad legitimacy in promoting coordination on the building blocks for risk assessment, and is a central institution in the context of transatlantic regulatory convergence. At the same time, more political energy and resources need to be invested in the OECD process and greater transparency and inclusiveness should be achieved in its work.

Closing knowledge gaps

Furthermore, regulators face two important knowledge gaps, with regard to the EHS risks associated with the production and use of nanomaterials, and the presence of nanomaterials in commercial products. These two dimensions of uncertainty are closely linked and complicate the search for effective regulatory answers. Knowing as soon as possible what types of nanoscale products are on the market, what types of nanomaterials are used and how they move through possible product life-cycles provides some grounding for establishing research needs in the field of EHS risks. Uncertainty in both these areas afflicts US and EU regulatory systems in equal measure. Transatlantic cooperation on reducing uncertainty with respect to the commercial use of nanomaterials and on EHS risks would help both sides in addressing certain regulatory challenges

Accordingly, as a matter of priority, governments on both sides of the Atlantic need significantly to increase funding for research into EHS risks of nanomaterials. International research coordination has its limits and can be difficult to achieve, but the benefits of improved transatlantic coordination of EHS research outweigh the costs. Against the background of strained public finances and urgent research needs, enhanced transatlantic cooperation would give a greater sense of strategic direction to existing research efforts and strengthen the basis for sustained research funding streams into the future.

Furthermore, we encourage regulators and policy-makers to explore all options available to them, whether through domestic reform or international agreement, for promoting better information-sharing of EHS risk-related data on nanomaterials that ensures commercially sensitive data remain protected.

A second knowledge gap concerns the state of the commercialization of nanomaterials. Many companies themselves are uncertain about the use of such materials within their own industry, and regulators on both sides of the Atlantic have acknowledged that they currently do not have comprehensive knowledge about their presence in commercially traded goods. Recently introduced voluntary substances reporting programmes are unlikely to close such knowledge gaps.

Given the persistence of these knowledge gaps, governments on both sides of the Atlantic should strengthen existing mandatory reporting requirements and, where necessary, create new ones, with a view to gaining a comprehensive overview of the commercial use of nanomaterials. Given the high degree of economic interdependence between the US and EU, any effort to enhance market transparency through improved reporting schemes would benefit from a coordinated effort by both sides.

Risk management and consumer labelling

Efforts to promote international coordination and cooperation are currently focused on establishing the scientific building blocks needed for risk assessment. In comparison, transatlantic coordination efforts on risk management are likely to be less productive, may be premature, and would face greater obstacles. At the same time, the internationalization of the nanosciences and nanotechnologies will inevitably bring any differences in risk management approaches into sharper focus in transatlantic relations. As more and more nanomaterials are adopted commercially and enter global supply chains, differences in national or regional risk management approaches may end up complicating the free flow of goods across national boundaries. For this reason, coordination in the area of risk management will need to be given greater prominence on the international agenda in the coming years.

One important but controversial element of risk management is consumer labelling. So far, neither the US nor the EU has introduced legally binding consumer labelling requirements that specifically target nanomaterials, but moves are under way, particularly in the EU, to introduce such technology-specific labelling systems and some limited labelling requirements already exist, e.g. in food regulation. Our interviewees expressed strongly divergent views on the need to go beyond this state of affairs by creating more comprehensive labelling requirements, and on whether more convergent approaches could and should be developed in this area.

In the light of the contentious nature of labelling, in terms of its general necessity and specific form of implementation, we conclude there is no overwhelming case for arguing that the US and EU should prioritize international efforts to create new, mandatory, labelling requirements or harmonize existing ones at this time. But US and EU authorities should explore the implications of potentially diverging consumer labelling requirements for nanomaterials, particularly in the context of international trade obligations.

Furthermore, if the US and EU were to explore the possibility of developing common approaches or standards for nanomaterials labelling, such an undertaking should involve a multi-stakeholder forum to engage relevant groups from industry and civil society in order to give full weight to the different commercial and ethical concerns. Such an effort would be less urgent than the creation of common building blocks for risk assessment, but is nevertheless important in its own right.

Addressing global dimensions

No efforts have been undertaken as yet to create a formal, treaty-based, international framework for nanomaterials regulation. Our research suggests little if any interest in pursuing the more ambitious objective of creating an international treaty on nanomaterials regulation. The political energies that would need to be invested in such a project are better spent on strengthening existing forums for international coordination and adjusting domestic regulatory frameworks where needed. Given the globalized nature of nanotechnological developments and commercialization, however, one cannot rule out the possibility that such a need for an international framework treaty might arise in the future, particularly as new players from the developing world are emerging in the global nanotechnology business.

In view of the ongoing and accelerating globalization of nanotechnologies, the EU and the US should perceive the global governance challenges arising from nanomaterials in broader terms. The OECD serves an important function as a forum for coordination among leading industrialized countries, but its work should be complemented by the development of international governance capacity in other areas, and there should be greater inclusion of developing countries. Other international organizations, such as the United Nations Environment Programme (UNEP) and the World Health Organization (WHO), play important roles in their respective areas of global environmental protection and health promotion, but are only just beginning to identify the EHS risks of nanomaterials as emerging areas of concern. The current imbalance in the development of international governance capacity should thus be redressed, not least to ensure that developing countries are better represented in global regulatory cooperation.

Comparative analysis: chemicals regulation

The key legal instruments for regulating chemicals in the US and EU are, respectively, the Toxic Substances Control Act (TSCA) (together with the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA), which addresses pesticides) and the Regulation on the Registration, Evaluation, Authorisation and Restriction of Chemicals (REACH) (together with the Regulation on Classification, Labelling and Packaging – CLP). This report focuses on the laws and regulations that apply to a range of industrial chemicals, as opposed to those specifically for pesticides, because TSCA and REACH are likely to govern a wider range of nanomaterials. Any comparison between the two regulatory systems must recognize that there is a long track record of TSCA implementation that allows for a more thorough assessment of how that system works in practice, while such an evaluation is not yet possible with respect to the recently enacted REACH. Furthermore, although a track record exists under TSCA for regulating conventional chemicals, until recently there was only minimal information available to the public about regulatory actions by the Environmental Protection Agency (EPA) in the US regarding nanomaterials, and that information is still limited because of claims of confidential business information..

Moreover, numerous factors will influence the degree to which the approaches converge over time. Neither regulatory system is completely independent. Multinational companies that operate in both the EU and US are subject to both regulatory systems and may choose to take similar approaches to the manufacture, use and distribution of their chemicals that contain nanomaterials. In addition, because EU importers are subject to REACH requirements, in some cases they may rely on their suppliers, including US exporters, to provide hazard data and safe use information required for registration. Furthermore, data generated or reported by companies under one system may be factored into regulatory requirements and decisions under the other. Finally, the extent to which regulators coordinate and share information on an informal and formal basis will influence the likelihood of similar regulatory decisions, despite differences in regulatory policies and authorities.

Pre-manufacture review and registration requirements. TSCA and REACH are similar in that they require companies to determine prior to manufacture whether a chemical is subject to regulatory requirements. Both US and EU regulators consider their authorities under TSCA and REACH broad enough to cover nanomaterials, although both regulatory schemes provide for exemptions and the standards and processes that govern whether a particular nanoscale chemical will be subject to government requirements differ considerably. A principal difference is that REACH eliminates the distinction between new and existing chemicals, in an effort to subject all chemicals to the same regulatory oversight, though it delineates between non-phase-in (new) and phase-in chemicals (existing) for purposes of registration time frames and in some cases data requirements. As a result, under REACH eventually all chemicals that fall within its jurisdiction will be subject to registration requirements. In most cases, chemicals may be manufactured shortly after registration materials are submitted regardless of whether regulators have conducted a dossier or substance evaluation.

In contrast, TSCA distinguishes between new and existing chemicals for purposes of the pre-manufacture obligations imposed on manufacturers and the corresponding regulatory tools available to the EPA. 'New' chemicals are automatically subject to pre-manufacture notification and review, enabling the agency to determine whether restrictions should be imposed prior to allowing the chemical to be manufactured. However, the information that companies are required to submit is typically limited in comparison to that required by REACH. The agency also can review a significant new use of an existing chemical, provided it has issued an applicable significant new use rule. Otherwise, a company may manufacture an existing chemical without any prior regulatory review.

Information and data-collection requirements. The approaches and authorities granted to regulators to require manufacturers to produce information, including EHS data, differ significantly under the two systems. Nevertheless, in theory both are science-based approaches that seek to assess the risk of chemicals. As a result, US and EU regulators face fundamentally similar challenges in regulating nanomaterials, including limited knowledge of human health and ecotoxicological effects and the need in some cases to adjust or develop test methods.

Both TSCA and REACH provide a range of information-gathering authorities and tools. One of the key differences is that manufacturers and others subject to REACH are required to provide certain information – without action by a regulator – regardless of whether the information is already available or has to be generated. The scope of the information and data required and the time frame for submission vary considerably, depending on the quantity manufactured and potential toxicity of the chemical. Under TSCA, manufacturers only are required to provide information automatically – without action by a regulator – if a chemical is 'new' and, therefore, subject to pre-manufacture review or if the EPA has issued a 'significant new use' rule that applies to an existing chemical. In both cases, the information that must be submitted is generally information that already exists and is reasonably ascertainable, as opposed to new information generated for the purposes of regulatory review.

Finally, both TSCA and REACH protect confidential business information (CBI), but allow for its disclosure when necessary to protect human health or the environment. The systems vary, however, in their treatment of CBI. For example, in contrast to TSCA, REACH allows for the disclosure of CBI to foreign governments pursuant to agreements that provide for appropriate protection of the information.

Regulatory controls. TSCA and REACH take differing approaches to regulating the manufacture, use and distribution of chemicals. One of the most notable differences is the REACH prioritization process. Regulators develop a list of substances of very high concern that may be subject to the authorization process under which manufacturers must apply for authorization of each use of a chemical and bear the burden of demonstrating that the risks associated with the use of the substance are adequately controlled or that the socio-economic benefits outweigh the risks. Manufacturers must also analyse whether a safer alternative exists and, if so, must prepare a substitution plan. TSCA does not prioritize chemicals in this manner and does not require manufacturers to perform substitution analyses. Several factors will influence the efficiency and effectiveness of the EU prioritization process, but the authorization process represents a significant departure from the approach taken under TSCA.

Another tool under REACH for regulating chemicals is the restriction process, which bears some similarity to the TSCA chemical review and regulatory process. Both require regulators to examine chemicals on a case-by-case basis and determine whether controls are needed, but the substantive and procedural burdens placed on the regulators vary considerably under the respective systems. It is difficult to determine at present how the REACH standards and procedures will work in practice and therefore how it will compare to TSCA's approach for imposing restrictions on new and existing chemicals; however, in seeking to impose restrictions EU regulators will have substantial information and data available to them as a result of the registration process.

Finally, in addition to the authorization and restriction process, REACH requires that manufacturers apply 'appropriate measures to control risks' that they identify in their chemical safety assessments. Although it is difficult to determine the practical effects of this requirement, it is notable that REACH imposes on manufacturers an affirmative duty to assess risks, identify control measures and implement them. TSCA does not have a corresponding requirement.

In sum, TSCA and REACH differ considerably in their approach to regulation of chemicals generally and nanoscale materials in particular, including differences in policies, authorities and requirements. Nevertheless, many factors will influence the extent and manner to which these differences in approach result in disparate regulatory actions. These factors include resources for implementation, interpretation of regulatory authorities, subsequent legislative reforms and, perhaps most importantly, the extent to which regulators coordinate and share information at this critical juncture in the regulation of nanoscale materials.

Comparative analysis: food regulation

The US and the EU take a similar approach to food regulation, basing regulatory authority on product categories, each of which is regulated according to its perceived risk level. Both apply a similar suite of regulatory tools to these product categories, ranging from pre-market review to labelling. Despite these broad similarities, however, the specific elements of food regulation and implementation differ. The EU's regulatory system has changed dramatically in the past decade and will continue to evolve in coming years as a result of the maturation of regulatory practice. In contrast, the US Food and Drug Administration (FDA) has a long history of food regulation and has previously considered emerging technologies in other contexts. However, even though its general practices are established, specific regulatory developments are likely in coming years to address nanomaterials.

Nano-specific regulation. The US and EU use two general approaches to regulating food products containing or made with nanotechnologies or nanomaterials. The first is to use a case-by-case assessment under existing regulatory processes, without specifically referencing nanomaterials or nanotechnologies. The second is to refer explicitly to nanotechnologies and/or nanomaterials and to establish specific safeguards for their use in food products or production processes. The latter approach is exemplified by the EU's proposed amendment of the novel foods regulation, which would specifically require pre-market safety assessment and mandate labelling of food products produced with new technologies derived from nanosciences. The EU appears more willing than the US to create such default rules; the US regulatory system will favour case-by-case analysis of products unless evidence emerges that indicates that all nanomaterials, or a subset of nanomaterials, may be potentially injurious to health and therefore require regulation as a group.

Definitions and product categories. Food products are regulated on the basis of product categories in both the EU and US. Such regulations differ in some respects with regard to both the product categories and the definitions that apply to them. First, the two jurisdictions have not established identical product categories. For example, the US does not separately regulate novel foods or food enzymes, while the EU does not uniquely regulate residues in its food authorities. Second, the definitions that delineate the scope of each product category may differ. For example, the definition of ‘food additive’ in the US appears to be broader than in the EU. Food contact materials fall under the definition of food additives in the US, but the EU regulates them under a specific framework regulation. These differences thus preclude generalization as to how a particular nano-enabled food ingredient will be regulated; a case-by-case analysis is required.

Pre-market regulatory tools. Pre-market review and approval powers are among the most powerful tools available to regulators for governing the development and sale of food products and for generating health and safety data. In both the US and the EU, some categories of food products require pre-market review and approval, while others can be marketed without agency review.

Pre-market review and approval applies to newly developed products proposed for use in food for the first time. Pre-market tools can also apply to new forms or uses of existing, approved products. In the US, products subject to pre-market approval are generally identified and regulated on the basis of their chemical identity or molecular composition and their proposed use, but the FDA may also seek information on their physical characteristics including particle size, as part of review processes. The risk assessment process in the EU roughly echoes that used in the US. Products are primarily identified by molecular structure, but product approvals can also be limited by use and other physical properties, including particle size. The scientific opinions of the European Food Safety Authority (EFSA) are carried out on a case-by-case basis and may be tailored to particular molecular sizes and uses as needed.

Broadly speaking, both EU and US regulations stipulate that companies seeking to use existing products for uses that are not allowed by an existing regulation must seek approval. When it comes to the introduction of the nanoscale form of an approved product, the regulatory situation differs somewhat in the US and EU. Determination of whether new nanoforms can legally be marketed depends on whether the regulation for that product includes a limitation on physical or chemical properties, including particle size. Most food regulations in the US do not limit particle size. In the EU, for some product categories, including novel foods and food additives, a change in the particle size of an approved substance automatically triggers a new approvals requirement, but for others, approval requirements are based on the language approving use of the bulk substance.

With regard to new processes, most product approval regulations in the US do not specify the production process required to for particular products. The use of a new production process (without changes to the end product or its use) generally do not require a new review process unless the applicable regulation states otherwise. In the EU, the Novel Foods Regulation applies not only to novel food products but also to foods that were produced with the help of novel processes, where these processes gives rise to significant changes in the composition or structure of the foods or food ingredients. Nanotechnology-enabled processes are likely to fall under this definition if they change the resultant food product.

Post-market regulatory tools. Similar types of post-market authorities (e.g. monitoring, inspection and recall powers, and mandatory labelling requirements) are available to regulators in both the US and EU. In general, the FDA may remove adulterated and misbranded food products from the US market. Its authority may differ for specific product categories, however. The post-market tools available to regulators in the EU may differ according to both Member State authority and product category. The post-market tools available in the US and EU are likely to differ for particular products, particularly given the different product categories that apply in each jurisdiction.

Labelling. Both the US and EU contain mandatory labelling requirements for food products, including disclosure of product ingredients. These requirements may differ by product category; for example, the EU food contact regulation contains a specific symbol that must be included on food contact material products. In general the EU requires more information disclosure on food product labels than the FDA. For instance, product labels for food contact materials in the EU must contain sufficient information to permit traceability of the product, whereas such information is generally not required in the US. In addition, the proposed revision of the EU’s Novel Foods regulation requires the ingredient list to disclose ingredients that are present in nano-form. Thus, regulatory requirements for labelling of nano-enabled food products may differ substantially between the US and EU, particularly for Novel Foods.

Data collection and sharing. Both the US and EU recognize that information limitations complicate determination of the health and safety risks of nanomaterials in food products. The production and collection of information on the risks of nano-enabled food products is thus an area of focus for regulators on both sides of the Atlantic. Both the FDA and EFSA have concluded that these information limitations require the use of a case-by-case assessment process. Differences in food laws and regulations impact on the availability of information for

regulatory agencies in the US and EU. The two jurisdictions may also differ with respect to the public disclosure of information used for product assessment. However, the relevant regulatory agencies may have the ability to share even confidential information through bilateral links and agreements to hold such information as confidential.

Comparative analysis: cosmetics regulation

Cosmetics regulation in the US and the EU follows similar pathways and uses similar regulatory tools. However, specific elements of these regulatory systems differ, with significant implications for how cosmetic products containing nanomaterials may be regulated in each location. In addition, the ongoing reframing of the Cosmetics Directive in the EU promises to significantly affect the relative treatment of cosmetic products.

Neither the US Federal Food, Drug and Cosmetic Act (FDCA) nor the EU Cosmetics Directive explicitly refers to nanomaterials, either in statutory language or (for the FDA) in regulations. However, the proposed EU Cosmetics Regulation, which will replace the existing Directive, includes specific reference to nanomaterials used in these products. In particular, it is the first binding legal authority to explicitly define 'nanomaterial', while noting the need for an evolving definition of the term in accordance with developing practice. In addition, it includes specific regulatory requirements that apply only to products meeting the definition of nanomaterial, including on submission of information and labelling. If adopted, these nano-specific requirements will mark a significant deviation from existing practice in the US, which regulates nanomaterials under its existing regulatory mechanisms, as it has done for other emerging technologies.

Definition of cosmetics. The US and EU have similar systems for determining which products are subject to cosmetics regulation; however, their categorization of products differs, especially with regard to determining whether a product is a cosmetic or a drug. The different definitions in use in each jurisdiction affect the regulatory treatment of specific product types.

Pre-market tools. In general, both the US and EU have established less stringent pre-market review requirements for cosmetics than for other product types. Thus, cosmetic products are not required to obtain approval from regulators in either jurisdiction prior to being placed on the market. However, other pre-market tools are used to limit what may be placed on the market.

Few limitations apply to products in the US, as the FDCA requires neither product approval nor submission of information to the FDA. That agency, however, can bar the use of specific ingredients in cosmetics in interstate commerce by declaring them adulterants. Unless particle size is explicitly included as an element in these regulations, nanoform and bulk substances are treated equally. The FDCA, however, does not bar the FDA from restricting the marketing of nanoscale cosmetic ingredients separately from their bulk counterparts.

The EU Cosmetics Directive includes more substantial pre-market requirements. First, producers must conduct a 'cosmetic product safety assessment' for each product. Second, producers must provide the Commission with certain information when they place a new cosmetic product on the market (not including the safety assessment). Third, like the US, the Commission may limit the inclusion of specific materials in cosmetic products as permitted, prohibited, or restricted by including them in an Annex to the Directive.

The proposed EU Cosmetics Regulation would expand pre-market regulation of products containing nanomaterials to include notification, but not authorization. Although no special consideration is due for nanomaterials in product safety assessments, the Regulation would enhance notification requirements, requiring disclosure of 'the presence of substances in the form of nanomaterials', their chemical identification, and their reasonably foreseeable exposure conditions.

The EU and US regulatory systems share the ability to restrict the use of specific nanomaterials in cosmetic products, although the requirements for such a determination differ and are likely to shift further if the proposed Regulation is approved. Furthermore, the proposed EU Cosmetics Regulation contains enhanced disclosure requirements for nanomaterials. These are likely to substantially increase the amount of information available to regulators on the presence of nanomaterials in cosmetics products.

- **Post-market regulatory tools.** Both the US and EU have established a similar suite of post-market tools for regulation of products (e.g. recalls, adverse event reporting, inspection of records, good manufacturing practices, and labelling), although they deploy these post-market regulatory tools in different ways.
- **Product recalls.** In the US, FDA has limited recall authority; it can request a voluntary recall of particular cosmetic products or remove adulterated or misbranded products from the market through court order. In

the EU, Member States can provisionally prohibit or condition the marketing of a particular product, even if that product is in compliance with the requirements of the Cosmetics Directive, provided the product represents a hazard to health.

- **Adverse event reporting.** Both US and EU authorities currently lack formal authority to require adverse event reporting. In the EU, however, the Cosmetics Directive does require responsible parties to maintain, as part of each product information file, existing data on the undesirable effects on human health caused by the product. The proposed EU Cosmetics Regulation explicitly requires responsible parties and distributors to notify the competent authority when a serious undesirable effect occurs.
- **Inspection of records.** The EU Cosmetics Directive authorizes inspectors to access regulated entities and view product information files upon request. Inspection authority in the US is more limited; the FDA does not have general authority to obtain manufacturers' records and safety-related data.
- **Good manufacturing practices (GMPs).** To ensure safety of production, regulators in both the EU and US require manufacturers to comply with good manufacturing practices for certain product categories. In the US, only non-binding guidance for good manufacturing practices has been issued. In the EU, the Directive and proposed Regulation both require compliance with GMPs.
- **Labelling.** The US and EU have developed unique rules for labelling, although important elements are common to both jurisdictions (e.g. ingredient lists, amount of contents, and the name and place of business of responsible entities). In the US, the FDA has indicated that it will not require the identification of nanoscale cosmetic ingredients on product labels, as it has determined that the risks and benefits of nanomaterials are uncertain and labelling would not provide substantial benefits to the public. In Europe, the Cosmetics Directive and the proposed Regulation both include specific requirements for product label contents. Unlike the existing Cosmetics Directive, the proposed Regulation requires that nanomaterials shall be clearly indicated in the list of ingredients.

Information-sharing. Regulators have acknowledged challenges in ascertaining adequate information both to allow evaluation of the safety of nanomaterials and the presence of products containing nanomaterials in cosmetics. Acquisition of this data in the cosmetics context may be limited both by the content of relevant laws and regulations and by limits on agency ability to share confidential information.

The EU Cosmetics Directive requires pre-market authorization for UV filters, colorants and preservatives, and the proposed Regulation would require notification prior to the marketing of *any* cosmetic product containing nanomaterials. Current notification and inspection authorities provide additional data sources, although they may lack specific data on nanomaterial ingredient safety. The FDA is not authorized to require similar disclosures for cosmetic products containing nanomaterials, although colour additives and drugs, including sunscreens, are subject to pre-market approval. The US instead established the Voluntary Cosmetic Registration Program (VCRP) to encourage voluntary submission of data about products in the marketplace, and the FDA also may obtain information from the Cosmetic Ingredient Review (CIR).

Agencies may seek to share relevant information they acquire, and may be unable to do so owing to statutory requirements, such as the prohibition on disclosure of trade secrets in the FDCA. However, relevant agencies are allowed to share even confidential or trade secret information, provided that the confidentiality of such information is protected. Bilateral memoranda of agreement have been created to enable such information-sharing as pertains to cosmetics. As a result, these agencies can share whatever information that they acquire, while such information (if confidential) will remain unavailable to the public. However, the content of that information is likely to remain limited with respect to inclusion of nanomaterials, pending adoption of the proposed Regulation.

The findings and policy recommendations in this report are the sole responsibility of the authors, and do not represent the views of the institutions of the project consortium, or those of the United States and European Union. For further information on the research project and approach, see chapter 1 of this report.

1 Introduction and Overview

Nanotechnologies are fast emerging as a transformative force in industrial society. Nanotechnologies allow for the manipulation of matter or creation of structures down to the molecular level (typically at a scale of approximately 100 nanometres or less, with a nanometre equal to one-billionth of a metre). They promise many benefits to society in areas as wide-ranging as consumer products, health care, chemicals, cosmetics, renewable energy generation and storage, and waste treatment. As is the case with many new technologies, we currently have only a limited understanding of potential risks. Some studies suggest that certain nanomaterials may have a negative impact on human health and the environment if exposure or release occurs, but reliable information on risks is scarce. Developing a governance system for nanosciences and nanotechnologies that is both effective and proportional to potential risks is, therefore, of the utmost importance if society is to realize the technology's full potential. The public needs to be assured that the scientific community, industry and government are investing enough energy into protecting society from potential harm.

Governments in leading industrialized countries are currently relying on existing regulatory frameworks for environmental, health and safety regulation to cover nanotechnology risks. EU and US regulators generally have concluded that any risks posed by nanomaterials can be addressed using existing frameworks, but minor adjustments to specific regulations and their implementation are currently being made in order to close any potential gaps or eliminate uncertainties. Identifying the appropriate response to uncertain risks is a difficult task for policy-makers and regulatory agencies. They are faced with a high degree of scientific uncertainty, and need to balance the costs and benefits of regulation as well as seeking a durable compromise between the often conflicting interests of scientific freedom, technological innovation, consumer safety and environmental protection.

The European Union and the United States are worldwide leaders in the scientific and commercial development of nanotechnologies. Their regulatory responses to potential emerging risks are therefore likely to send an important signal worldwide. In the past, they have cooperated in international efforts to develop harmonized tools for their respective risk regulation, through bodies such as the Organization for Economic Cooperation and Development (OECD) and the World Trade Organization (WTO). Where successful, such efforts have sought to promote high levels of protection while enabling scientists and industries to operate freely in the transatlantic economic space.

In some cases, however, transatlantic coordination and cooperation have proved difficult. Differences in legislative frameworks, regulatory cultures and societal risk perceptions can contribute to a divergence of regulatory responses in the EU and US. This was the case, for example, with high-profile transatlantic disputes over hormone-treated beef and genetically modified food, which have had a negative impact on transatlantic relations and trade. These experiences have shown the importance of identifying technological risks and promoting international cooperation at an early stage in the policy process.

This report aims to contribute to the debate on how best to address the risks of emerging nanotechnologies and how to promote coordinated and convergent approaches in the EU and US. It presents the findings of a project that was carried out by a consortium of research institutions from both sides of the Atlantic: the London School of Economics and Political Science (LSE) and Chatham House (the Royal Institute of International Affairs) in the UK, and the Environmental Law Institute (ELI) and the Project on Emerging Nanotechnologies (PEN) at the Woodrow Wilson International Center for Scholars in the United States. The project was supported by a grant from the European Commission, and many experts on nanosciences and nanotechnology in Europe and North America contributed to the research effort. The findings of the report reflect the views of the authors and should not be taken to be the views of the institutions of the project consortium, the European Union or the United States.

1.1 Background: call for proposals on 'Policy Approaches to Promoting the Safety of Nanomaterials'

The impetus for this project came out of the April 2007 US–EU summit, at which US President George W. Bush and German Chancellor Angela Merkel launched an initiative to seek closer cooperation on transatlantic trade and regulation. By signing the *Framework for Advancing Transatlantic Economic Integration between the United States of America and the European Union*, the two sides set an ambitious agenda of promoting transatlantic commerce

through fostering cooperation and removing regulatory burdens. A Transatlantic Economic Council is to oversee efforts outlined in this plan. The 'Framework' notes as a key aim of the partnership:

our shared commitment to removing barriers to transatlantic commerce; to rationalizing, reforming, and, where appropriate, reducing regulations to empower the private sector; to achieving more effective, systematic and transparent regulatory cooperation to reduce costs associated with regulation to consumers and producers; to removing unnecessary differences between our regulations to foster economic integration; to reinforce the existing transatlantic dialogue structures in regulatory cooperation both by intensifying our sector-by-sector EU-US regulatory cooperation and our dialogue between the European Commission services and the US Office of Management and Budget on methodological issues¹...

Responding to this initiative, the European Commission in the summer of 2007 issued a request for proposals from research institutions that would provide policy-relevant analysis of a number of issues that are of importance to transatlantic regulatory convergence, among them policy approaches to promoting the safety of nanotechnologies.² In its request for proposals, the Commission set out the general objective of the projects:

*The **general objective** of the pilot projects is to promote mutual understanding and learning among EU and US policy researchers and policymakers on a number of challenges with a global dimension. The projects are to fund comparative analyses on current EU and US policies, conferences where findings are to be discussed and recommendations made, and publications to disseminate the results of the projects to the relevant policy community.*

Specifically with regard to research on 'Policy Approaches to Promoting the Safety of Nanomaterials', the Commission's request for proposals stated:

- the need for international cooperation with economically advanced countries in nanoscience and nanotechnologies;
- the need to strengthen international dialogue on common issues;
- the great benefits to be derived from nanotechnologies, but also the potential risks arising from their commercial application; and
- the need to 'fill data and knowledge gaps, to re-evaluate risk assessment methods, and to assess risk on a case-by-case basis at a time when those materials are rapidly emerging on the market', posing 'serious policy challenges, in particular as regards regulation and implementation, international safety standards and citizens' expectations and concerns'.

The Request for Proposals explicitly referred to the opinion of the Commission's Scientific Committee on Emerging and Newly Identified Health Risks (SCENIHR), namely that

current risk assessment methodologies require some modification in order to deal with the hazards associated with nanotechnology and in particular that existing toxicological and eco-toxicological methods may not be sufficient to address all the issues arising with nanoparticles.³

In the context of such concerns about the implementation of existing regulations with regard to potential risks of nanomaterials, the project was asked to perform the following tasks:

- make a comparative assessment of the effectiveness of available policy measures in the EU and the US to ensure the safety of nanoparticles and nanoparticle products;
- review processes which foster the identification of best practices and the establishment of international requirements for and congruent approaches to safety in order to establish an international level playing field and promote regulatory convergence between the EU and the US;
- examine means of addressing the safety and ethical concerns expressed by citizens, and understand the implications of calls in the US and the EU for the labelling of nanomaterial products from the point of view of safety, legislation and international trade.

1 European Commission (2007a).

2 European Commission (2007b).

3 European Commission (2006).

In responding to this call for proposals, the project consortium – consisting of the London School of Economics, Chatham House, the Environmental Law Institute and the Project on Emerging Nanotechnologies – set out a research agenda that addresses the main issues raised by the European Commission. A brief outline of this agenda is provided below, before a discussion of the project's research design.

1.2 Research agenda for this project

This project set out to provide an analysis of current regulatory developments in the field of nanotechnologies, with a view to informing the debate on transatlantic cooperation and regulatory convergence. Nanotechnology oversight is a rapidly changing domain that is characterized by high degrees of scientific uncertainty, as well as limited experience with the implementation of existing and emerging regulations. Some findings of this project are, therefore, time-bound and are likely to be overtaken by developments in the coming years.⁴ Others, however, explore regulatory challenges and options for future developments that are likely to be relevant for years to come.

In the light of the European Commission's call for proposals and the objectives contained within it, it is important to emphasize at the outset the scope and limitations of this research project:

- *Focus on regulation of environmental, health and safety risks of nanomaterials:* The project is concerned primarily with the various regulatory instruments that seek to deal with environmental, health and safety (EHS) risks. The original request for proposals speaks of 'ensuring the safety' of nanomaterials, and we put this notion into operation by focusing on such EHS risks. This means that policies aimed at the promotion of nanosciences and nanotechnological innovation are not the primary focus of this study. The chosen focus on EHS risks of nanotechnology does not indicate a judgment on our part about the relative importance of safety versus technology promotion, but merely reflects the objectives set for this project by the European Commission.
- *Focus on existing nanomaterials in commercial use:* The project is concerned primarily with what is commonly referred to as first-generation nanotechnologies and nanomaterials, some of which have been introduced for commercial use. In order to provide policy-relevant insights into the regulatory challenges that emerging new generations of nanotechnologies might pose, the consortium commissioned two analytical papers that investigate next-generation nanotechnologies and synthetic biology.⁵ This report, however, focuses entirely on the regulatory challenges posed by existing nanomaterials, and the ways in which existing regulatory frameworks are responding to them.
- *Focus on transatlantic dimensions of existing regulations:* In examining existing regulatory frameworks in the EU and US, the report focuses on those aspects that are relevant to the comparative, transatlantic, dimension. Given constraints of space and time, the project consortium did not attempt a full comparative study of the entire regulatory framework for nanotechnologies in the EU and US. Instead, we sought to describe in sufficient detail the main outlines of existing frameworks, to put them in a broader transatlantic context, and to identify some of the key similarities and differences in the way in which each framework deals with emerging nanotechnology risks. There are clear and inevitable limits to what we could achieve in our comparative analysis: we were guided by the need to discuss the relevance of existing regulations for nanomaterials; we were dealing with a fast-changing regulatory environment with legal changes and amendments on the statute books that are not yet in force; and we were analysing regulatory domains with often only limited experience with implementation.
- *Focus on promoting congruent approaches and regulatory convergence:* The analysis is guided by the overarching question of how to develop 'congruent approaches to safety' and how to 'promote regulatory convergence between the EU and the US'. This objective reflects the intentions of the EU-US Summit of 2007 communiqué and is central to the Commission's call for proposals. Thus, our focus on questions of congruence and convergence in nanotechnology regulation does not reflect a judgment on our part on the need for greater convergence between the EU and the US. Instead, the report lays out different options and policy ideas for promoting greater congruence and convergence, in order to inform policy debates on the desirability and modalities of such convergence efforts. We discuss the meaning of key concepts such as 'regulatory convergence', and how we have put them into operation, further below in this chapter.
- *Focus on key sectors (chemicals, food and cosmetics):* Given restrictions of time and space, we have had to focus on a small number of policy domains within which nanotechnology regulation is being developed and practised. Because of its cross-cutting nature as an enabling technology, nanotechnology has been applied commercially in a wide range of sectors, including chemicals, food, cosmetics, medicine, pollution

⁴ The report is based on research conducted between January 2008 and July 2009.

⁵ Davies (2009); Rodemeyer (2009).

treatment and electronics. In order to provide a sufficiently detailed analysis of regulatory frameworks and capture the state of the debate in those sectors that are currently at the forefront of regulatory and political developments, we chose to focus on the regulation of chemicals, food and cosmetics. Chemical regulation is of central importance as many nanomaterials first enter the process of regulatory oversight in this regulatory domain. We have therefore provided an expanded analysis of regulatory frameworks in the chemicals area. Food and cosmetics regulation are relevant as many of the emerging commercial applications of nanotechnology can be found in these sectors, and politically sensitive issues relating to consumer trust and labelling are important concerns in both regulatory contexts. Given our selective focus, we could not discuss other important areas in which risks of nanomaterials have arisen, such as worker safety and medical uses, but hope that our findings will be of broader relevance.

In responding to the Commission's request for proposals, the project consortium took the stated objectives as the starting point for our research. We did not base our work on any pre-existing normative claims or policy positions with regard to the desirability of greater regulatory oversight of nanomaterials, the need to reform existing frameworks for nanotechnology regulations in the EU and the US, the benefits and costs of increased convergence between EU and US regulatory systems, or any other related questions of policy. Instead, we defined our task as that of providing an objective knowledge base for future discussions – among policy-makers, regulators and other interested parties – on the need and options for promoting more effective, congruent and convergent approaches to nanotechnologies regulation.

Inevitably, our analysis reflects professional judgments based on legal and political science analysis. Readers will have different views on certain assessments and recommendations contained in this report, and it is our hope to stimulate further discussion of such policy options. Inevitably, many of the questions and policy ideas that we address are contested. As will become apparent in our analysis, a lively debate exists in the academic literature, and among regulators and stakeholders, about the state of nanotechnology oversight, differences between US and EU approaches, and the need for developing greater convergence between them. By basing our analysis on a wide-ranging review of this debate and taking into account the views of a large number of experts from government, industry, civil society and academia, we hope to have reflected the variety of views expressed in expert circles. Nevertheless, the assessments and conclusions reached in this report, as well as any mistakes and omissions, are ours, and ours alone.

To provide further background on the project, we briefly discuss its research design and methodology in the next section, before outlining key concepts related to the debate on regulatory convergence.

1.3 Research design

The research involved legal and political analysis and was guided by the following four principles:

- a. *Independent analysis:* While funding for this project was received through a European Commission research grant, the research and its findings are based on independent analysis. The research team alone, in close cooperation with the project's Steering Committee, decided on the precise focus and approach for the study, taking into account the objectives of the project laid down in the call for proposals. The team consulted widely and drew on the expertise of a broad range of nanotechnology experts and stakeholders, but it is the authors of the report who are responsible for what is contained in it.
- b. *Comparative approach:* The research was guided by a focus on the transatlantic dimensions of nanotechnology regulation in the EU and US. While a growing number of studies of national and/or issue-specific regulatory frameworks for nanotechnologies have been conducted in recent years, this study seeks to bring out the comparative dimension in this emerging research field. There are, of course, certain limits to how far one can compare different regulatory systems, some of which we have already highlighted above. Each regulatory system has to be seen and analysed in its own legal and institutional context. We have sought to do justice to the national and regional specificity of nanotechnology regulation by devoting separate sections of our analysis to US and EU approaches in the fields of chemicals (chapter 4), food (chapter 5) and cosmetics regulation (chapter 6). Each of these chapters is concluded with a comparative analysis that considers the main similarities and differences in the way in which these systems deal with EHS risks of nanomaterials. In other words, we are not providing a fully-fledged comparative analysis of EU and US law and regulatory practice as such, but an outline analysis of the most salient points in comparing US and EU regulatory responses to emerging nanotechnology risks. Nor do we attempt to develop a full-scale evaluation of existing regulatory approaches and their effectiveness. Our emphasis is on the comparative dimension. Establishing the effectiveness of US and EU approaches would be premature in the current situation, given that there is as yet very little experience of the application of existing laws and regulations to newly emerging nanomaterials and their potential risks.

- c. *Consultation with key experts and stakeholders:* Apart from analysing legal and other documents and reviewing the research literature, we have, as mentioned above, consulted widely among regulatory experts and stakeholders in the field of nanotechnology. The aim of this consultation exercise was to develop an overview of the state of the transatlantic debate on nanotechnology regulation and to gain a better understanding of the perspectives of different stakeholders in this debate. Our main methods for researching the views of nanotechnology experts and stakeholders were:
- *Standardized questionnaire:* At an early phase of the project, the research team designed a questionnaire that included a list of open-ended questions to which we sought responses from a selected group of experts in the field of nanotechnology regulation.⁶ These experts were drawn from a list of key actors from regulatory agencies, industry, civil society and academia, which we had identified at the beginning of the research phase. The research team received questionnaire responses from 40 respondents, of whom 29 were from the EU and 11 from the US.
 - *Semi-standardized interviews:* Building on the results of the questionnaire responses and our own research, we interviewed a representative selection of experts from the above list. Interviews were conducted in meetings lasting on average one hour. Where face-to-face meetings proved impractical, the research team communicated with stakeholders in writing or by phone. The interviews were semi-structured, i.e. we used the standardized questionnaire as a starting point but gave interviewees the flexibility to take the conversation in a different direction, depending on their area of expertise.⁷ In order to compensate for the uneven questionnaire return rates from the EU and US, we carried out more interviews in the US than in Europe. The team interviewed a total of 68 experts, 25 from the EU and 43 from the US. Interviewees represented the following groups: government (30); industry/trade associations (15); non-governmental organizations (NGOs) including consumer organizations (11); law firms (4); congressional/parliamentary committee staff (4); and academics (4).

Given the sensitive nature of many of the issues covered in our research, and in order to facilitate frank and open expressions of views and perspectives, we guaranteed full anonymity to all those who responded to our questionnaires and/or were willing to be interviewed. We therefore refer to such views in anonymous form throughout the report, by referring only to experts' organizational affiliation ('industry representative', 'NGO representative').

- d. *Peer review:* This report was reviewed extensively by a number of experts in the field of nanotechnology regulation. The peer review process involved, in first instance, the members of the Steering Committee, who not only guided our research efforts but also provided critical reviews of the draft report. The project team held two review workshops, in London and in Washington, DC, at which a select group of experts reviewed the report and discussed its policy recommendations. We also received detailed written comments from other experts, including from US government and European Commission officials. While we have sought to do justice to the meticulous work of our reviewers and to take on board as many of their suggestions as possible, the authors bear ultimate responsibility for the content of this report. It goes without saying, therefore, that all remaining mistakes are their responsibility, too.

1.4 The concept of regulatory convergence

Much of what follows in the subsequent analysis involves technical language from the fields of nanosciences and nanotechnologies, as well as the regulation of environment, health and safety risks. We explain technical terms as they are introduced in the text, but a preliminary discussion of the key concept of 'regulatory convergence' is needed at the outset, as it plays a central role in our policy recommendations on how to develop congruent regulatory approaches in the EU and US.

As stated above, we were asked to analyse existing regulatory approaches with a view to identifying the potential for regulatory convergence. The term 'regulatory convergence' is widely used in debates on how to achieve greater integration between the economies of the EU and the US, and it has a well established place on the agenda of the annual EU-US summits and the Transatlantic Business Dialogue (TABD).⁸ But the concept of convergence is a complex and controversial one, and is often ill-defined in public as well as scholarly debates. Depending on how it is used, the concept can overlap with other notions such as policy diffusion, coordination, cooperation and harmonization. In order to bring greater clarity to this debate, we lay out the different meanings of these concepts and how they are related to the idea of transatlantic regulatory convergence.

6 On the flexible nature of standardized questionnaires, see McNabb (2004).

7 On the need for flexibility in elite interviews, see Richards (1996).

8 For a recent overview of the dimensions of recent debates on transatlantic cooperation, integration and convergence, see Peterson and Steffenson (2009).

Convergence is normally defined as ‘the tendency of policies to grow more alike, in the form of increasing similarity in structures, processes, and performances’.⁹ While this formulation refers to policy convergence more generally, it can also be applied to regulatory convergence, i.e. the increasing similarity in regulatory structures, processes and performances. Regulatory convergence thus applies to both the legal framework for regulation and its implementation. An important aspect of this definition is the process dimension of convergence. Convergence denotes a *trend towards* more harmonized regulatory approaches in different countries, but not necessarily the endpoint of full harmonization.

Other concepts that are sometimes used interchangeably with convergence include ‘policy diffusion’, ‘coordination’, ‘cooperation’ and ‘harmonization’. For our purposes, these concepts can be seen as mechanisms, or stages in the process of producing greater convergence.

In many ways, the process of *policy diffusion* from one state to another is a first step towards creating greater convergence. It takes place where national political institutions (such as regulatory agencies) engage in informal processes of communication, policy learning and policy transfer, adapting their behaviour on the basis of policy ideas and models from abroad.¹⁰

International coordination and cooperation constitutes a formal or informal process that involves collaboration between different regulatory agencies in creating convergent behaviour. It can involve international standardization but not deep changes to national regulatory systems.

International cooperation represents a higher level of convergence in that it is usually based on a formal agreement to create common standards, rules and principles, often in the form of an international treaty. It represents a higher step on the way towards convergence, but unlike harmonization, international cooperation allows states to design their own domestic rules and regulations to implement the international agreement.¹¹

Treaty-based harmonization represents the most advanced level of convergence. It involves the setting of internationally agreed standards, invariably through formal treaties, and the adjustment and revision of domestic legislation and regulation to conform to the newly created international standard. Legislative acts are usually needed to bring domestic regulation in line with the international agreement, thus producing a deep level of regulatory convergence.¹²

Table 1 provides an overview of the different mechanisms and processes of convergence.

Table 1: Convergence: mechanisms and processes

Convergence processes	Definition	Examples
Policy diffusion	Informal process of communication and policy learning between regulators.	Bilateral links between regulatory agencies (e.g. between US EPA and European Commission on REACH).
International coordination and cooperation	Formal or informal international process of developing congruent approaches without large-scale adjustment of domestic laws and regulation.	OECD-based guidelines (e.g. OECD Test Guidelines and Principles of Good Laboratory Practice).
Treaty-based harmonization	Formal negotiation of an international agreement on common rules and standards for domestic regulation.	WTO trade agreements (e.g. Trade-related aspects of intellectual property rights (TRIPS) agreement).

The goal of regulatory convergence and the reduction of trade barriers in a transatlantic and international context are usually seen in a positive light, but contrasting views exist with regard to the specific benefits and costs of moving towards greater regulatory convergence. This is not the place to rehearse this debate, but a few points are worth mentioning, not least to illustrate why the question of transatlantic convergence in nanotechnology regulation proves to be controversial. Our research of stakeholder views on this question has indeed produced a wide range of opinions, from warm endorsement to cool indifference and outright rejection.

9 Drezner (2001: 53). For an overview of the political science literature on policy and regulatory convergence, see Holzinger et al. (2008) and Vogel and Kagan (2002).

10 On policy diffusion, see Dobbin et al. (2007).

11 On theories of international cooperation and regime-building, see Hasenclever et al. (1997).

12 See Simmons (2001).

On the positive side, regulatory convergence is widely seen to promote global economic integration. Uniform regulatory standards lower international business costs by reducing the need to comply with different regulatory requirements and by increasing opportunities for economies of scale. Regulatory agencies can also benefit from greater coordination of their activities. With the growing scientific complexity of emerging technologies and associated EHS risks, regulators can improve the effectiveness of regulatory systems through the increased sharing of scientific knowledge and the development of harmonized risk assessment methods. And as more and more technologies and products are created and traded internationally, regulators inevitably need to take a more global view and identify EHS risks along globally integrated supply chains.

But regulatory convergence also produces costs. Countries with a lower level of risk regulation may not wish to increase regulatory burdens in order to comply with higher international standards. Likewise, countries with a higher level of risk regulation may not want to see their domestic regulatory safeguards diluted through convergence on a lower international standard. The 'optimal level' of regulation need not be the same in all countries, and what seems to be a legitimate effort to increase public protection in one country may be an unwarranted and intrusive extension of regulatory powers in another. Important aspects of risk management systems are rooted in national contexts, which are characterized by distinctive societal values and cultural identities. National frameworks for food safety and consumer protection, for example, reflect not only available scientific knowledge but also the values and identities that define what might be called a society's 'risk culture'. For this reason, significant differences exist in regulatory standards, not just between developed and developing countries, but also among developed economies. Moreover, the benefits of greater regulatory convergence need to justify the costs of convergence efforts (e.g. participation in international efforts and negotiations; domestic legal change). Such costs may not necessarily be high, but when compared with modest or uncertain gains from international coordination, they can seem prohibitive.¹³

Finally, given the uncertainties involved in risk regulation, it is not inevitable that greater convergence will always be the most desirable outcome. In fact, a significant body of scholarship suggests that regulatory competition, and not convergence, is what is needed in certain circumstances, and that such competition need not result in lower standards overall.¹⁴ Competition between different regulatory systems allows for a more experimental approach to the governance of risk and gives regulatory authorities a chance to learn from different experiences. In this view, uneven regulatory standards promote a process of policy experimentation and learning from the bottom up, rather than the imposition of a negotiated compromise between different regulatory approaches. Particularly in fields characterized by high degrees of scientific uncertainty such as nanotechnology, 'rigid forms of harmonization could limit the ability to learn through trial and error'.¹⁵

In sum, despite an overall trend in the post-1945 era towards greater international coordination and harmonization of regulatory standards, significant differences in national approaches to risk regulation persist today. Safety regulation of nanomaterials does not exist in a vacuum, but is embedded in a wider institutional and cultural framework. Domestic imperatives are a powerful force in shaping the direction of regulatory developments, and European and American regulatory frameworks remain wedded to different legal and political traditions. Regulatory approaches are not immune to change, of course, but any such change will be a slow and complex process.¹⁶

Achieving transatlantic convergence in nanotechnology regulation can therefore be a difficult task, one that requires sustained efforts at international cooperation between regulators, policy-makers and stakeholders. Reflecting on the experience of the 1990s, David Vogel remarked that 'transatlantic differences in public values and in regulatory objectives and approaches remained large enough to make the goal of regulatory convergence elusive'.¹⁷ It remains to be seen whether the emerging challenges of risk regulation in the 21st century provide the required impetus for greater transatlantic regulatory convergence today.

1.5 Overview and structure of the report

The introductory *chapter 1* sets out the principal objectives and research design for this project. It explains the background, and the specific objectives set out in the request for proposals which served as a general guide for the project. The first chapter also lays out a general conceptual framework for discussing regulatory convergence, which is central to the transatlantic theme of the project and report.

The next two chapters provide general background information on nanotechnology and the regulatory context in the US and EU. More experienced readers may well wish to go straight to the detailed analysis of regulatory

13 See Hood et al. (2001: 29–30).

14 Esty and Geradin (2001); Genschel and Plumper (1997).

15 Breggin (2006: 109–10).

16 On the embeddedness of national regulatory approaches, see Vogel (1986); Vig and Faure (2004).

17 Vogel (1997: 13).

frameworks in chapters 4 to 6. *Chapter 2* introduces the field of nanosciences and nanotechnologies and charts major commercial applications of nanomaterials today. *Chapter 3* lays out the broad outlines of the institutional framework for nanomaterials regulation in the EU and US and gives an overview of major international initiatives in this area.

The core of the comparative analysis of EU and US nanomaterials regulation is presented in *chapters 4, 5 and 6*, which describe the main elements of existing regulatory frameworks in the three sectors that we focus on in this report: chemicals (*chapter 4*), food (*chapter 5*) and cosmetics (*chapter 6*). These chapters first analyse regulatory frameworks in each jurisdiction before putting them in a comparative perspective and concluding with an overall assessment of their main commonalities and differences.

Building on this analysis, *chapter 7* then proceeds to present the main policy-relevant findings of this project, with regard to developing effective regulatory responses while promoting congruent approaches and regulatory convergence between the US and EU. Here we return to the broader question of whether, and to what extent, regulatory coordination and convergence are desirable and feasible in the field of nanomaterials. This chapter identifies both opportunities and barriers to regulatory convergence, with a view to stimulating the policy debate on how to meet common policy challenges in a transatlantic context.

2 Nanotechnologies and Nanomaterials

The ‘nanotechnology revolution’¹⁸ can be traced to a 1959 lecture by Richard Feynman, ‘There’s Plenty of Room at the Bottom,’¹⁹ which called for research into the manipulation of substances at the molecular scale. Largely unnoticed at the time, Feynman’s lecture has since proved prophetic: in the subsequent decades, nanotechnology research has grown exponentially, leading to a wide range of applications, especially in the areas of improved production processes, data processing and new materials. Future applications are expected in areas of medical treatment and health care; air, water and soil quality advancement; and clean energy production, storage and transportation – to name just a few.

This report focuses on nanomaterials²⁰ currently in production. Some newly created nanomaterials have unique properties related to their stiffness, conductivity, colour or magnetism, and a number of other physical and chemical properties, when compared to bulk materials. Carbon in the form of nano-tubes, for example, is one of the strongest and stiffest of all currently existing materials. Some of the unique properties of nanomaterials, however, may be harmful to human health and the environment in unconventional and unexpected ways. The effects of inhaling some forms of carbon nanotubes, for instance, may cause harm in ways reminiscent of asbestos fibres; releasing silver nanomaterials with anti-bacterial properties into waste water may have negative environmental effects; and the ability of certain nanomaterials to penetrate cells in living organisms may cause human health concerns.²¹ To be sure, nanomaterials are not inherently harmful and in many cases their risk profiles may be similar to those of the same materials in bulk form, but scientific uncertainty surrounding the known and unknown effects of nanomaterials poses a challenge for regulators.

It is for this reason that policy-makers, civil society, industry representatives and scientists have called for a careful review of whether current regulatory frameworks are equipped to adequately deal with the potential risks related to some nanomaterials. We provide a comparative analysis of US and EU regulatory frameworks in the fields of chemicals, food and cosmetics in chapters 4, 5 and 6. In this chapter, we review the basic characteristics of nanosciences and nanotechnologies; their commercial and economic dimensions; associated EHS risks; and the general problems facing regulators.

2.1 Terminology: nanosciences, nanotechnologies and nanomaterials

As was noted in the 2004 report by the UK’s Royal Society and Royal Academy of Engineering, nanosciences and nanotechnologies are as yet ill-defined fields. They ‘encompass a broad and varied range of materials, tools and approaches. Apart from a characteristic size scale, it is difficult to find commonalities between them, complicating clear definitions of relevant terms.’²² Different definitions have been offered to describe their development and use. The Royal Society and Royal Academy of Engineering produced the following definition:

Nanoscience is the study of phenomena and manipulation of materials at atomic, molecular and macromolecular scales, where properties differ significantly from those at a larger scale.

*Nanotechnologies are the design, characterisation, production and application of structures, devices and systems by controlling shape and size at the nanometre scale.*²³

18 As nanotechnologies lead to entirely new methods in mechanical, electrical and bio-engineering, they are often compared to new technologies that led to the industrial revolution in the 18th and early 19th centuries (for example, see the Foresight Institute’s ‘Molecular Nanotechnology: The Next Industrial Revolution’, available at <http://www.foresight.org/nano/ieeecomputer.html>, accessed 5 July 2009).

19 A reproduction of the lecture can be found on the homepage of Zyvex, a molecular nanotechnology company, available at <http://www.zyvex.com/nanotech/feynman.html> (accessed 5 July 2009).

20 Throughout this report, we refer to intentionally created nanomaterials (also referred to as engineered or manufactured nanomaterials), rather than incidental ones (e.g. car exhaust emissions) or those occurring naturally.

21 The International Council on Nanotechnology (ICON) provides a useful overview of the relevant toxicological literature, available at http://cohesion.rice.edu/centersandinst/icon/resources.cfm?doc_id=12722 (accessed 5 July 2009).

22 The Royal Society and the Royal Academy of Engineering (2004).

23 Ibid.

The National Nanotechnology Initiative (NNI) in the United States adopted a single definition that encompasses both science and technology: ‘Nanotechnology is the understanding and control of matter at dimensions of roughly 1 to 100 nanometers, where unique phenomena enable novel applications.’²⁴

Nanotechnology (in the singular) can thus be taken to refer to a wide range of different technologies.²⁵ In this report, we refer to ‘nanotechnologies’ and ‘nanotechnology’ throughout, with the latter signifying the wider field of science and technology that encompasses the full range of nanotechnologies and applications. We refer to ‘nanomaterials’ as a generic term for the structures, devices and systems created through nanoscale engineering, including nanoparticles, nanostructures and nanoscale substances, which have recently been defined by the International Organization for Standardization’s (ISO) nanotechnology technical committee (TC 229).²⁶

2.2 Different generations of nanotechnologies

It is common to differentiate between four different conceptual categories, or ‘generations’, of nanotechnologies.²⁷ As outlined in the EPA’s 2007 Nanotechnology White Paper,²⁸ the first generation of nanotechnologies focuses on manufacturing coatings, polymers and more reactive catalysts, among others. A second generation includes nanoparticles for targeted drug delivery systems, adaptive structures and actuators, for example. Both first- and second-generation nanotechnologies are currently in the research, development and/or commercialization stage. Third-generation nanotechnologies, which may not be ready for commercial use for another decade, include novel robotic devices, three-dimensional networks and guided assemblies. Even further into the future are fourth-generation nanotechnologies that may result in molecule-by-molecule design and self-assembly capabilities. While first-generation nanotechnologies have mostly led to so-called passive nanostructures, second-, third- and fourth-generation nanotechnologies will lead to nanostructures that may perform an ‘active’ function. In this report, we focus on first-generation nanomaterials. Two papers commissioned for this project examine the regulatory challenges of future generations of nanotechnologies.²⁹

2.3 Commercial and economic dimensions

It is difficult to predict precisely how nanotechnology will develop owing to the diversity of potential commercial pathways and the complexity of the nanotechnology value chain. However, the commercial promise of nanotechnology is beyond doubt: increasing economic value of nanotechnologies in different market sectors, proliferation of innovations, as reflected in patent filings, and expanding investment in research by both private companies and national governments all suggest that nanotechnology is to assume an ever-expanding role in industrial society.

The growth of commercial products incorporating nanotechnology is difficult to measure, with projections for the future growth of commercial applications of nanotechnology ranging from \$1 trillion to \$3.1 trillion by 2015.³⁰ Because nanotechnologies are enabling technologies, such estimates do not always distinguish clearly enough between the more limited value-added of nanotechnologies and the larger face-value of products that ‘contain’ nanotechnology product.³¹

An inventory³² of consumer products containing nanomaterials, maintained by the Project on Emerging Nanotechnologies (PEN) at the Woodrow Wilson International Center of Scholars, lists over 1,000 nano-enabled products that are currently on the market in 21 different countries. The vast majority of these products appear in

24 Nanoscale Science Engineering and Technology Subcommittee (2004). While 100 nanometres is a commonly used cut-off point for defining nanomaterials, it is important to note that from a regulatory point of view it is the unique chemical and physical properties of nanomaterials that are of primary interest, and that these properties extend to materials above 100 nanometres, in some cases up to 300 nanometres.

25 See also the definition of nanotechnology in the American Society for Testing and Materials’ ‘Standard Terminology Relating to Nanotechnologies’, available at <http://www.astm.org/Standards/E2456.htm> (accessed 5 July 2009).

26 For terminology and definitions of nano-objects, see ISO (2008). A further distinction can be made between naturally occurring nanomaterials and (deliberately) manufactured nanomaterials. The latter are of primary concern in the context of this report. Another distinction can be made between transitive and non-transitive nanomaterials, with the former exhibiting ‘size-related intensive properties that differ significantly from that observed in fine particles or bulk materials’ while the latter do not. When using the term ‘nanomaterials’, this report implicitly refers to deliberately manufactured transitive nanomaterials.

27 Roco (2004).

28 EPA (2007a).

29 Davies (2009); Rodemeyer (2009).

30 Roco and Bainbridge (2001: 3); Lux Research (2008).

31 See, for example, Michel Berger (2007), ‘Debunking the trillion dollar nanotechnology market size hype’, available at <http://www.nanowerk.com/spotlight/spotid=1792.php> (accessed 5 July 2009).

32 Available at <http://www.nanotechproject.org/inventories/consumer/> (accessed 5 July 2009).

the cosmetics, clothing, personal care, sporting goods, sunscreens and filtration sectors and are available primarily on the US market, with East Asia and Europe following in second and third place. The materials most frequently mentioned as being contained in products are nanoscale silver, carbon, titanium, silicon, zinc and gold. While the PEN inventory relies on self-identified products and may thus potentially overstate (but also understate) the true degree of commercialization of 'nanoproducts', it is indicative of the wide range of commercial applications of nanotechnologies in consumer products.³³

Nanosciences and nanotechnologies have wide-ranging and ever-expanding commercial applications. Existing products deriving added value from nanotechnologies include cars, clothing, airplanes, computers, consumer electronics devices, pharmaceuticals, processed food, plastic containers, appliances and other products.³⁴ This diversity of commercialization has led some to consider nanotechnology a 'general purpose' or 'platform' technology like biotechnology and the Internet.³⁵

Nanosciences and nanotechnologies will thus drive the development of a broad array of products and industries in various industry sectors ranging from manufacturing and materials to electronics and IT, and healthcare and life sciences. For instance, between 2004 and 2006 the value of manufactured goods and materials incorporating nanomaterials expanded from \$13 billion to \$50 billion, and in 2006, \$1.5 billion worth of nano-enabled drugs were sold. Market research estimates suggest that by 2014 as much as 4% of total manufacturing and materials sector output may incorporate nanotechnologies, and 50% of manufactured output in electronics and IT and 16% of manufactured goods in healthcare and life sciences may be nano-enabled.³⁶

The growing importance of nanotechnologies can also be seen from the proliferation of scientific discoveries at the nanoscale and the associated explosion of patent filings. Between 1985 and 2005, the number of nanotechnology patents issued by the US Patent and Trademark Office (USPTO) increased from 125 to 4,995 at a compound annual growth rate of 20%. As of 2005, USPTO also had a backlog of 2,714 published applications.³⁷ According to research supported by the US National Science Foundation, in 2006 alone the USPTO published 1,156 nanotechnology patents. That same year, the European Patent Office (EPO) published 679 patents.³⁸

Governments play a big part in promoting the research and development of nanotechnologies. In fiscal year 2009 the US plans to invest \$1.5 billion in nanotechnologies-related research and development, in addition to independent funding by states.³⁹ The budget proposal for 2010 provides \$1.64 billion to the National Nanotechnology Initiative, which would increase the cumulative investment in the NNI since its inception in 2001 to nearly \$12 billion.⁴⁰ Under its Seventh Framework Programme (FP7), the European Union plans to fund nanotechnology-related projects worth a total of €3.5 billion between 2007 and 2013, a near threefold increase in funding over the 2002 to 2006 period,⁴¹ in addition to the funding provided by EU Member States. Total global public and private funding for nanotechnology-related research and development is estimated to have amounted to \$13.9 billion in 2007 alone.⁴²

2.4 Environment, health and safety (EHS) risks: scientific knowledge and uncertainty

With the commercialization of first-generation products of nanotechnologies proceeding at an ever-increasing pace, a gap has emerged between the development of nanotechnologies and our understanding of how nanomaterials interact with the environment and human health. Research into the EHS risks of nanomaterials is being stepped up, but there is a growing recognition that, as Klein notes, 'our understanding of the interaction of nanoscale objects with living matter, even at the level of single cells, has not kept pace with the explosive development of nanoscience in the past decades'.⁴³

33 Analyses of the impact of nanotechnologies in different economic sectors are carried out by a range of private analysis and consulting enterprises including, for example, Lux Research and Cientifica. The EU-funded ObservatoryNANO (available at <http://www.observatory-nano.eu/project/>, accessed 5 July 2009) currently tracks scientific and technological trends in nanosciences and nanotechnologies and analyses 'economic realities'. In the interim review of its Nanoscale Materials Stewardship Program, the EPA identified 'over 200 existing chemicals that are produced at the nanoscale for commercial and R&D purposes, of which 91 are likely to be manufactured for commercial purposes' (EPA 2009a: 18).

34 Lux Research (2008: 9).

35 Klein (2007); Lane and Kalil (2005).

36 Lux Research (2008).

37 Owing to delays driven by the difficulty of assessing developments in novel technologies, the time it takes for USPTO to reach a decision has increased from an average of 33 months in 1985 to 47 months in 2005 (Lux Research 2008).

38 Chen et al. (2008).

39 President's Council of Advisors on Science and Technology (2008).

40 http://www.nano.gov/NNI_2010_budget_supplement.pdf.

41 See http://cordis.europa.eu/fp7/cooperation/nanotechnology_en.html (accessed 5 July 2009).

42 President's Council of Advisors on Science and Technology (2008).

43 Klein (2007).

A central problem in establishing whether nanomaterials pose a risk is that they may react differently to the equivalent material in bulk form.⁴⁴ A workshop on predicting nano-biointeractions organized by the International Council on Nanotechnology (ICON), for instance, found that ‘because nanoparticles change as they interact with living systems, it is unlikely that their physicochemical properties at any one stage in the life cycle alone will predict biological behaviour’.⁴⁵ Moreover, ‘when a nanoparticle is put into a biological fluid or the environment, it becomes coated with bio-molecules in a complex and dynamic matter that is not well understood’.⁴⁶ Existing approaches to researching EHS risks may thus not be sufficiently robust for establishing the safety of nanomaterials.

The potential risks associated with certain nanomaterials may depend on their chemical composition, their state of aggregation and agglomeration, the number of particles per unit mass, their physical form, the median size and size distribution, their surface area and surface charge, their solubility or miscibility, their state of dissolution, and their partition coefficient.⁴⁷ All these qualities are to be taken into account when categorizing and evaluating nanomaterials for potential (eco)toxicity.

Early results of research into EHS risks suggests that the safety of all nanomaterials cannot be taken for granted. Two recent studies by Takagi et al. (2008) and by Poland et al. (2008), for example, have indicated that some forms of multiwalled carbon nano-tubes (MWCNTs) have the potential to cause mesothelioma in the linings of the lungs if they are inhaled and can migrate to the edge of the lungs. Further life-cycle analysis is needed to establish likely exposure levels of such materials, from factory workers to consumers and the environment. In the light of the first findings of such EHS risks, scientists have called for the development of better and more adequate testing methods.⁴⁸ Conventional toxicological methods are seen by some as too slow, too expensive, and not able to accurately capture all risks presented by new nanomaterial properties.⁴⁹

Developing alternative research and testing methods for EHS risks of nanomaterials is complicated, however, by the multitude of nanotechnology applications, properties expressed, routes of exposure, and means of disposal. Case-by-case risk assessment of specific materials and their use patterns is needed. As Maynard notes, ‘nanotechnology more closely represents a way of thinking or doing things [...] than a discrete technology’, which ‘makes it particularly difficult to discuss potential risks in general terms’.⁵⁰

In addition, the ongoing expansion of nanoscience and nanotechnologies is likely to produce novel nanostructures that may cause currently unknown forms of hazard. This is likely to further complicate the search for adequate risk regulation approaches, as the US EPA has noted:

*The convergence of nanotechnology with biotechnology and with information and cognitive technologies may provide such dramatically different technology products that the manufacture, use and recycling/disposal of these novel products, as well as the development of policies and regulations to protect human health and the environment, may prove to be a daunting task.*⁵¹

2.5 Key regulatory issues and challenges

Regulators face a number of challenges in dealing with the potential risks of nanomaterials. These challenges are related to a series of uncertainties, with regard to the development and commercial application of nanomaterials, hazards and exposure pathways, the direction and speed of technological change, and the suitability and effectiveness of existing regulation frameworks. Understanding these uncertainties and reacting effectively and proportionally is a key imperative for regulators and policy-makers as much as for industry and civil society.

2.5.1 Rapid technological change

To date, nanotechnology developments have mostly focused on passive nanomaterials. But the US Environmental Protection Agency is not alone in predicting that future developments will include active nanomaterials and will converge with other technologies such as information, bio- and cognitive technologies.⁵² These second-, third- and future-generation nanomaterials will develop in a way that is difficult to foresee. Regulators will need to monitor

44 Service (2008).

45 Workshop at http://cohesion.rice.edu/CentersAndInst/ICON/emplibrary/ICON_RNA_Report_Full2.pdf. International Council on Nanotechnology 2008, p. 7.

46 Ibid., p. 8.

47 ICON (2008).

48 See, for example, SCENIHR (2009).

49 Service (2008).

50 Maynard (2008: 3); Youtie et al. (2008).

51 Ibid.

52 See EPA (2007a).

these developments and react flexibly to newly emerging risks. They will need to constantly expand their knowledge base, covering multiple areas of scientific and engineering inquiry, and develop flexible responses to a constantly changing technological environment.

How much funding and time will be required to test the nanomaterials flowing into the marketplace? Neither the OECD nor national regulatory bodies have provided public estimates but a recent study indicated that assessing the risks of 190 nanomaterials now in production would require an investment of \$249 million (assuming optimistic assumptions about hazards).⁵³ The use of tiered testing strategies could reduce this sum and the current low production volumes of some materials may reduce the need to test at all. But the risk assessment challenge is likely to increase in complexity and cost as more materials enter the market and, importantly, as second- and third-generation nanotechnology products and materials enter commercial production.

2.5.2 Uncertainty of commercialization paths

While the number of existing commercial products using nanomaterials keeps growing, uncertainty exists regarding future commercialization paths. Nanotechnologies allow for a broad range of product and process innovations without regard to sectoral boundaries. As the range of commercial applications expands, governments will have to address potential risks of nanomaterials in diverse regulatory contexts covering different industries and commercial applications, also involving 'borderline products' that cross different regulatory contexts (e.g. cosmetic products with medicinal effects). This need not be a problem in itself but may add to existing uncertainty about the regulatory coverage of emerging nanomaterials risks.

2.5.3 Uncertainty regarding nanomaterials risks

A lack of data on hazards and exposure pathways of certain nanomaterials, combined with uncertainty about the applicability of some existing testing methods, is a widely recognized impediment to the effective implementation of regulations. Risk regulation under conditions of uncertainty is, of course, not uncommon in areas such as chemical and food safety. Given the significant knowledge gaps on EHS risks of certain nanomaterials, however, it is too early to establish whether existing regulatory frameworks can and will be effective in the face of potential risks. Governments in various countries are currently engaged in more systematic efforts to promote research into EHS risks and the further development of testing methods, but given rapidly evolving nanotechnology research and commercialization, such efforts pose a continuous challenge.

2.5.4 Uncertainty regarding the suitability of regulatory frameworks

Analysts have debated for some years whether current laws provide adequate oversight for certain applications of nanotechnologies or whether new legislative instruments are needed.⁵⁴ US and EU regulatory agencies suggest that the existing regulatory framework, consisting of a range of laws and regulations, is broadly sufficient to deal with potential risks associated with nanomaterials, and that only small adjustments or amendments may be needed to regulations and implementation guidelines, in order to close any potential gaps.⁵⁵ This, however, remains a matter of debate; we discuss these matters below in chapters 4, 5 and 6, where we point to independent analyses that raise questions about how well existing statutes and regulations address potential risks. It is important to note that much of this depends on how they are implemented. Adequate guidance for implementation and the provision of the necessary resources for regulatory oversight thus become critical factors in developing effective regulatory responses. Uncertainty regarding the regulatory capacity of existing institutions in this area cannot be ruled out, not least because of the novel nature of nanomaterials risks and the limited experiences that regulatory agencies have been able to develop in this area.

2.5.5 Uncertainty regarding regulatory and scientific resources

One area that is a recurring theme in debates on regulatory capacity is the question of resources for the implementation of risk regulation frameworks. The challenges that novel technologies such as nanotechnology present require significant investment in human resources. Statutes are a necessary but insufficient condition for success if the regulators lack enforcement capacity, scientific expertise and foresight. It is too early to say whether regulatory institutions on both sides of the Atlantic have sufficient scientific capacity to deal with the manifold challenges of regulating nanomaterials. What is clear, however, is that the public sector will increasingly have to compete with industry for talent in these emerging technology areas. The search for talent, particularly in the scientific area, thus needs to become a strategic priority, just as it is already in industry.

53 Choi et al. (2009).

54 See, for example, the American Bar Association's Section Nanotechnology Project, which has produced a series of studies of different regulatory contexts (at: <http://www.abanet.org/enviro/nanotech/>). See also Davies (2006); Environmental Defense Fund (2006); and Taylor (2006).

55 For example, see FDA (2007a) and European Commission (2008a) and the respective Staff Working Paper, available at [http://www.euractiv.com/29/images/SEC\(2008\)%202036_tcm29-173474.pdf](http://www.euractiv.com/29/images/SEC(2008)%202036_tcm29-173474.pdf) (accessed 5 July 2009).

As this brief discussion suggests, the emergence of nanotechnologies creates a number of challenges to regulators and policy-makers. Before we investigate these in greater detail with regard to the specific areas of chemicals, food and cosmetics regulation, the next chapter provides a brief background overview of the broader contours of emerging regulatory frameworks for nanomaterials, in the US and EU as well as at the international level.

3 Relevant National and International Institutions and Regulatory Frameworks

The emergence of nanotechnologies poses important challenges to regulatory oversight entities in both the United States and the European Union. Governments on both sides of the Atlantic have taken steps to apply their existing regulatory frameworks in the light of these challenges. This chapter provides an overview of the key US and EU agencies and institutions, and the relevant legal authorities they implement. As chapters 4 to 6 discuss in detail regulatory frameworks for applications of nanotechnologies in the chemical, food and cosmetics sectors, the discussion below will be for the most part limited to those regulations and institutions that are not discussed in later chapters. It then briefly outlines the key intergovernmental and private international initiatives. The summary below of institutions and regulatory frameworks is limited to the United States and the EU and thus does not include the many important initiatives and bodies elsewhere, most notably in Japan, Canada and Australia. Interested readers may consult a collection of documents, published by the OECD, that provides a good overview of the relevant regulatory activities in those and other countries.⁵⁶

3.1 The United States

3.1.1 *The US regulatory system*

The United States is a federal system in which the states hold plenary authority over all matters not expressly granted to the federal government by the constitution. In matters within its purview, however, the federal government has supremacy over the states and can pre-empt their regulatory authority.

The federal government is composed of three independent branches: the legislative, executive and judicial. The legislative branch, Congress, enacts laws. Before they go into effect, laws must be signed by the president, who heads the executive branch. Laws are administered by agencies, which are under the president's control, are part of the executive, and can be created by law or executive order. Agencies fulfil their statutory duty to administer laws by promulgating regulations and other guidance that define specifically how the agency will interpret and enforce the law. Most environmental laws describe how they are to be implemented and enforced by assigning responsibility to one or more executive agencies. Agencies propose and adopt regulations independently, but they cannot exceed their statutory mandate and must follow process requirements, established by laws such as the Administrative Procedure Act, that require them to follow certain processes such as allowing public participation and petitions for rulemaking. Plaintiffs can challenge both laws and regulations in the third branch of government – the judiciary. Laws and regulations subject to judicial review can be overturned if they are unconstitutional or otherwise unlawful.

While state and local governments may be important actors in nanotechnology regulation, the federal government has long maintained primary responsibility for regulating the environment and public health. Nonetheless, the federal and state governments commonly work cooperatively to implement national environmental laws, with federal agencies delegating responsibilities to their state counterparts if the state meets standards set in the specific law. Although formalized 'cooperative federalism' is less common outside environmental law, state and federal agencies often work together closely in this area. State governments have often enacted laws analogous to existing federal programmes, even in the absence of formal agreement. States also may enact their own environmental laws in the absence of federal legislation, where there are gaps in federal law, or in areas that are outside the scope of federal power, such as general protection of public health and welfare. The state of California recently requested that manufacturers of carbon nanotubes provide the state agency that regulates toxic substances with information regarding analytical test methods, fate and transport in the environment, and other relevant information.⁵⁷

56 OECD, Publications in the Series on the Safety of Manufactured Nanomaterials, http://www.oecd.org/document/53/0,3343,en_2649_37015404_37760309_1_1_1_1,00.html (accessed 5 July 2009).

57 California Department of Toxic Substances, Nanocallin, http://www.dtsc.ca.gov/TechnologyDevelopment/Nanotechnology/nanocallin.cfm#Carbon_Nanotubes (accessed 27 July 2009).

3.1.2 Key federal entities and regulations

In practice, federal agencies have been the primary entities working to address the implications of nanotechnology environment, health and safety risks in the United States. Several agencies have statutory responsibility or discretionary authority to regulate environmental, health and safety aspects of nanotechnologies. These agencies' legal authorities, resources and regulatory strategies vary considerably, as do their nanotechnology-related regulatory activity to date. Key agencies include the:

- Environmental Protection Agency;
- Food and Drug Administration;
- Consumer Product Safety Commission;
- Occupational Safety and Health Administration; and
- Department of Agriculture.

In addition to the agencies discussed below, many other federal agencies and entities, such as the Department of Energy and the Department of Defense, are engaged in research and development activities related to nanoscience and nanotechnologies. For the most part, these agencies do not regulate, but conduct research on nanotechnologies. In total, thirteen federal agencies have research and development budgets, but a small portion of each of these budgets is allocated to EHS research.

The Environmental Protection Agency (EPA) was established in 1970 and now has 17,000 employees who administer a multitude of laws intended to protect the environment. Its activities include promulgating and enforcing regulations, distributing grants for research projects, and overseeing and working cooperatively with state and local environmental agencies.

The EPA's EHS nanotechnology regulatory activities to date have focused on chemicals and pesticides.⁵⁸ The EPA also sponsors a related voluntary reporting programme, the Nanoscale Materials Stewardship Program (NMSP).⁵⁹ The EPA administers US chemical regulation under the Toxic Substances Control Act (TSCA) and regulates pesticides under the Federal Insecticide, Fungicide and Rodenticide Act (FIFRA). The EPA is also responsible for many other statutes, including, but not limited to, the Clean Water Act (CWA), the Clean Air Act (CAA),⁶⁰ the Resource Conservation Recovery Act (RCRA) and the Comprehensive Environmental Response, Compensation and Liability Act (CERCLA or Superfund, governing polluted site clean-up). Several independent analyses of the applicability of these latter statutes to nanomaterials highlight aspects of the laws that can be applied to nanomaterials and make suggestions on how they may need to be amended to apply more effectively in the nano context.⁶¹

In some cases, federal environmental regulatory programmes under these statutes may be delegated to the states if they meet requirements specified in the statutes.⁶² Accordingly, states may regulate nanotechnology under such delegated programmes in the future, although no action of this nature has been taken to date. Not all programmes, however, can be delegated to the states. For example, TSCA is one of the few federal environmental statutes that do not authorize the EPA to do so.⁶³ In addition, FIFRA authorizes states to regulate the sale and use of federally registered pesticides, but only if the state regulations are at least as restrictive as federal standards. Furthermore, states may not impose labelling or packaging requirements in addition to, or that are different from, FIFRA requirements.⁶⁴

The Food and Drug Administration (FDA) was established in 1906 to protect the public from adulterated and misbranded foods and drugs. Today, it has about 14,000 employees⁶⁵ and regulates a diverse array of products, including prescription and over-the-counter drugs, medical devices, food, food additives and packaging, dietary supplements and cosmetics. The FDA's authorities are drawn from the Federal Food, Drug, and Cosmetic Act (FFDCA) and Public Health

58 In addition to its regulatory activities, the EPA also conducts a wide range of nanotech-related research, including investigation of the use of nanoscale materials for environmental remediation. See EPA (2007a).

59 See US EPA, Nanoscale Material Stewardship Program, <http://www.epa.gov/oppt/nano/stewardship.htm>, for information on the NMSP (accessed 30 July 2009); see generally NMSP, Office of Pollution Prevention and Toxics, US EPA – EPA (2009a), for a report on voluntary information submission under the NMSP (accessed 30 July 2009).

60 EPA stated in its Nanotechnology White Paper that it had 'received and is reviewing an application for registration of a diesel additive containing cerium oxide. Cerium oxide nanoparticles are being marketed in Europe as on- and off-road diesel fuel additives to decrease emissions and some manufacturers are claiming fuel economy benefits.' EPA (2007a).

61 See generally Breggin and Pendergrass (2007), for a discussion of the use of RCRA and CERCLA; American Bar Association, Section of Environment, Energy, and Resources, 'Section Nanotechnology Project,' <http://www.abanet.org/enviro/nanotech/> (accessed 5 July 2009) (analysing the application of US environmental laws to nanotechnologies); Environmental Defense Fund (2006).

62 The Clean Water Act, Clean Air Act, and Resource Conservation and Recovery Act all allow the EPA to delegate authority to the states. 33 U.S.C. § 1342(b); 42 U.S.C. § 7410; and 42 U.S.C. § 6926(b).

63 But see 15 U.S.C. § 2617 (addressing pre-emption of state law).

64 7 U.S.C. § 136(v).

65 US OIG (2006) (noting that at the end of 2003, the FDA employed 13,973 individuals).

Service Act (PHSA). The agency's precise legal authorities differ by product category and may include both pre-market approval of new products, including drugs, devices, food additives and food packaging, and ongoing, post-market review of products sold to consumers, such as cosmetics, foods, food ingredients 'generally recognized as safe' (GRAS) and dietary supplements. In 2006, the FDA created a Nanotechnology Task Force to determine regulatory approaches for FDA-regulated products that use 'nanotechnology materials'. The Task Force finalized its report in 2007.⁶⁶

The Consumer Product Safety Commission (CPSC), which has fewer than 400 employees, was created in 1972 to protect the public 'against unreasonable risks of injury associated with consumer products'.⁶⁷ Under the Consumer Product Safety Act (CPSA), the Federal Hazardous Substances Act (FHSA), the Poison Prevention Packaging Act (PPPA), and the recently enacted Consumer Product Safety Improvement Act, the CPSC has regulatory jurisdiction over thousands of consumer products⁶⁸ in and around the home, ranging from electronic devices to appliances, but has no pre-market review authority. The CPSC can create standards for product safety and, in collaboration with producers, can issue recalls of products that are unsafe. Manufacturers under CPSA are obligated to report immediately on products that fail to meet safety standards, contain defects or create 'an unreasonable risk of serious injury or death'.⁶⁹ One estimate suggested that about 300 products related to nanotechnologies already fall under the CPSC's jurisdiction, and that this number is likely to rise in the future.⁷⁰ To date, the CPSC has not taken any regulatory actions with respect to nanomaterials in consumer products.⁷¹ In a 'Nanomaterial Statement' issued in October 2005, the CPSC asserted that its approach to nanotechnology products would be essentially the same as its review of other products.⁷²

The Occupational Safety and Health Administration (OSHA), part of the Department of Labor, was created in 1971 to administer the Occupational Safety and Health Act (OSH Act). With 2,150 employees, it is responsible for promulgating and enforcing safety and health regulations covering the workplace. The OSH Act was enacted to ensure safe and healthful working conditions for working men and women.⁷³ The Act requires each employer to provide a place of employment and working conditions that are free of recognized hazards that are causing or are likely to cause death or serious injury to employees. Employers are also required to comply with all standards set under the Act, while employees are required to comply with all standards that apply to their actions.⁷⁴ The OSHA promulgates standards and enforces the Act. The OSHA is authorized to set exposure limits for toxic materials at levels that adequately ensure, to the extent feasible, that 'no employee will suffer material impairment of health or functional capacity even if such employee has regular exposure to the hazard ... for the period of his working life'.⁷⁵ The OSHA has not clarified its approach to regulation of nanomaterials under the OSH Act.⁷⁶

The OSHA is assisted in its responsibilities by the National Institute for Occupational Safety and Health (NIOSH), part of the Center for Disease Control and Prevention (CDC). Also created by the OSH Act, the NIOSH carries out scientific research and 'makes recommendations for the prevention of work-related injury and illness'.⁷⁷ It has a programme to study nano-bio interactions related to workplace health and safety, as well as several additional initiatives. It has published a range of studies on the occupational health implications of nanomaterials.⁷⁸

The Department of Agriculture (USDA) implements a broad array of laws related to agriculture. Since its creation in 1862, its authority has expanded significantly and now includes forestry, animal husbandry, crop production, agricultural research and education, among other areas. From a nanotechnology perspective, the department's key authorities are related to food safety, but mainly pertain to administration of other agencies' standards and research rather than active policy-making. The USDA's Food Safety and Inspection Service (FSIS) monitors agricultural products for animal drug and pesticide residues, and the Cooperative State Research, Education, and Extension Service (CSREES) conducts some nanotechnology EHS research in the area of food and feed safety. One area where

66 See discussion of FDA nano-specific regulation in chapter 4.

67 15 U.S.C. § 2051(a)(3); *Ibid.* at § 2053(a)(establishing the Commission).

68 *Ibid.* at § 2052(a)(1)(defining 'consumer product').

69 *Ibid.* at § 2064(b).

70 Felcher (2008).

71 CPSC Commissioner Thomas H. Moore stated that 'I do not pretend to understand nanotechnology and our agency does not pretend to have a grasp on this complicated subject either'. Statement Before the Subcomm. on Consumer Affairs, Insurance, and Automotive Safety of the S. Comm. on Commerce, Science, and Transportation (2007), available at <http://www.cpsc.gov/pr/moore2007.pdf> (accessed 5 July 2009).

72 The US Consumer Product Safety Commission, CPSC Nanomaterials Statement, <http://www.cpsc.gov/library/cpscnanostatement.pdf> (accessed 29 July 2009).

73 29 U.S.C. § 651(b).

74 *Ibid.* at § 654.

75 *Ibid.* at § 655(b)(5).

76 Davies (2008).

77 National Institute for Occupational Safety and Health, NIOSH Topic: Nanotechnology, <http://www.cdc.gov/niosh/topics/nanotech/default.html> (accessed 5 July 2009).

78 *Ibid.*

the department makes policy is in standards for organic food. The National Organic Standards Board discussed nanotechnology in organic food at its meeting from 4 to 6 May 2009.⁷⁹

In addition to work by its regulatory agencies, the American government and NGOs have developed initiatives targeted at support, development and coordination of nanotechnology research, including:

- the National Nanotechnology Initiative;
- the National Institute of Standards and Technology;
- the American National Standards Institute;
- ASTM International.

The National Nanotechnology Initiative (NNI), created by President Bush as a 2001 budget initiative, is an important institution for coordination of nanotechnology research on the federal level. The Nanoscale Science, Engineering, and Technology Subcommittee (NSET) of the National Science and Technology Council (NSTC) is responsible for overseeing the NNI. The council was established by executive order in 1993 and is made up of cabinet-level departmental heads who coordinate interagency science and technology policy.

The NNI's goal is to coordinate federal research and development by 'serving as a central locus for communication, cooperation, and collaboration for all Federal agencies that wish to participate'.⁸⁰ Twenty-five government departments and agencies participate in the NNI, 13 with individual nanotechnology research and development budgets, including the Departments of Defense, Energy and Homeland Security, the National Science Foundation, the National Institutes of Health, the NIST and the NIOSH among others. Only a small portion of these budgets are allocated to EHS research. Furthermore, the NNI's budget is the collective sum of each agency's nanotechnology budget; the NNI itself does not fund research. Instead, the NNI and NSET accomplish their goals by preparing and publishing federal budget supplements and research strategies, among other activities. The NNI released its strategy for nanotechnology-related EHS research in February 2008.⁸¹

The National Institute of Standards and Technology (NIST) is a federal agency within the Department of Commerce. Its mission is 'to promote US innovation and industrial competitiveness by advancing measurement science, standards, and technology in ways that enhance economic security and improve our quality of life'.⁸² As a result it has several important roles in nanotechnology. Its laboratories conduct research on nanotechnology and its Center for Nanoscale Science and Technology provides measurement methods, instrumentation and standards to support all phases of nanotechnology development, from discovery to production. Its research covers characterization and metrology of nanomaterials. The NIST also promotes US standards, tests and calibration data to facilitate the marketing of American products internationally.

The American National Standards Institute (ANSI) is an NGO that coordinates voluntary standards activities in the United States and manages American participation in the ISO and the International Electrotechnical Commission (IEC). It also approves standards as American National Standards. It has formed a Nanotechnology Standards Panel that works with other groups to develop standards, including the ISO's and IEC's Technical Committees dealing with nanotechnology. The ANSI-Nanotechnology Panel has focused in particular on terminology and nomenclature.

ASTM International is an NGO founded in 1898 which establishes consensus-based standards. Originally known as the American Society for Testing and Materials, it has been involved at the national and international levels in establishing standards for, among others, terminology related to nanotechnology, testing and handling of engineered nanoscale particles, and practices for measuring nanoparticles. Committee E56 on Nanotechnology addresses standards and guidance materials related to nanotechnology and nanomaterials and has four technical subcommittees.⁸³

3.2 The European Union

3.2.1 Key European entities and regulations

The European Union is a supranational entity that is neither a nation-state nor an international organization.⁸⁴ Its

79 US Dept. of Agriculture, Agriculture Marketing Service, NOSB May 2009 Agenda, <http://www.ams.usda.gov/AMSv1.0/ams.fetchTemplateData.do?s tartIndex=2&&template=TemplateN&navID=NationalOrganicProgram&leftNav=NationalOrganicProgram&page=May2009Agenda&description=NOSB%20May%202009%20Agenda&acct=nosb> (accessed 24 July 2009).

80 See National Nanotechnology Initiative (2009).

81 See National Technology Initiative (2008).

82 See NIST (2009).

83 ASTM International has published a range of standards. ASTM International, Published Standards Under E56 Jurisdiction, <http://www.astm.org/COMMIT/SUBCOMMIT/E56.htm> (accessed 5 July 2009).

84 The 1992 Maastricht Treaty established the European Union (EU) as a separate entity, with the European Community (EC) as the first pillar dealing with economic, social and environmental policies (including the regulatory framework for nanomaterials). For convenience, we refer to the EU instead of the EC throughout the report.

rule-setting and decision-making powers are shared between the European Commission, the Council of the European Union ('the Council') and the European Parliament. Although these three institutions have legislative and executive powers in certain areas, they do not add up to a 'government' in the conventional sense, and their respective powers cannot easily be compared to those of equivalent legislative or executive institutions within nation-states.

All three EU institutions are involved in creating laws and regulations that are relevant for nanomaterials. The European Commission develops proposals for laws and policies, which must be agreed by the Council, representing the Member States, and involving the Parliament in a complex form of interaction. The Commission is the main executive organ of the EU and oversees the implementation of European law. The main legal and regulatory instruments of the EU are:

- *Regulations*: binding legal acts that are directly applicable in each Member State;
- *Directives*: binding policy objectives for Member States that still leave room for Member States in designing implementation;
- *Decisions*: legally binding for specific contexts, but not generally applicable to all Member States;
- *Recommendations and Opinions*: non-binding but may prepare legislation in Member States;
- *Communications*: preliminary documents that may be followed by proposals for legislation.⁸⁵

The Commission is divided into various Directorates General (DGs), roughly equivalent to national ministries, that prepare proposals for regulations in their respective field of competence. The Commission works closely with representatives of the Member States and various stakeholders through a system of working groups and committees. In the field of nanotechnologies, nanosciences and nanomaterials, the Commission's Interservice Group on Nanotechnology supports the implementation of the measures set out for the Commission in an action plan for nanosciences and nanotechnologies in Europe for 2005–09.⁸⁶

Implementation of EU law is largely the responsibility of Member States, in coordination with EU institutions. The EU has created specific regulatory agencies that inform, coordinate, supplement or replace the work of national agencies. The level of centralization of the regulatory authority in the hands of the EU varies considerably. EU institutions play a stronger role in the oversight of chemical and food safety, for instance, whereas Member States play a larger role in the areas of worker safety and environmental protection.

The key EU institutions and bodies addressing manufactured nanomaterials are:

- DG Health and Consumers (SANCO);
- DG Environment (ENV);
- DG Enterprise and Industry (ENTR);
- DG Employment (EMPL);
- DG Information Technologies (INFOS);
- DG Research (RTD);
- DG External Relations (RELEX);
- the European Chemicals Agency (ECHA);
- the European Food Safety Authority (EFSA);
- the European Medicines Agency (EMA);
- the European Agency for Safety and Health at Work (EU-OSHA).

The European Chemicals Agency (ECHA), located in Helsinki, Finland, started work in mid-2007. It manages the Registration, Evaluation, Authorization, and Restriction of Chemical Substances (REACH) Regulation as well as the recently introduced Classification, Labelling, and Packaging (CLP) Regulation (1272/2008/EC). Insofar as REACH and CLP cover applications of nanotechnologies, the ECHA is responsible for managing their registration and notification, and shares responsibility with the Member States and the Commission for evaluation, authorization and restriction of nanoscale substances.

85 Treaty establishing the European Economic Community (EEC), Rome, 25 March 1957, Article 189. The citation of regulations includes the provenance (Council, Parliament and/or Commission), the relevant institutional treaty (EEC, EC etc.), the legislation number and the enactment date. The REACH Regulation would thus be properly cited as 'Regulation (EC) No. 1907/2006 of the European Parliament and of the Council'. The notation for Directives puts the date of enactment first, followed by legislation number and treaty. The Cosmetics Directive would thus be notated as 'Council Directive 76/768/EEC'. The Treaty of Maastricht, which established the European Union in 1992, contains reference to a principle of subsidiarity that requires the EU to act in areas outside its exclusive competence only when adequate action of a lesser entity (i.e. national, regional or local level) is less effective. Treaty on European Union, *Official Journal* C 191, 29 July 1992, art. G, art. 3b, available at <http://eur-lex.europa.eu/en/treaties/dat/11992M/htm/11992M.html> (accessed 27 July 2009).

86 European Commission (2005).

The European Food Safety Authority (EFSA), set up in 2002 and based in Parma, Italy, provides independent scientific advice and risk assessment on food and feed safety, nutrition, animal welfare and plant protection. It was established by Regulation EC/178/2002, which also outlines the general principles of food law and lays out food safety procedures. In February 2009, the EFSA published an opinion on 'potential risks arising from nanoscience and nanotechnologies on food and feed safety'.⁸⁷ In January 2008, the Commission, in a Proposal for a revised Novel Foods Regulation (COM(2007) 872), proposed to give more authority to the EFSA with regard to risk assessment and risk management for nanotechnologies in the food area.

The European Medicines Agency (EMA) is located in London, United Kingdom, and was established in 1995 to carry out the scientific evaluation of medicinal products that are to be marketed across the European Union, among other responsibilities. All medicinal products derived from biotechnology or other 'high technology processes' must go through its centralized procedure of scientific evaluation. It has established a 'nano group' that meets with applicants to 'discuss informally about bottlenecks in the development of nanomedicinal products, and explore possible scientific and regulatory solutions'.⁸⁸

The European Environment Agency (EEA) in Copenhagen, Denmark, and the European Agency for Safety and Health at Work (EU-OSHA) in Bilbao, Spain, mostly inform, coordinate, and monitor current national and European regulatory efforts in their respective areas of work. Their EU-wide authority is more limited than that of the ECHA and EFSA.

Most of the relevant EU regulatory frameworks are implemented at the level of Member States. In addition to regulatory frameworks discussed in chapters 4 to 6, relevant regulations for applications of nanotechnologies may include the:

- Worker Protection Framework Directive (89/391/EEC);⁸⁹
- Plant Protection Product Directive (91/414/EEC);
- Biocidal Product Directive (98/8/EC);
- General Product Safety Directive (2001/95/EC);⁹⁰
- Marking Directive (93/68/EEC);
- Unfair Commercial Practices Directive (2005/29/EC);
- Medical Devices Directive (93/42/EEC);
- Active Implantable Medical Devices Directive (90/385/EEC);
- In Vitro Diagnostic Directive (89/97/EC);⁹¹
- Integrated Pollution, Prevention, and Control Directive (96/61/EC and 2008/1/EC);
- Water Framework Directive (2000/60/EC);
- Air Quality Directive (96/62/EC);
- Seveso II Directive (96/82/EC);
- Waste Directive (2008/98/EC); and
- Environmental Liability Directive (2004/35/EC).

87 EFSA (2009). For more information on this and other opinions by EFSA, see chapter 5.

88 <http://www.emea.europa.eu/htms/human/mes/emergingtechnologies.htm>. See also EMA (2006).

89 Of particular interest: see Council Directive 89/656/EEC, available at <http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=CELEX:31989L0656:EN:HTML> (accessed 28 July 2009) (personal protective equipment); see Directive 2004/37/EC of the European Parliament and the Council, available at <http://osha.europa.eu/data/legislation/directive.2004-02-07.5735076588> (accessed 28 July 2009) (risks related to exposure to carcinogens and mutagens at work); see Directive 1999/92/EC of the European Parliament and of the Council, available at <http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=CELEX:31999L0092:EN:HTML> (accessed 28 July 2009) (explosive atmospheres); Council Directive 98/24/EC, available at <http://osha.europa.eu/data/legislation/75> (accessed 28 July 2009) (safety and health risks related to chemical agents).

90 Of particular interest: Council Directive 85/374/EEC, available at http://eur-lex.europa.eu/smartapi/cgi/sga_doc?smartapi!celexapi!prod!CELEXnumdoc&lg=EN&numdoc=31985L0374&model=guichett (accessed 28 July 2009), Directive 1999/34/EC of the European Parliament and of the Council, available at http://eur-lex.europa.eu/smartapi/cgi/sga_doc?smartapi!celexapi!prod!CELEXnumdoc&lg=EN&numdoc=31999L0034&model=guichett (accessed 28 July 2009) (producer liability); Council Directive 88/378/EEC, available at <http://ec.europa.eu/enterprise/toys/intlmarket.htm> (accessed 28 July 2009) (toys); Council Directive 76/768/EEC, available at http://ec.europa.eu/enterprise/cosmetics/index_en.htm (accessed 28 July 2009) (cosmetics); Regulation (EC) No 1907/2006 of the European Parliament and of the Council (chemicals); Council Directive 89/686/EEC, available at http://ec.europa.eu/enterprise/mechan_equipment/ppe/index.htm (accessed 28 July 2009) (personal protective equipment); European Commission, Enterprise and Industry, Pharmaceuticals, http://ec.europa.eu/enterprise/pharmaceuticals/eudralex/eudralex_en.htm (accessed 28 July 2009); see European Commission, Recreational Marine Industry: an Overview of European Policies, http://ec.europa.eu/enterprise/maritime/maritime_regulatory/rc_introduction.htm (accessed 28 July 2009) (recreational crafts); Directive 98/37/EC of the European Parliament and of the Council, available at http://ec.europa.eu/enterprise/mechan_equipment/machinery/welcdir.htm (accessed 28 July 2009) (machinery).

91 Medicinal products are regulated by the EU Pharmaceutical Legislation under an extensive body of regulations and directives. See European Commission, Enterprise and Industry, Pharmaceuticals, http://ec.europa.eu/enterprise/pharmaceuticals/eudralex/eudralex_en.htm (accessed 28 July 2009).

We do not discuss these statutes here in detail. Interested readers may consult the European Commission's review of regulatory aspects of nanomaterials, which it published, along with a Staff Working Document, in June 2008. This review evaluates the above and other regulations and directives with regard to their coverage of nanomaterials and concludes that 'current legislation covers to a large extent risks in relation to nanomaterials [...]. However, current legislation may have to be modified in the light of new information becoming available, for example as regards thresholds used in some legislation.'⁹² In February 2008, the Commission also published a code of conduct for responsible research in nanosciences and nanotechnologies in the form of a Recommendation.⁹³

The Scientific Committee on Consumer Safety (SCCS, formerly the Scientific Committee on Consumer Products, SCCP) and the Scientific Committee on Emerging and Newly Identified Health Risks (SCENIHR), both managed by DG Health and Consumers, have formulated opinions on nanotechnology EHS risks.⁹⁴ These opinions followed the Commission's request for advice on specific risk assessment issues. The SCENIHR focused mainly on the appropriateness of existing risk assessment methodologies, while the SCCP addressed the safety of nanomaterials in cosmetic products. The EFSA (with respect to food and feed)⁹⁵ and the EMEA (with respect to medicinal products)⁹⁶ have also published opinions on the specific aspects on the safety assessment of nanomaterials. The Scientific Committee on Occupational Exposure Limits (SCOEL) of chemical agents traditionally has contributed to the preparation of Community measures on occupational exposure limits (OELs).

The European Committee for Standardization (CEN) is a pan-European technical non-profit organization founded in 1961 by national standards bodies in the then European Economic Community (EEC) and European Free Trade Association (EFTA) countries to develop consensus standards. The CEN set up a technical committee (CEN/TC 352) on nanotechnologies in 2005 to develop standards in: (a) classification, terminology and nomenclature, (b) metrology and instrumentation, including specifications for reference materials, (c) test methodologies, (d) modelling and simulation, (e) science-based health, safety and environmental practices, and (f) nanotechnology products and processes. The CEN also participates in the work of the ISO.

The Technical Standards and Regulations Directive (98/34/EC)⁹⁷ defines standards as technical specifications approved by a recognized standardization body for repeated or continuous application, with which compliance is not compulsory and which is an international standard, a European standard or a national standard, adopted respectively by an international standardization organization, a European standardization body and a national standardization body, and made available to the public. Standards can play different roles in regulation, as defined by the legislator, such as creating a presumption of conformity, e.g. in the New Approach (medical devices); they can be made compulsory or qualify as means to demonstrate conformity.

On the whole, the major trends in European regulation of nanotechnologies are set at the EU level. However, countries that have heavily invested in nanotechnologies, such as the United Kingdom and Germany, still play an important role in shaping these policy developments within the EU's decision-making system, making specific regulatory decisions where they have the authority to do so, and generally promoting nanotechnology R&D and EHS-related research.⁹⁸ The UK's Department for Environment, Food, and Rural Affairs (DEFRA), for example, has run between 2006 and 2008 a 'voluntary reporting scheme' for manufactured nanomaterials, while the German authorities decided to conduct a survey on the manufacture and use of nanomaterials of 10 kg per year and more.⁹⁹ In early 2009, the French government proposed to amend its environmental legislation to require manufacturers and importers of 'substances in nanoparticulate state' to provide authorities with information on the identity, quantity

92 European Commission (2008a).

93 Commission of the European Communities, Commission Recommendation on a Code of Conduct for Responsible Nanosciences and Nanotechnologies Research, C (2008) 424 final (7 February 2008), available at <ftp://ftp.cordis.europa.eu/pub/fp7/docs/nanocode-recommendation.pdf> (accessed 6 July 2009).

94 SCCP (2007); SCENIHR Opinion on the Appropriateness of Existing Methodologies to Assess the Potential Risks Associated with Engineered and Adventitious Products of Nanotechnologies, SCENIHR/002/05, available at http://ec.europa.eu/health/ph_risk/committees/04_scenihr/docs/scenihr_o_003.pdf (accessed 28 July 2009), Modified Opinion After Public Consultation (SCENIHR 2006) (arguing that 'existing toxicological and ecotoxicological methods may not be sufficient to address all of the issues arising with nanoparticles').

95 EFSA (2009).

96 EMEA (2006).

97 Directive 98/34/EC of the European Parliament and of the Council, available at <http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=OJ:L:1998:204:0037:0048:EN:PDF> (accessed 28 July 2009) (establishing a procedure for the provision of information in the field of technical standards and regulations).

98 See, for example, Federal Ministry of Education and Research (Germany), Nano-Initiative – Action Plan 2010, available at http://www.bmbf.de/pub/nano_initiative_action_plan_2010.pdf (accessed on 6 July 2009) (outlining strategy for evaluating the effects of nanomaterials on human health and the environment).

99 BAuA (2008).

and use of these substances.¹⁰⁰ It is beyond the scope of this report to discuss the many research and regulatory activities in all EU Member States. Interested readers may wish to refer to existing literature on these activities.¹⁰¹

3.3 International developments

Existing intergovernmental and international private initiatives have different institutional rules, compositions, legal settings and legal effects, and, accordingly, have a different impact on regulatory policy-making in the United States and the EU. The two most important international entities for regulatory cooperation and information sharing are the OECD and the ISO. While technically a non-governmental organization, the ISO is grouped with intergovernmental entities as its standards often directly influence regulatory decisions. There exist a few private initiatives that are not directly international in nature but nevertheless have had an indirect influence on debates at the international level. We will briefly discuss these in section 3.3.2.

Much of what is discussed below, especially with regard to the work of the OECD and ISO, are ongoing projects with new developments and results being published frequently. The information is correct as of July 2009, but readers are encouraged to look for more recent developments under the relevant web links provided in the footnotes.

3.3.1 Intergovernmental cooperation

The OECD Working Party on Manufactured Nanomaterials (WPMN)

The OECD's work on the safety of nanomaterials began in its Chemicals Committee in November 2004. Following two events on the safety of manufactured nanomaterials in 2005,¹⁰² the committee established the Working Party on Manufactured Nanomaterials (WPMN) in 2006.¹⁰³ The goal of the WPMN is 'to promote international co-operation in human health and environmental safety related aspects of manufactured nanomaterials (MN), [with a focus] on the industrial chemical sector'.¹⁰⁴ It brings together a wide range of experts from OECD member countries, some non-member countries including Brazil, China, Russia and Thailand, and observers and invited experts from the UN Environment Programme (UNEP), the World Health Organization (WHO), the ISO, the Business and Industry Advisory Committee (BIAC), the Trade Union Advisory Committee (TUAC) and environmental NGOs.

The work of the WPMN is divided into eight projects. The first, chaired by Australia, has created an *online database* on planned, ongoing and completed research projects on EHS issues related to manufactured nanomaterials. This database builds on an existing one maintained by the Project on Emerging Nanotechnologies¹⁰⁵ and is linked to databases maintained by the International Council on Nanotechnology (ICON) at Rice University, Houston, Texas,¹⁰⁶ and the NIOSH.¹⁰⁷ The database, launched in April 2009,¹⁰⁸ currently lists almost 700 individual projects and in the future seeks to expand information on life-cycle assessments of nanomaterials and also add information on the uses of nanomaterials.

100 Ministère de l'écologie, de l'énergie, du développement durable et de l'aménagement du territoire (2009: Titre V, Chapitre II, Article 73); see also SafeNano, SingleNews-Mandatory Nanomaterial Declaration proposed by French Government, <http://www.safenano.org/SingleNews.aspx?NewsID=590> (accessed 28 July 2009).

101 OECD, Publications in the Series on the Safety of Manufactured Nanomaterials, http://www.oecd.org/document/53/0,3343,en_2649_37015404_37760309_1_1_1_1,00.html (accessed 29 July 2009); European Commission, *Nanosciences and Nanotechnologies: An action plan for Europe 2005-2009. First Implementation Report 2005-2007*, COM (2007) 505 final (6 September 2007), available at http://eur-lex.europa.eu/LexUriServ/site/en/com/2007/com2007_0505en01.pdf (accessed 30 July 2009) (detailing risk assessment and risk management activities); see also European Commission, *Key Documents*, EU Policy for Nanosciences and Nanotechnology, http://ec.europa.eu/nanotechnology/pdf/eu_nano_policy_2004-08.pdf (accessed 30 July 2009) (first two pages compile relevant documents on EU Policy); Aguar, P. and J. J. M. Nicolas, Research DG, European Commission, *EU nanotechnology R&D in the field of health and environmental impact of nanoparticles* (2008), <ftp://ftp.cordis.europa.eu/pub/nanotechnology/docs/final-version.pdf> (accessed 30 July 2009).

102 See OECD, Work on the Safety of Manufactured Nanomaterials, PowerPoint presentation, <http://www.oecd.org/dataoecd/34/6/37852382.ppt#292> (accessed 30 July 2009).

103 OECD, Safety of Nanomaterials: About, http://www.oecd.org/about/0,3347,en_2649_37015404_1_1_1_1,00.html (accessed 29 July 2009).

104 Kearns et al. (2009).

105 See the Project on Emerging Nanotechnologies (PEN), Nanotechnology Environment, Health and Safety Research, <http://www.nanotechproject.org/inventories/ehs/>, to access the PEN database (accessed 30 July 2009).

106 International Council on Nanotechnology, the Virtual Journal of Nanotechnology Environment, Health and Safety, <http://icon.rice.edu/virtualjournal.cfm> (accessed 30 July 2009).

107 NIOSH, Nanoparticle Information Library, <http://www2a.cdc.gov/niosh-nil/> (accessed 6 July 2009).

108 See OECD, Database on Research into the Safety of Manufactured Nanomaterials, <http://webnet.oecd.org/NanoMaterials/Pagelet/Front/Default.aspx>, for access to the database (accessed 28 July 2009); see also OECD, Database on Research into the Safety of Manufactured Nanomaterials, http://www.oecd.org/document/26/0,3343,en_2649_37015404_42464730_1_1_1_1,00.html#Additional_Info (accessed on 6 July 2009), for further information on the database.

The second project, chaired by Germany, focuses on *research strategies* and seeks to list EHS research needs, create an overview of completed, current and planned EHS research, identify and facilitate additional research, consider mechanisms for cooperative international research and recommend research priorities for the short, medium and longer term. As of mid-2008, the project had 'developed a comprehensive list of research themes and compiled the current/planned research projects and the urgent and medium/long term research priorities'. It had also 'identified research themes which already have wide current coverage ("hot spots") and research themes less covered ("gaps")', and proposed possible research projects for international co-operation.¹⁰⁹ The output of this project was recommended for declassification in June 2008 but had not been declassified as of July 2009.¹¹⁰

The third project, chaired by the United States and the European Commission, has established *lists of 14 representative nanomaterials* that are or can be expected to be commercially relevant, and of 59 endpoints relevant for hazard assessment in order to develop dossiers on identification, physical-chemical properties and characterization, environmental fate and toxicology, mammalian toxicology, and material safety.¹¹¹ On the basis of these lists, the OECD is currently running a 'Sponsorship Programme for the Testing of Manufactured Nanomaterials',¹¹² where different countries and industry (represented by the OECD's Business and Industry Advisory Committee – BIAC) take responsibility for conducting, coordinating or supporting the testing of these 14 materials. The division of labour is as follows:¹¹³ fullerenes (Japan and United States), single-walled carbon nanotubes (Japan and United States), multi-walled carbon nanotubes (Japan and United States), silver nanoparticles (Korea and United States), iron nanoparticles (China), titanium dioxide (France and Germany), cerium oxide (United States and United Kingdom/BIAC), zinc oxide (United Kingdom/BIAC), silicon dioxide (France and the European Commission). For carbon black, aluminium oxide, polystyrene, dendrimers and nanoclays, no lead sponsor had been identified as of July 2009. This first phase of testing is planned to be completed by the end of 2010 and a second phase will follow.¹¹⁴

The fourth project, chaired by the United States and the European Commission, *reviews the adequacy of existing test guidelines* for nanomaterials and identifies the need for new or revised guidelines. As of June 2008, the project has finalized a 'preliminary review of test guidelines related to physical chemical properties, effects on biotic system, degradation and accumulation, and health effects'.¹¹⁵ The recent OECD review of existing test guidelines concludes that 'Many of the OECD Test Guidelines are applicable, with conditions in some cases, while some are inadequate for testing Manufactured Nanomaterials (MN) as measuring, dosing, delivery and tracking nanomaterials are not reliably accomplished at this stage'.¹¹⁶ It therefore calls for a guidance document for sample preparation and dosimetry, which should be independent from existing OECD guiding documents.¹¹⁷

The fifth project, chaired by Canada, *analyses national voluntary and mandatory information gathering programmes* and identifies 'common elements relating to the risk assessment and risk management' of nanomaterials through such programmes.¹¹⁸ It has prepared recommendations on specific approaches and elements to be considered in such programmes. In June 2008, it recommended that these results be declassified and made available to the public, which had not happened as of July 2009.¹¹⁹ The project has also undertaken a survey via a questionnaire for WPMN delegations to identify 'various components of regulatory regimes which are or may be applicable to nanomaterials', the report on which is currently being finalized.¹²⁰ It has sought ways to compare and share data collected in national reporting programmes. The majority of work in this project seems to have been completed in 2008, but the results have not been made public to date.

The sixth project, chaired by Canada and the United Kingdom, seeks to 'exchange, collate and synthesise information on risk assessment approaches for chemicals that may apply to manufactured nanomaterials', to 'undertake a gap analysis of current risk assessment approaches as these apply to manufactured nanomaterials', and to 'prepare recommendations for addressing and filling identified gaps'.¹²¹ By mid-2008, the project had developed a report on the first two objectives, which had not been declassified as of July 2009. The project is organizing a workshop on risk assessment of nanomaterials, to be held in September 2009.

109 OECD (2008: 91).

110 Ibid.

111 Ibid.

112 OECD, Sponsorship Programme for the Testing of Manufactured Nanomaterials, http://www.oecd.org/document/47/0,334_3,en_2649_37015404_41197295_1_1_1_1,00.html (accessed 29 July 2009).

113 A document with lead sponsors for each research area, as well as a list of co-sponsors and contributors, is available on the OECD website. OECD, <http://www.oecd.org/dataoecd/15/25/42059046.doc> (accessed 28 July 2009).

114 OECD (2008: 92).

115 Ibid.

116 OECD (2009b: 13).

117 Ibid.

118 Ibid.

119 Ibid.

120 Ibid.

121 Ibid.

The seventh project, chaired by Germany and the European Commission, *reviews and evaluates the suitability of alternative test methods* for testing nanomaterials. It also seeks to produce a guidance document on testing strategies that minimize animal testing and integrate *in vitro* and *in silico* testing methods into *in vivo*-based testing of nanomaterials.¹²² The results of this project will feed into the work of the third and fourth projects, on representative testing and guidelines, respectively.

The eighth project, chaired by the United States, focuses on exchanging information on *guidance documents for exposure measurement and exposure mitigation*.¹²³ It is divided into three phases. The first considers exposure in occupational settings and the respective mitigation; the second considers exposure to ‘humans resulting from contact with consumer products and environmental releases’ of manufactured nanomaterials; and the third considers exposure to ‘environmental species resulting from environmental releases of [manufactured nanomaterials] including releases from consumer products containing [manufactured nanomaterials]’.¹²⁴ The first phase of this project has been completed and guidance of occupational exposure measurement and mitigation has been published on the OECD website. Furthermore, the project will engage with a Sponsorship Programme for exposure assessment of 14 nanomaterials in the three core domains.¹²⁵

The OECD Working Party on Nanotechnology (WPN)

The Working Party on Nanotechnology (WPN) is the second group of the OECD working on nanotechnologies, meeting twice a year. It was set up in 2007 and is, in contrast to the WPMN that is part of the Chemicals Committee, part of the OECD’s Directorate for Science, Technology and Industry. Whereas the WPMN focuses primarily on international cooperation in human health and environmental safety-related aspects of nanotechnology, the WPN’s primary goal is to ‘advise on emerging policy-relevant issues in science, technology and innovation related to the responsible development of nanotechnology’.

The WPN takes a broader approach to informing policy debates and its members have prepared draft reports on a range of topics including nanotechnology indicators and statistics, business impact, public engagement, policy dialogue and water.¹²⁶ As of July 2009, these reports had not yet been published. The WPN has set a timeframe for work until 2010 and divides its projects into six different groups, which may be reduced to three or four projects after prioritization.¹²⁷ Much of the working programme of the WPN is currently under development and some of the projects outlined below reflect planned rather than actual work.

The first project focuses on developing a *statistical framework for nanotechnology* and addresses nanotechnology definitions, statistical methodology, questionnaire design for company surveys, and other relevant metrics. The aim of this project is to ‘outline, develop and contribute to the provision of internationally comparable indicators and statistics on the nature and development of nanotechnology’ and is planned to be completed in 2010.¹²⁸

The second project is complementary to the first in that it focuses on *monitoring and benchmarking nanotechnology developments*. This includes working closely with the first project but also with the sixth, on policy roundtables (see below). It also seeks to promote undertaking case studies on national policy systems relevant to nanotechnology. In 2008, this project identified a set of key themes that policy-makers should consider when planning, managing or commissioning public engagement activities.¹²⁹

The third project seeks to *identify and explore opportunities and challenges for nanotechnology commercialization*. It has completed a set of case studies that indicate business challenges in the areas of, among others, research and development, intellectual property, public perception, and EHS aspects. It proposes to consider the latter, in particular, in more detail.¹³⁰

122 Ibid.

123 OECD (2008: 93).

124 Ibid.

125 OECD (2009a).

126 See OECD, Fourth meeting of the Working Party on Nanotechnology (Paris, 17–18 December 2008), http://www.oecd.org/document/24/0,3343,en_21571361_41212117_42329944_1_1_1_1,00.html, for a discussion of these WPN draft reports (accessed 28 July 2009).

127 The details of proposals under these projects, as well as the projects themselves, were planned to be finalized in mid-2009. See OECD, Working Party on Nanotechnology (2008), *Work Programme 2009–2010*, available at <http://www.oecd.org/dataoecd/9/10/42482123.pdf>, for an overview of the projects (accessed 28 July 2009).

128 OECD, Statistical framework for nanotechnology, http://www.oecd.org/document/53/0,3343,en_21571361_41212117_42324533_1_1_1_1,00.html (accessed 29 July 2009).

129 See OECD, Monitoring and benchmarking nanotechnology developments, http://www.oecd.org/document/17/0,3343,en_21571361_41212117_42324625_1_1_1_1,00.html (accessed 30 July 2009); see also OECD, Conference on Outreach and Public Engagement in Nanotechnology (Delft, Netherlands, 30 October 2008), http://www.oecd.org/document/2/0,3343,en_21571361_41212117_42324482_1_1_1_1,00.html (accessed 29 July 2009).

130 See OECD, Addressing challenges in the business environment specific to nanotechnology, http://www.oecd.org/document/21/0,3343,en_21571361_41212117_42325205_1_1_1_1,00.html (accessed 29 July 2009).

The fourth project aims to develop policy proposals in a range of areas related to *fostering nanotechnology to address global challenges*. In 2008, the project began exploring the role of nanotechnology in contributing to the sustainable provision of clean water; it aims to finish this work towards the end of 2009.¹³¹ Potential future areas to be considered starting in 2009 include the environment, health and foods, climate change, agriculture or energy.¹³²

The fifth project aims to facilitate *international research collaboration and scientific cooperation* in nanotechnology.¹³³ It has developed a list of relevant national websites¹³⁴ and seeks to establish a policy roundtable on 'International Scientific Co-operation in Nanotechnology' in the course of 2009.

The sixth project aims to assist in the *development of policy roundtables* on nanotechnology more generally. Aside from the above roundtable on scientific cooperation, this project also seeks to establish in late 2009 policy roundtables on 'the economics of nanotechnology' and on 'risk governance for nanotechnology'.¹³⁵

The ISO and other standardization efforts

The ISO Technical Committee 229–Nanotechnologies was created in 2005 and works on various issues related to standardization and nanomaterials, including terminology and definitions, protocols for toxicity testing and environmental impact studies, measurement techniques, calibration procedures, and reference materials.¹³⁶ It has four subcommittees on (1) terminology and nomenclature, (2) measurement and characterization, (3) health, safety and environmental aspects, and (4) material specifications. Most of the 34 standards currently under development are in the proposal or preparatory stage.¹³⁷ Two have been published, one on 'Health and safety practices in occupational settings relevant to nanotechnologies' (ISO/TR 12885: 2008) and the other on 'Terminology and definitions for nano-objects – nanoparticle, nanofibre and nanoplate' (ISO/TS 27687: 2008).¹³⁸

There are 28 participating and eight observing countries at the ISO/TC 229.¹³⁹ Aside from the national standards organizations, ISO/TC 229 works closely with other bodies including the International Electrotechnical Commission (IEC/TC 113), the Thailand Science Park Project (ANF HQ), the International Bureau of Weights and Measures (BIPM), the European Environmental Citizens Organization for Standardization (ECOS), the European Commission's Joint Research Centre (DG JRC), the Institute for Reference Materials and Measurements (IRMM), the OECD, and the Versailles Project on Advanced Materials and Standards (VAMAS). Some of the challenges of establishing standards for measurement and characterization of nanotechnologies were addressed at a joint workshop of the ISO, the IEC, the NIST and the OECD in February 2008.¹⁴⁰ The recommendations of the workshop included better communication within and between various standards organizations, a centralized database on existing standards and current projects, wider participation by stakeholders and the prioritization of EHS-related concerns.

Other intergovernmental activities

As mentioned before, nanotechnology-related work in the OECD and the ISO dominates the intergovernmental discussion on risk assessment of nanomaterials. There is also a range of other intergovernmental discussions that are at times more focused, for example on a specific sector, or tailored to the existing work of a specific forum, and have led to a range of specific projects, events, workshops or dialogues. Some of them explicitly refer to international approaches to risk governance in the area of nanotechnologies. The following is a small selection of these activities.

The International Dialogue on Responsible Research and Development of Nanotechnology is a biennial gathering to 'facilitate good governance in nanotechnology, aiming at a development of nanotechnology that corresponds to the needs of society as a whole, without creating new economic or knowledge disequilibria, [...]. In this respect this

131 See OECD, Workshop on Nanotechnology and the Global Challenge of Access to Clean Water (Copenhagen, 25 September 2008), http://www.oecd.org/document/42/0,3343,en_21571361_41212117_42324394_1_1_1_1,00.html, for a workshop report of some results from the fourth project (accessed 29 July 2009).

132 See OECD, *Fostering nanotechnology to address global challenges*, http://www.oecd.org/document/29/0,3343,en_21571361_41212117_42325213_1_1_1_1,00.html (accessed 29 July 2009).

133 See OECD, *Fostering international scientific co-operation in nanotechnology*, http://www.oecd.org/document/16/0,3343,en_21571361_41212117_42325264_1_1_1_1,00.html (accessed 29 July 2009).

134 See OECD, *Nanotechnology-related resources (portals, networks and research facilities) by country*, http://www.oecd.org/countrylist/0,3349,en_21571361_41212117_42325621_1_1_1_1,00.html, for a list of national websites (accessed 29 July 2009).

135 See OECD, *Policy roundtables on key policy issues related to nanotechnology*, http://www.oecd.org/document/38/0,3343,en_21571361_41212117_42325350_1_1_1_1,00.html (accessed 28 July 2009).

136 See generally ISO, *TC 229-Nanotechnologies, Business Plan: ISO/TC 229 Nanotechnology*, available at http://isotc.iso.org/livelink/livelink/fetch/2000/2122/687806/ISO_TC_229_Nanotechnologies.pdf?nodeid=6507632&vernum=0 (accessed 29 July 2009).

137 ISO, *TC 229-Nanotechnologies*, http://www.iso.org/iso/iso_catalogue/catalogue_tc/catalogue_tc_browse.htm?commid=381983&development=on (accessed 29 July 2009).

138 ISO, *TC 229-Nanotechnologies, Published Standards*, http://www.iso.org/iso/iso_catalogue/catalogue_tc/catalogue_tc_browse.htm?commid=381983&published=on&includesc=true (accessed 29 July 2009).

139 ISO, *ISO Members*, http://www.iso.org/iso/about/iso_members.htm (accessed 29 July 2009).

140 See ISO (2008).

dialogue wants to be inclusive, involving all countries and stakeholders interested in the responsible and sustainable development of nanotechnology.¹⁴¹ Its third meeting, in 2008, was attended by representatives of 49 countries in addition to other stakeholders from international organizations, multinational bodies, industries and academia. Due to its inclusive nature and broad scope, this dialogue has not yet produced any tangible results, but may play a more important role in coordinating global risk governance approaches.

The International Cooperation on Cosmetic Regulations is an initiative of the EU, America's FDA, Japan's Ministry of Health, and Health Canada, which aims at streamlining cosmetic regulatory requirements between the parties involved, wherever this is possible within the respective regulatory frameworks. Nanotechnology is one of the topics on the agenda.¹⁴²

The FAO and the WHO held an expert meeting in June 2009 on the application of nanotechnologies in the food and agriculture sectors and potential safety implications.¹⁴³ Among the main objectives of this meeting were to take stock of actual and anticipated applications in the food and agriculture sectors, to identify potential safety implications, to identify data and research gaps, to identify priority areas for FAO/WHO work, and to advise on multi-stakeholder dialogue.

The UN Industrial Development Organization's International Centre for Science and High Technology (ICS UNIDO) has hosted training, networking and dialogue projects to promote the diffusion of nanotechnology to developing countries and to foster joint research projects between developed and developing countries.

The Intergovernmental Forum on Chemical Safety (IFCS) seeks to promote international cooperation on chemical safety. In its sixth session in 2008, it considered the opportunities and challenges of nanotechnology and manufactured nanomaterials, and issued the 'Dakar Declaration' calling for more international cooperation in risk assessment, information-sharing and the development of a Global Code of Conduct. In October 2008, the IFCS requested to be integrated in the ICCM (see below) as an advisory body.¹⁴⁴

In 2006, UNEP's International Conference on Chemicals Management (ICCM) adopted the Strategic Approach to International Chemicals Management (SAICM), which calls for the 'sound management of chemicals' and provides a roadmap towards more effective international cooperation in risk reduction and technical cooperation in this area. In May 2009, the ICCM held its second meeting (ICCM.2) which focused on nanotechnologies and manufactured nanomaterials, among other issues. In its final resolution, ICCM recognized potential environmental and human health risks associated with nanotechnologies and manufactured nanomaterials, and requested that governments and other stakeholders facilitate access to relevant information and develop a report on this issue with special attention to developing countries.¹⁴⁵

The Asia Pacific Nanotechnology Forum (APNF) consists of a network including Australia, China, Korea, Japan, Malaysia, New Zealand, Singapore, Taiwan, Thailand and Vietnam. It seeks to foster regional cooperation on nanotechnology research and development and has organized a series of international conferences towards that end, including one on EHS-related issues.

3.3.2 International private initiatives

There is a range of private initiatives on nanotechnology EHS-related issues and on the wider question of international risk governance. There also exist some national initiatives such as industry codes of conduct or technical guiding documents with some relevance to the international arena.

The International Council on Nanotechnology (ICON) at Rice University, founded in 2004, is an extension of the US National Science Foundation Center for Biological and Environmental Nanotechnology (CBEN) and aims to facilitate international communication and cooperation in health and environmental risks related to nanotechnology. It is composed of stakeholders from academia, industry, government and NGOs and aims to make scientific EHS data accessible to policy-makers, journalists and other non-specialists through forums, events, an electronic database and online publications.

The International Alliance for NanoEHS Harmonization (IANH) was founded in September 2008. The IANH is a voluntary initiative of laboratories and other stakeholders from Europe, Japan and the United States to create protocols on toxicology tests on a number of representative nanoparticles to enable a 'round robin' study on the results. Its goal is to create a 'neutral and scientific platform for generating knowledge' on nano-bio interactions

141 Tomellini and Giordani (2008: v5).

142 See International Cooperation on Cosmetic Regulation, Press Statement: ICCR-2 (2008), available at http://ec.europa.eu/enterprise/cosmetics/doc/outcome_iccr_2008.pdf (accessed 29 July 2009).

143 Food and Agriculture Organization and World Health Organization, United Nations, Joint FAO/WHO Expert Meeting on the Application of Nanotechnologies in the Food and Agriculture Sectors: Potential Food Safety Implications, http://www.fao.org/ag/agn/agns/expert_consultations/Nanotech_EC_Scope_and_Objectives.pdf (accessed 30 July 2009).

144 Letter from Ndiaye Cheikh Sylla, Executive Director, IFCS, to Achim Steiner, Executive Director, United Nations Environment Programme (6 October 2008), http://www.who.int/ifcs/saicm/conference_chemicals/letterunep_en.pdf (accessed 30 July 2009).

145 See *Earth Negotiations Bulletin* (2009).

through international scientific cooperation. It also seeks to cooperate with national and international bodies by providing them with relevant scientific input. First results of *in vivo* tests of the toxicology of nanoparticles in rodents and environmentally sensitive aquatic species are expected towards the end of 2009.¹⁴⁶

Founded in 2003 to help the 'understanding and management of emerging global risks', the International Risk Governance Council (IRGC) regularly convenes high-level meetings of key stakeholders in nanotech risk governance and publishes recommendations based on these meetings. Its nanotechnology programme is a key forum for dialogue and is financed by, among others, Swiss Re, a reinsurance company, the US Environmental Protection Agency and the US Department of State.

The Meridian Institute has organized international dialogues and workshops on responsible research and development, a voluntary pollution prevention scheme, general regulatory issues, and opportunities and risks of nanotechnology for the global poor.

Two private initiatives have had a direct impact on the OECD WPMN work on exposure measurement and mitigation in occupational settings (project eight).¹⁴⁷ One is the cooperation between the US chemical company DuPont and the Environmental Defense Fund, an environmental advocacy group. Together they have developed a comprehensive Nano Risk Framework that is mainly targeted at companies working with nanomaterials.¹⁴⁸ It advises them how to evaluate and address potential risks associated with nanomaterials. The second initiative provides guidance on the handling and use of nanomaterials in the workplace, and was jointly developed by the German Chemical Industry Association (VCI) and the German Federal Institute for Occupational Safety and Health (BAuA).¹⁴⁹

3.4 Conclusion

In both the United States and the European Union, regulatory authority over nanomaterials is divided among several institutions. With established agencies such as the EPA and the FDA, the United States builds on a relatively centralized oversight structure. In Europe, the regulatory authority is exercised by the Council, the Parliament and the Commission, as well as the specialized agencies that assist the latter in its implementation at the EU level, while the Member States' Competent Authorities are responsible for implementing EU legislation at the national level. So far, the United States and the European Union rely primarily on existing laws, regulations and institutions to cover potential risks associated with the production, use and disposal of nanomaterials.

The OECD and the ISO, among others, are important international forums for exchanging information and for developing standards and guidelines for terminology, measurement, test methods, and risk assessment. In addition, various civil society and industry initiatives seek to foster international and public dialogue, at both a scientific and a policy level.

¹⁴⁶ See generally IANH (2009).

¹⁴⁷ OECD (2009a: 13, 28).

¹⁴⁸ Nano Risk Framework, <http://nanoriskframework.com/page.cfm?tagID=1095> (accessed 28 July 2009).

¹⁴⁹ See generally BAuA (2008).

4 Chemicals Regulation

4.1 US chemicals regulation

Two principal laws govern chemicals regulation in the United States: TSCA and FIFRA. The former provides authorities to regulate most chemicals, while the latter addresses pesticides in particular.

4.1.1 *The Toxic Substances Control Act (TSCA)*

TSCA was enacted in 1976 with three principal policy objectives. First, ‘adequate data should be developed’ on the effects of chemicals on health and the environment and the development of data ‘should be the responsibility’ of chemical manufacturers. Second, the law states that ‘adequate authority should exist to regulate’ chemicals. Third, this regulatory authority over chemicals ‘should be exercised in such a manner as not to impede unduly or create unnecessary economic barriers to technological innovation’ while fulfilling the primary purpose ... to assure that such innovation and commerce ... do not present an unreasonable risk of injury to health or the environment’.¹⁵⁰

Over 30 years later, TSCA has aptly been characterized as a statute with ‘dramatic strengths and weaknesses’.¹⁵¹ The statute covers a broad range of chemicals and provides far-reaching regulatory tools for the EPA to address unreasonable risks posed by chemicals, yet it also imposes numerous substantive and procedural hurdles that have limited the extent to which these authorities are used.

As a result, a multitude of critiques have characterized the statute as, for example, being a ‘serious underperformer among US environmental laws’,¹⁵² having ‘significant shortcomings’¹⁵³ and providing ‘limited assurance that health and environmental risks are identified’.¹⁵⁴ Nevertheless, TSCA has also had its supporters, most notably the EPA, which administers the law. Over the years, the EPA has generally maintained that TSCA provides the statutory tools necessary to protect public health and the environment, particularly when coupled with the agency’s voluntary reporting initiatives.¹⁵⁵ The new EPA Administrator has indicated, however, that toxic chemicals are a top priority, although it is unclear what types of administrative and/or legislative reforms the administration may support. In addition, the principal trade association for the chemical industry, the American Chemistry Council, has traditionally praised TSCA as a ‘strong, robust regulatory framework’ that ‘protects health and the environment, promotes innovation, and addresses new questions about hazards, exposures and potential risks’,¹⁵⁶ although recently it too has acknowledged the need for ‘modernization’ of the statute.¹⁵⁷

We now look in detail at the specific regulatory authorities under TSCA and how they have been used to address potential risks posed by nanoscale materials.

(a) New chemicals and significant new uses of chemicals

General regulatory authorities. Section 5 of TSCA requires that manufacturers, importers, producers and processors (hereinafter collectively referred to in this section as ‘manufacturers’) of chemical substances notify the EPA at least 90 days prior to manufacturing or introducing a new chemical by filing a pre-manufacture notice (PMN). In addition, the statute requires that notice be provided prior to manufacturing or introducing a ‘significant new use’ of a chemical.¹⁵⁸

For ‘significant new uses’ of chemicals, however, the EPA must first issue a rule (Significant New Use Rule – SNUR) before the requirements apply. Such rules must be based on the application of certain statutory criteria

150 15 U.S.C. § 2601.

151 Davies (2006).

152 Applegate (2008: 723).

153 GAO (2009a: 22–24).

154 GAO (2006); see also Sachs (2009) (characterizing the statute as the ‘lapdog of US environmental law’).

155 See e.g. Committee on Environment and Public Works, US Senate (2008) (statement of Jim Gulliford).

156 See e.g. Committee on Environment and Public Works, US Senate (2006) (statement of Michael Walls).

157 American Chemistry Council (2009).

158 15 U.S.C. § 2604(a); see also 15 U.S.C. § 2602(7), (11) (defining covered entities).

that determine whether a 'significant new use' exists.¹⁵⁹ In order to conclude that a use is 'new,' the use may not be 'ongoing'.¹⁶⁰ SNURs are subject to public comment; although the procedures may vary depending on whether the SNUR covers a new, as opposed to an existing, chemical.¹⁶¹ A SNUR does not impose regulatory restrictions on the chemical covered, but rather requires an entity that wants to produce or use the chemical, in a manner identified in the SNUR as a significant new use, to first file a Significant New Use Notice (SNUN) that is comparable to the PMN that is filed for new chemicals.¹⁶²

Both PMNs and SNUNs must include 'reasonably ascertainable' information including, but not limited to, the known environmental or health effects of the chemical, the proposed categories of use, reasonable estimates of the total amount to be manufactured or processed, and reasonable estimates of the number of individuals who will be exposed to the substance in their places of employment.¹⁶³ Pre-manufacture testing, however, is not a required component of pre-manufacture or SNUN requirements.¹⁶⁴ The EPA estimates that 'most premanufacture notices do not include test data of any type and only about 15 per cent include health or safety test data'.¹⁶⁵ As discussed below, the EPA can require the submission of test data under certain circumstances. In lieu of reliance on chemical-specific data, however, the EPA typically predicts potential exposure and levels of toxicity of new chemicals by using models and comparing new chemicals to chemicals with similar molecular structures for which toxicity data are developed.¹⁶⁶

In addition, the statute and the EPA's implementing regulations provide exemptions to these pre-manufacture notice reporting requirements that could apply to certain nanomaterials. These include, but are not limited to, exemptions for low volume;¹⁶⁷ low release and low exposure;¹⁶⁸ polymers;¹⁶⁹ and research and development.¹⁷⁰ Some of the exemptions, such as the polymer and research and development exemptions, are 'self-executing' and do not require regulatory approval. Of the estimated 1,500 new chemical notices the EPA receives annually, approximately half are exemption requests.¹⁷¹

In most cases, the exemptions also have associated record-keeping requirements.¹⁷² The EPA's regulations provide that certain exemptions, such as the low-volume exemption and the low-release, low-exposure exemption, 'may' be granted by the EPA 'if it determines that the chemical will not present an unreasonable risk of injury to health or the environment'.¹⁷³

Upon review of a pre-manufacture notice, if the agency finds a 'reasonable basis' to conclude the chemical presents an 'unreasonable risk', it may prohibit or limit the amount of the chemical that may be manufactured, processed, or distributed in commerce.¹⁷⁴ TSCA provides the agency with several regulatory options, including, for example, requiring any substance containing the chemical to be labelled or accompanied by warnings and instructions; regulating the manner or method of commercial use; and directing manufacturers or processors to give notice of unreasonable risk of injury to distributors.¹⁷⁵ As discussed below, however, this authority is rarely used in response to a new chemical notice.

159 15 U.S.C. § 2604(a)(2)(A)–(D). These criteria include but are not limited to 'the extent to which a use changes the type or form of exposure of human beings or the environment' and 'the extent to which a use increases the magnitude and duration of exposure of human beings or the environment'. In issuing a chemical-specific SNUR, the EPA may rely on its generic SNUR regulations, which set out categories of significant new uses, such as 'any manner or method of manufacturing, importing, or processing associated with any use of the substance' without establishing a worker protection programme that includes, for example, certain personal protective equipment. See e.g. 40 C.F.R. § 721.63.

160 Duvall and Wyatt (2009: 7).

161 SNURs for new chemicals can be issued using expedited rulemaking procedures in some cases that do not require full notice and comment rule-making procedures. See US EPA Amendment for Expedited Process to Issue Significant New Use: Rules for Selected New Chemical Substances, available at <http://www.epa.gov/fedrgstr/EPA-TOX/1995/March/Day-29/pr-59.html> (accessed on 6 July 2009); see also Environmental Defense Fund (2006) (noting that SNURs for existing chemicals are subject to full notice and comment rulemaking).

162 40 C.F.R. § 721.25.

163 15 U.S.C. § 2604(d).

164 Ibid. § 2604(b).

165 GAO (2005: 11).

166 GAO (2005: 12–15) (discussing the merits and weaknesses of EPA's approach); see also Committee on Energy and Commerce, US House of Representatives (2009) (J.C. Davies stating that '[u]nder the best of circumstances structure-activity relationship analysis has limitations, but it is useless when there are no similar chemicals with known risks, as is the case with nanomaterials').

167 40 C.F.R. § 723.50 (applies when 10,000 kilograms or less of the substance will be manufactured or imported each year).

168 Ibid.

169 Ibid. § 723.250.

170 40 C.F.R. § 720.36; see also 15 U.S.C. § 2604(h)(3).

171 GAO (2007: 8).

172 See e.g. 40 C.F.R. § 720.50(a) (test data submission requirement).

173 40 C.F.R. § 723.50.

174 15 U.S.C. § 2604(f) (providing authority to the EPA to issue a proposed rule, a proposed order, or apply for a judicial injunction).

175 Ibid. § 2604(f)(2).

The statute also allows the EPA to regulate a new chemical when it determines that there is insufficient information to evaluate health and environmental effects and the chemical ‘may present an unreasonable risk of injury to health or the environment’ or will be produced in ‘substantial quantities’ that could result in significant human and environmental exposure.¹⁷⁶ In such cases, the EPA may issue an order, typically in the form of a consent order,¹⁷⁷ that may prohibit or limit the manufacture, processing and distribution in commerce, use or disposal of a chemical, but only pending development of information.¹⁷⁸

The EPA reviews approximately 1,500 pre-manufacture and SNUNs annually.¹⁷⁹ In 2005, it reported that of the 40,000 chemicals it had reviewed under TSCA, it had restricted 1,600, almost all under its authority to regulate on a temporary basis pending development of information. A similar number were withdrawn voluntarily by industry, ‘often in the face of EPA action’. The EPA also reported that it had issued 700 SNURs.¹⁸⁰

Regulatory actions specific to nanomaterials. In a January 2009 report, the EPA stated that since January 2005, it had received and reviewed ‘more than fifty new chemical notices under TSCA for nanoscale materials including carbon nanotubes and fullerenes’. The report further explained: ‘Where necessary, the Agency has taken steps to control or limit exposures to nanoscale materials submitted for TSCA new chemical review, including: limiting the uses of the nanoscale materials; requiring the use of personal protective equipment, such as impervious gloves and NIOSH approved respirators; and limiting environmental releases’. In addition, it stated that it had ‘required testing to generate health and environmental effects data where appropriate. The EPA has permitted limited manufacture of new chemical nanoscale materials by using administrative orders under section 5(e) of TSCA and/or Significant New Use Rules under section 5(a) (2) of TSCA.’¹⁸¹

Although the report provides some indication of the extent of the agency’s regulatory actions on nanomaterials, many of the details are unavailable to the public. This lack of transparency is due in part to confidential business information (CBI) claims that prevent public disclosure of information submitted by companies to the EPA.¹⁸² Approximately 95% of all pre-manufacture notices contain some CBI assertion.¹⁸³ CBI is discussed in more detail below, including the limitations on sharing it with foreign governments.¹⁸⁴

With respect to exemptions from pre-manufacture notice requirements, the EPA reports that as of November 2008 it has allowed fewer than ten new nanoscale materials to be manufactured under the terms of regulatory exemptions and ‘only in circumstances where exposures were tightly controlled to protect against unreasonable risks (using, for example, specific protective equipment and stringent environmental release limitations)’.¹⁸⁵ Some stakeholders, however, have noted that it may not be reasonable to assume that traditional approaches to controlling exposure to chemicals will work in the context of nanomaterials.¹⁸⁶ It is difficult to estimate the extent to which the research and development exemption has been relied upon with respect to nanomaterials because it is self-executing and does not require prior regulatory approval. However, 60 of the approximately 100 nanoscale materials for which information has been reported under the EPA’s Nanoscale Materials Stewardship Program are used exclusively for research and development, which suggests at least the potential for substantial reliance on the exemption.¹⁸⁷ As a general matter, stakeholders are continuing to debate whether and how these exemptions should be modified to apply effectively to nanomaterials.¹⁸⁸

176 Ibid. § 2604(e)(1)(A).

177 Bergeson and Hester (2008: 18).

178 Ibid.

179 Ibid. at 62, app. VI.

180 Ibid.

181 EPA (2009a: 23); see also EPA (2008d: 65751–2) (for siloxane-modified silica and siloxane-modified alumina nanoparticles); EPA (2009g: 29990–91, 29998) (four section 5(e) SNURs issued for multi-walled and single-walled carbon nanotubes).

182 GAO (2005: Cover Page) (according to the Government Accountability Office, ‘TSCA prohibits the disclosure of confidential business information, and chemical companies claim much of the data submitted as confidential. Although EPA has the authority to evaluate the appropriateness of these confidentiality claims, EPA states that it does not have the resources to challenge large numbers of claims’).

183 GAO (2005: 32)

184 GAO (2005: 13–15); GAO (2007: 42).

185 EPA (2009a: 23). The EPA separately has indicated that the exemptions are under the low-release, low-exposure exemption. See also EPA (2009b) (according to EPA, the ‘exemption is intended to encourage companies to develop manufacturing, processing, use, and disposal techniques which minimize exposures to workers, consumers, the general public, and the environment’).

186 Denison (2005: 4); see also Nanosafe, Efficiency of Fibrous Filter and Personal Protective Equipments Against Nanoaerosols, available at http://www.nanosafe.org/home/liblocal/docs/Dissemination%20report/DR1_s.pdf (accessed 6 July 2009).

187 EPA (2009a: 10).

188 Davies (2006: 11) (noting that the low-volume exemption ‘would exclude almost all NT products’ and ‘clearly does not make sense if TSCA is to be applied to NT’); compare Schierow (2008a: 13–14) (stating that the statute ‘clearly excludes from its requirements substances that are produced and used only in research laboratories.... [t]his exclusion might apply to most of the various nanomaterials currently in existence.’) with Bergeson and Hester (2008) (concluding that exemptions ‘may prove to be a good fit’ and noting that EPA must approve certain exemptions and cannot under the statute grant exemptions that present an unreasonable risk of injury to human health or the environment).

(b) Regulation of existing chemicals

General regulatory authorities. TSCA Section 6 grants the EPA certain authorities to regulate existing chemicals or those already listed on the TSCA Chemical Substance Inventory (commonly referred to as the ‘TSCA Inventory’).¹⁸⁹ If the agency determines that there is ‘a reasonable basis to conclude that the manufacture, processing, distribution in commerce, use, or disposal of a chemical ... presents or will present an unreasonable risk of injury to health or the environment’, it may impose a range of requirements or restrictions ‘to protect adequately against such risk’, provided it uses the ‘least burdensome requirements’ possible.¹⁹⁰

In ordering such restrictions, TSCA requires the EPA to publish a statement that addresses the human health and environmental effects and magnitude of exposure to the chemical.¹⁹¹ Significantly, the agency also must address the benefits of the chemical for various uses and the availability of substitutes, in addition to the ‘reasonably ascertainable economic consequences of the rule, after consideration of the effect on the national economy, small business, technological innovation, the environment, and public health’.¹⁹² Since TSCA was enacted in 1976, the EPA has issued rules under this authority for only five chemicals: polychlorinated biphenyls (PCB), fully halogenated chlorofluoroalkanes, dioxin, and asbestos and hexavalent chromium. In most cases, the Agency restricted specific uses or sources of the chemical, but did not ban the chemical.¹⁹³

The burden on the EPA in regulating existing chemicals under TSCA is compounded by a particularly stringent standard of judicial review of challenges to rules it issues under the statute. Specifically, an EPA rule is ‘unlawful’ if a court finds that it is not supported by ‘substantial evidence’ in the rulemaking record.¹⁹⁴ This is a more stringent standard than the ‘arbitrary and capricious’ standard of judicial review that governs the review of most federal environmental rules.¹⁹⁵

Finally, in certain limited circumstances, the EPA has the authority under TSCA section 7 to seize an ‘imminently hazardous’ chemical substance or mixture.¹⁹⁶ Such chemicals are defined to include those that present an ‘imminent and unreasonable risk of serious or widespread injury to health or the environment’ that is likely to result before a final rule can be issued under TSCA Section 6 to protect against the risk.¹⁹⁷ This authority is rarely used, however, and to do so the EPA must commence a civil action in a district court.¹⁹⁸

Regulatory actions specific to nanomaterials. A key issue in the regulation of nanomaterials under TSCA is whether a particular nanomaterial is considered a *new* chemical. This determination is significant from a regulatory perspective because *existing* chemicals are not subject to pre-manufacture notice requirements and the corresponding process that provides the EPA with the opportunity to perform an assessment and identify and address potential risks prior to manufacture and distribution. If a chemical is determined to be on the Inventory, the chemical may be manufactured without review in most cases.

In its ‘TSCA Inventory Status of Nanoscale Substances – General Approach’, published in early 2008, the EPA describes the manner in which it determines whether a nanoscale substance is a new or existing chemical substance. According to the document, if a nanoscale material has the same ‘molecular identity’, which the EPA defines as the same structural and compositional features as opposed to physical and chemical properties, as a chemical

189 15 U.S.C. § 2605(a). See also EPA, *What is the TSCA Chemical Substances Inventory?*, <http://www.epa.gov/oppt/newchemicals/pubs/invntory.htm> (accessed 6 July 2009) (there are approximately 83,000 chemical substances on the Inventory at this time); Stephen Johnson Speech, Global Chemical Regulations Conference, 18 March 2008, available at <http://yosemite.epa.gov/opa/admpress.nsf/8d49f7ad4bbcf4ef852573590040b7f6/a47e97b97a782c48852574100048d8dd9!OpenDocument> (accessed 6 July 2009) (noting that the EPA has initiated a programme to ‘reset’ the Inventory by removing many chemicals no longer in commercial use).

190 15 U.S.C. § 2605(a) (Although the standard for imposing requirements differs with respect to new and existing chemicals, the types of requirements that can be imposed are similar and include, for example, prohibiting or limiting the amount of manufacturing, processing or distribution of the chemical; requiring any article containing the chemical to be labelled or accompanied by warnings and instructions; regulating the manner or method of commercial use; and directing manufacturers or processors to give notice of unreasonable risk of injury to distributors).

191 *Ibid.* § 2605(c).

192 *Ibid.* § 2605(c)(1)(C), (D).

193 GAO (2005): 58–60.

194 15 U.S.C. § 2618(c).

195 See *Corrosion Proof Fittings v. Env'tl. Prot. Agency* 947 F.2d 1201 (5th Cir. 1991); see also GAO (2007: 20) (stating that ‘the court found that EPA ... failed to show that the control action it chose was the least burdensome reasonable regulation required to adequately protect human health or the environment ... the proper course of action for EPA, after an initial showing of product danger, would have been to consider the costs and benefits of each regulatory option available under Section 6, starting with the less restrictive options, such as product labeling, and working up through a partial ban to a complete ban’).

196 15 U.S.C. § 2606(a).

197 *Ibid.* § 2606(f).

198 *Ibid.* § 2606(a).

substance listed on the TSCA Inventory, it is considered an 'existing' chemical substance.¹⁹⁹ More specifically, the agency recognized that although 'a nanoscale substance that has the same molecular identity as a non-nanoscale substance listed on the Inventory differs in particle size and may differ in certain physical and/or chemical properties resulting from the difference in particle size, the EPA considers the two forms to be the same chemical substance'.²⁰⁰ The debate preceding and following the issuance of the EPA's statement has been divisive, with industry generally supporting its position and NGOs opposed to it.²⁰¹

In October 2008, the EPA published a Federal Register notice²⁰² in which it clarified that carbon nanotubes 'are not necessarily identical to graphite or other allotropes of carbon' and if 'a particular CNT [carbon nanotube] is not on the TSCA Inventory, anyone who intends to manufacture or import that CNT is required to submit a PMN (or applicable exemption) under TSCA section 5 at least 90 days before commencing manufacture'.²⁰³

Testing. TSCA provides the EPA with the authority to issue rules that require manufacturers, importers and processors to undertake testing to 'develop data with respect to the health and environmental effects' of certain chemicals, provided the agency first makes certain findings.²⁰⁴ First, it must find that either: 1) the chemical may present an 'unreasonable risk of injury to health or the environment'; or 2) the chemical 'will be produced in substantial quantities' and 'may reasonably be anticipated to enter the environment in substantial quantities' or result in 'substantial human exposure'.²⁰⁵ Second, it must determine that current data are 'insufficient' to determine or predict the health and environmental effects of the chemical.²⁰⁶ Third, it must find that testing is 'necessary to develop such data'.²⁰⁷ After making these findings, it must then issue a proposed test rule for public notice and comment prior to issuing a final rule. The process can take up to ten years.²⁰⁸ In total, the EPA has issued test rules for approximately 140 of the 62,000 chemicals in commercial use since it began reviewing chemicals under TSCA in 1979.²⁰⁹

Partly because of the burdensome test rule process, the EPA often uses voluntary approaches to gather data. For example, as an alternative to the rule-making process, it can negotiate agreements with companies to conduct testing. In 2007, it reported that it had entered into consent agreements with chemical companies to develop tests for about 60 existing chemicals.²¹⁰ In addition, the agency has relied on voluntary reporting programmes, such as the High Production Volume (HPV) Challenge Program,²¹¹ to collect EHS chemicals data.

Regulatory actions specific to nanomaterials. Consistent with its prior use of voluntary reporting programmes to collect environmental, health and safety data, the Nanoscale Materials Stewardship Program (NMSP) is perhaps the most high-profile nanotechnology governance initiative that the EPA has sponsored to date.²¹² Under this voluntary programme, the agency seeks to collect data to inform appropriate risk assessment and risk management practices for nanoscale chemical substances.²¹³ The NMSP is divided into two parts. The Basic Program requests that manufacturers and importers provide information on their current use of engineered nanoscale materials. The

199 EPA (2008a: 2–3).

200 Ibid. at 6.

201 See e.g. Denison (2008a) (concluding that the EPA's recent statement 'flies in the face of nano science, which makes clear that a nanomaterial's properties are dictated at least as much by its physical characteristics as by its chemical structure'); see also Bergeson and Hester (2008: 22–28) (emphasizing the alternative authorities available to the EPA to regulate nanomaterials that are not considered 'new' chemicals, most notably its authority to regulate significant new uses of existing chemicals).

202 EPA (2008e: 64946).

203 Ibid. at 64947.

204 15 U.S.C. § 2603(a); see also *Chem. Mfrs. Ass'n v. US Evtl. Prot. Agency* 859 F.2d 977, 984 (D.C. Cir.1988) (upholding EPA's test rule).

205 15 U.S.C. § 2603(a)(1)(A)(i), (B)(i); see also Denison (2008b) (explaining: '[i]n virtually all cases where it has issued test rules for conventional chemicals, EPA has relied on making the second, exposure-based finding. For nanomaterials, however, making such a finding may prove much more difficult. These values are virtually astronomically high for most nanomaterials').

206 15 U.S.C. § 2603(a)(1)(A)(ii), (B)(ii).

207 Ibid. § 2603(a)(1)(A)(iii), (B)(iii).

208 GAO (2007: 20).

209 GAO (2005: 4); see also EPA (2007b: 4, 15). The EPA determines which chemicals to test based in part on the recommendations of the Interagency Testing Committee, which is comprised of representatives from 16 federal governmental entities. ITC is required to consider several factors in making its recommendations including, but not limited to: the quantities manufactured; the quantities that will enter the environment; and the number of individuals who will be exposed in their places of employment. EPA is required within 12 months either to initiate a test rule for a chemical ITC places on its priority list or justify its decision to decline to test the chemical. 15 U.S.C. § 2603(e)(1).

210 GAO (2007: 10).

211 EPA (2009c) (under the HPV program, 'companies are "challenged" to make health and environmental effects data publicly available on chemicals produced or imported in the United States in the greatest quantities').

212 See EPA, Nanoscale Material Stewardship Program, available at <http://www.epa.gov/oppt/nano/stewardship.htm> (accessed 6 July 2009).

213 See EPA (2008c), available at <http://www.epa.gov/fedrgstr/EPA-TOX/2008/January/Day-28/t1411.htm> (accessed 6 July 2009).

In-Depth Program asks participants to partner with the EPA to identify data gaps, engage in testing, and develop new data.

In its 2009 Interim Report on the programme, the EPA states that as of 8 December 2008, 29 companies and trade associations had submitted information covering 123 nanoscale materials based on 58 different chemicals, and another seven companies had committed to submit information. Four companies agreed to participate in the in-depth programme.²¹⁴

The EPA concludes that:

*Most submissions included information on physical and chemical properties, commercial use (realized or projected), basic manufacturing and processes as well as risk management practices. However, very few submissions provided either toxicity or fate studies. Because many submitters claimed some information as confidential business information, the Agency is limited in the details of what it can report for any particular submission.*²¹⁵

It further concludes that 'nearly two-thirds of the chemical substances from which commercially available nanoscale materials are based' and 'approximately 90% of the different nanoscale materials that are likely to be commercially available' were not reported under the Basic Program. Furthermore, a number of the submissions did not contain exposure or hazard-related data, but 'exposure and hazard data are two of the major categories of information the EPA identified in its concept paper for the NMSP that are needed to inform risk assessment and risk management of nanoscale materials'. Finally, it notes that the low rate of engagement in the In-Depth Program 'suggests that most companies are not inclined to voluntarily test their nanoscale materials'.²¹⁶

The EPA states in the report that owing to 'the limited participation in the In-Depth Program,' of the NMSP, it will 'consider how best to apply rulemaking under TSCA Section 4 to develop needed environmental, health, and safety data'.²¹⁷ The report led to renewed calls for mandatory reporting and testing of nanomaterials.²¹⁸ After its release, the EPA stated in its Unified Regulatory Agenda that a Section 4 test rule 'may be needed' for multi-wall carbon nanotubes.²¹⁹

(c) Record-keeping and reporting requirements

General regulatory authorities. TSCA imposes certain record-keeping and reporting requirements on manufacturers, distributors and processors of chemicals. For example, they are required to maintain records of 'adverse reactions to health or the environment' caused by a chemical and must submit copies of records if requested by the EPA.²²⁰ In addition, manufacturers must immediately notify the EPA if they obtain information that a chemical 'presents a substantial risk of injury to health or the environment'.²²¹

Under Section 8(a) of TSCA, the EPA also has authority to require manufacturers and processors, *other than small manufacturers and processors*,²²² to maintain and submit records with respect to a wide range of information about a chemical 'insofar as known to the person making the report or insofar as reasonably ascertainable'. For example, it may require submission of information about a chemical's molecular structure, the total amount manufactured or processed, all existing data concerning the environmental and health effects, the number of individuals exposed, and reasonable estimates of the number who will be exposed in their places of employment and the duration of such exposure.²²³

Pursuant to its authority under Section 8(a), the EPA issued its Inventory Update Rule (IUR) that requires chemical manufacturers to report to it once every five years the identity of and basic manufacturing information on chemicals processed or imported in quantities of more than 25,000 pounds. In addition, basic domestic processing and use information is required for chemicals imported or manufactured in quantities of 300,000 pounds or more.²²⁴

214 See EPA, Nanoscale Material Stewardship Program, available at <http://www.epa.gov/oppt/nano/stewardship.htm> (listing participating companies and trade associations and the nanoscale materials covered by the reporting).

215 EPA (2009a: 9).

216 Ibid. at 27.

217 Ibid. at 28.

218 See e.g. Denison (2009b).

219 General Services Administration, View Rule, Multiwall Carbon Nanotubes, available at <http://www.reginfo.gov/public/do/AgendaViewRule?pubId=200904&RIN=2070-AJ47> (accessed 4 August 2009).

220 15 U.S.C. § 2607(c).

221 Ibid. § 2607(e).

222 See Environmental Defense Fund (2007: 22) (addressing the small manufacturer exemption).

223 15 U.S.C. § 2607(a); see also EPA (2009d) (explaining that 'Section 8(a) regulations can be tailored to meet unique information needs (e.g., via chemical-specific rules) or information can be obtained via use of 'model' or standardized reporting rules,' such as the 'Preliminary Assessment Information Rule' (or PAIR), which requires producers and importers of a listed chemical to report certain site-specific information on a two page form').

224 40 C.F.R. § 710.52.

Reporting is not required for chemicals manufactured or imported 'solely in small quantities for research and development'.²²⁵ IUR data, such as the identity of a chemical substance, the site identity, production volume, and other data, can be designated as CBI by the manufacturer. Accordingly, the agency protects this information from disclosure when it aggregates IUR data for public use.²²⁶

The EPA is also authorized to issue rules that require chemical companies to submit lists or copies of existing health and safety studies. By 2007, it had used this authority approximately 50 times for 1,000 chemicals.²²⁷

Finally, TSCA provides the agency with subpoena authority, although it rarely is used. It can require witness testimony and the production of reports, papers, documents, answers to questions and other information.²²⁸

Regulatory actions specific to nanomaterials. The EPA stated recently in assessing the results of its voluntary programme that it 'will consider how to best apply regulatory approaches under TSCA section 8(a) to address the data gaps on existing chemical nanoscale material production, uses and exposures'.²²⁹ Furthermore, it has received reports related to nanomaterials under section 8(e), which, as discussed above, requires manufacturers to report to it substantial risk of injury to health or the environment. Many of the details are unavailable to the public, however, because the information is protected as confidential business information.²³⁰

(d) Confidential business information

Information that firms are required to submit to the EPA under TSCA may contain commercially sensitive information, such as information about new products, new technologies and manufacturing schedules. TSCA seeks to protect this information by prohibiting the EPA from disclosing CBI except in very limited circumstances.²³¹ These exceptions include disclosure when necessary to protect health or the environment against an unreasonable risk of injury.²³² The statute does not contain an exception for disclosure to foreign (or state, local or Tribal) governments; however, CBI may be shared with other countries' governments in certain notices of regulatory action taken against chemicals exported to other countries.²³³

The statute also specifically states that it 'does not prohibit' the disclosure of health and safety studies submitted for chemicals that are: 1) offered for commercial distribution; or 2) that are subject to testing under Section 4 or the PMN process. The statute tempers this provision by stating that it does not authorize the release of any data which disclose processes used in the manufacturing or processing or that disclose the portion of a chemical mixture that is comprised of any specific chemical in the mixture.²³⁴

In practice, companies claim as CBI substantial amounts of information that they submit under TSCA and, therefore, the information is not available to the public. As noted earlier, no fewer than 95 per cent of all pre-manufacture notices contain some CBI assertion.²³⁵ According to the Government Accountability Office: 'chemical companies claim much of the data submitted as confidential ... [a]lthough EPA has the authority to evaluate the appropriateness of these confidentiality claims, EPA states that it does not have the resources to challenge large numbers of claims'.²³⁶

As a result, the CBI provisions in the statute and the manner in which they have been implemented have both been subject to substantial criticism. In 2007, the GAO recommended that Congress consider amending TSCA to:

- *clarify that health and safety data cannot be claimed as confidential business information;*
- *require substantiation of confidentiality claims at the time that the claims are submitted to EPA;*
- *limit the length of time for which information may be claimed as confidential without reaffirming the need for confidentiality;*
- *establish penalties for the false filing of confidentiality claims; and*
- *authorize states and foreign governments to have access to confidential business information when they can*

225 Ibid. § 710.30.

226 Ibid. § 710.58; see also EPA (2008b).

227 15 U.S.C. § 2607(d); see also GAO (2007: 10).

228 15 U.S.C. § 2610(c); see also Greenwood (2009: 10039) (noting that EPA has 'virtually ignored' its subpoena power under Section 11).

229 EPA (2009a: 28).

230 See e.g. EPA, 8(e) and FYI Submissions Received October 2008, available at <http://www.epa.gov/opptintr/tscas8e/pubs/8emonthlyreports/2008/8eoct2008.htm> (accessed 6 July 2009); see also Denison (2008c).

231 See e.g. 40 C.F.R. §§ 704.7, 707.75, 710.58, 712.15, 716.55, 717.19, 720.80, 720.85; 720.87, 720.90, 720.95, 790.7 (EPA has issued numerous regulations that implement the statutory requirements and processes that must be used by manufacturers in making CBI claims and the procedures EPA must follow if it seeks to disclose CBI).

232 15 U.S.C. § 2613.

233 40 C.F.R. §§ 707.70, 707.75; see also GAO (2005: 13–15).

234 15 U.S.C. § 2613.

235 GAO (2005: 32); GAO (2007: 8).

236 GAO (2005: Cover Page).

*demonstrate to EPA that they have a legitimate need for the information and can adequately protect it against unauthorized disclosure.*²³⁷

These concerns are echoed by non-governmental organizations. As explained by the Environmental Defense Fund:

*Although health and safety studies and associated data are not eligible for CBI protection, chemical identity can be eligible. This allowance can lead to perverse outcomes, such as that a chemical's adverse effects on mammalian reproduction must be disclosed but identification of which chemical causes the effect may be kept a secret.*²³⁸

The chemical industry emphasizes the critical importance of protecting CBI, because of the rapidly developing and highly competitive nature of the industry.²³⁹ In recent Congressional testimony the President of the American Chemistry Council testified, however, that 'EPA should have the authority to share appropriate confidential business information with state, local and select foreign governments when it is relevant to a decision on chemical safety and when there are appropriate safeguards against inappropriate disclosure.'²⁴⁰

4.1.2 The Federal Insecticide, Fungicide and Rodenticide Act (FIFRA)

Chemicals that are pesticides are regulated separately under FIFRA. Pesticides are defined under the statute as substances or mixtures of substances intended for preventing, destroying, repelling or mitigating pests. Pesticides include not only insecticides, but also herbicides, fungicides and other pest control substances.²⁴¹ The EPA has stated that pesticide products that use nanomaterials will be subject to FIFRA review and registration requirements.²⁴²

Pesticide registration. FIFRA requires that new pesticides, with limited exceptions, be registered with the EPA before they can be distributed or sold.²⁴³ To register a pesticide, an applicant is required to submit certain information, including the pesticide label and directions for use, the formula, and a description of the test data upon which the claims are based, citations to data in the public literature, or data previously submitted to the EPA. Regulations issued under the statute detail the required contents of applications, which specify data required by the agency to determine that using the pesticide according to label directions will not cause unreasonable adverse effects on the environment.

In addition, the regulations require applicants to provide 'any factual information' regarding adverse effects of the pesticide on the environment that the statute requires registrants to report after a pesticide has been registered.²⁴⁴ The EPA recognizes that the FIFRA application process 'often requires the submission of extensive environmental, health, and safety data.'²⁴⁵

The EPA also recognizes that 'because nanoscale materials may have special properties, EPA's data requirements may need to be tailored to the specific characteristics of the product under consideration.'²⁴⁶ According to the agency, the 'special properties that make nanoscale materials of potentially great benefit also can present new challenges for risk assessment and decision-making'. As a result, it is 'currently examining potential hazard, exposure, policy, regulatory, and international issues that may be associated with pesticides that are a product of nanotechnology or that contain nanoscale materials'.²⁴⁷

In its analysis of the application of FIFRA to nanomaterials, the American Bar Association's Section on Environment, Energy and Resources observes that the EPA's authority to regulate 'existing' chemicals under FIFRA is 'more comprehensive' than its authorities to regulate 'new' chemicals under TSCA. This is in part because FIFRA expressly provides the EPA authority to require the generation of data necessary for risk assessment.²⁴⁸

The EPA may register a pesticide either unconditionally or with conditions. It must grant an unconditional

237 GAO (2007: 41–42).

238 Denison (2007: VII-1). (Footnote omitted.)

239 Grad (1973: 4B59); see also American Chemistry Council (2007).

240 See Committee on Energy and Commerce, US House of Representatives (2009) (statement of Cal Dooley).

241 7 U.S.C. § 136(u); see also EPA, About Pesticides, available at <http://www.epa.gov/pesticides/about/index.htm> (accessed 6 July 2009).

242 EPA (2007a: 66).

243 7 U.S.C. § 136a(a).

244 40 C.F.R. § 152.50; see also 7 U.S.C. § 136d(a)(2).

245 EPA (2007c).

246 EPA (2009f).

247 Ibid.

248 American Bar Association (2006: 5); see also Davies (2007: 26) (stating that '[i]n contrast to TSCA, it is clear that in almost every case a nanopesticide will be considered "new" and will have to go through the FIFRA registration process... However, EPA probably will need to make some changes in the data it requires to be submitted for registration, and perhaps it will need to modify or add to other regulations to deal with nanopesticides...').

registration if it makes certain determinations based on the application materials submitted. These determinations include, but are not limited to: 1) the pesticide 'will perform its intended function without unreasonable adverse effects on the environment'; and 2) 'when used in accordance with widespread and commonly recognized practice it will not generally cause unreasonable adverse effects on the environment.'²⁴⁹

The statute defines 'unreasonable adverse effects on the environment' to include: 1) any unreasonable risk to man or the environment, taking into account the economic, social, and environmental costs and benefits of the use of any pesticide, or 2) a human dietary risk from residues that result from a use of a pesticide in or on any food inconsistent with the standard under section 408 of the Federal Food, Drug, and Cosmetic Act.²⁵⁰

The agency specifies the approved uses and conditions of use that must be set out on the product label, including safe methods of pesticide storage and disposal. Furthermore, the EPA may classify and register a pesticide product for general or restricted use. It may restrict the use of a pesticide because it determines that it is necessary to protect the pesticide applicator or the environment. Restricted-use pesticides can be applied only by or under the direct supervision of people who have been trained and certified.²⁵¹ Furthermore, as part of the registration process, if a pesticide is proposed for use on a food crop, the EPA must determine a safe level of pesticide residue, or a 'tolerance'.²⁵²

In some cases, the agency may issue conditional registrations for new pesticides while the data needed for a full analysis of the pesticide are developed. Conditional registrations are authorized in several types of cases, including for pesticides containing an active ingredient that is not contained in any currently registered pesticide. The registration only may be issued, however, for a period reasonably sufficient for the generation and submission of required data. Such registrations are conditional upon the EPA receiving the required data and the data not meeting or exceeding regulatory risk criteria. In addition, a conditional registration of this type may only be granted if the EPA determines that use of the pesticide during the designated period will not cause 'any unreasonable adverse effect on the environment and that use of the pesticide is in the public interest'.²⁵³

The EPA reports that it has 'met with several companies to discuss requirements for some specific nanoscale materials being considered for use as pesticides. No formal applications, however, have been submitted'.²⁵⁴

In March 2008, however, the agency's Region 9 office issued a \$208,000 fine against the computer company IOGEAR for violations of FIFRA that involved a nano-based pesticide. According to the EPA, the company had failed to register as pesticides nano-silver products designed to repel germs prior to distribution, and had made unsubstantiated claims about their effectiveness.²⁵⁵ Although the enforcement action involved a pesticide that contained nanomaterials, the presence of nanomaterials was not the basis of the action. Rather, the action was brought for failure to register a pesticide and for unproven claims about its effectiveness. Specifically, the EPA has clarified that: 'not all products containing silver, whether nanoscale or not, are pesticides ... [but any] product containing silver – in any form – that makes claims to control pests must first be evaluated and registered by EPA to ensure it meets FIFRA human health and environmental safety standards before it can be distributed or sold'.²⁵⁶

A few months later, in May 2008, the International Center for Technology Assessment (ICTA) and a coalition of consumer and environmental groups filed a petition with the EPA, asking it to review approximately 260 nano-silver products under FIFRA.²⁵⁷ The petition included the request that the EPA classify nano-silver as a pesticide, issue 'stop sale, use, or removal orders' for unapproved nano-silver products, and develop labelling and registration requirements specific to nano-silver products.²⁵⁸ On 19 November 2008, the EPA made the petition available for public review and comment.²⁵⁹

249 7 U.S.C. § 136a(c)(5)(C)–(D). In addition, EPA must determine that the pesticide's 'composition is such as to warrant the proposed claims for it,' and 'its labeling and other material required to be submitted comply with the requirements' of FIFRA. See *ibid.* § 136a(c)(5)(A)–(B).

250 *Ibid.* § 136(bb).

251 40 C.F.R. §§ 152.160–75; see also EPA, Restricted and Cancelled Uses, available at <http://www.epa.gov/pesticides/regulating/restricted.htm> (accessed 6 July 2009); Schierow (2008b).

252 Schierow (2008b); see also EPA, Setting Tolerances for Pesticide Residues in Food, available at <http://www.epa.gov/pesticides/factsheets/stprf.htm#registration> (accessed 6 July 2009).

253 7 U.S.C. § 136a(c)(7)(C).

254 EPA (2009f).

255 See EPA, US EPA Fines Southern California Technology Company \$208,000 for 'Nano Coating' Pesticide Claims on Computer Peripherals, available at <http://yosemite.epa.gov/opa/admpress.nsf/dc57b08b5acd42bc852573c90044a9c4/16a190492f2f25d585257403005c2851!OpenDocument> (accessed 6 July 2009).

256 EPA (2009f).

257 International Center for Technology Assessment (2008).

258 *Ibid.*

259 EPA, Petition for Rulemaking Requesting EPA Regulate Nanoscale Silver Products as Pesticides, <http://www.epa.gov/EPA-PEST/2008/November/Day-19/p27204.htm> (accessed 3 August 2009).

Post-registration reporting requirements, cancellation and suspension. The statute contains a host of provisions that allow the EPA to address environmental, health and safety concerns that may arise after a pesticide is registered. It requires registrants of pesticides to submit adverse effects information about their products to the agency, which has issued regulations and guidance documents that outline for registrants details on ‘what, when and how’ to report this information.²⁶⁰ As some observers have noted, however: ‘Given the inherent uncertainties currently associated with the toxicological and environmental properties of nanoscale materials, there would appear to be a need for additional EPA guidance’ with respect to the application of the adverse effects reporting requirement for nanoscale materials.²⁶¹

The EPA may take steps to cancel or change a pesticide’s registration if it ‘appears’ that a pesticide or its labelling does not comply with statutory requirements or ‘when used in accordance with widespread and commonly recognized practice, generally causes unreasonable adverse effects on the environment’. The EPA is required, however, to provide notice to the public and the registrant. It must also consider certain factors in making a determination to issue a cancellation notice, including the impact on ‘production and prices of agricultural commodities, retail food prices, and otherwise on the agricultural economy’. In addition, the agency must notify the Secretary of Agriculture and give the Secretary an opportunity to provide comments.²⁶²

The statute also provides the EPA with the authority to issue an immediate ban on the production or distribution of a pesticide; it may order the immediate suspension or an emergency suspension of a pesticide if it determines the action is necessary to prevent ‘an imminent hazard’, during the time required for cancellation or a change in classification of a pesticide registration. The EPA must first provide notice that includes its findings, and then must provide an opportunity for an expedited hearing on the question of whether an imminent hazard exists. If it determines that an emergency exists that does not permit it to hold a hearing before suspending a registration, it may issue an emergency order.²⁶³

Pre-registration Experimental Use Permits (EUP) and exemptions. The EPA may issue an experimental use permit if it finds that the applicant needs the permit in order to accumulate information necessary to register a pesticide under the statute. If the use of a pesticide may reasonably be expected to result in any residue on or in food or feed, the EPA may establish a temporary tolerance level for the residue of the pesticide before issuing the experimental use permit. The EPA may subject the experimental use to conditions and time limits. If the EUP is issued for a pesticide containing any chemical or combination of chemicals that are not included in a previously registered pesticide, the EPA may require studies to be conducted ‘to detect whether the use of the pesticide under the permit may cause unreasonable adverse effects on the environment’. The results of the studies must be reported to the EPA before the pesticide can be registered.²⁶⁴

Pesticide imports and exports. Imported pesticides are subject to the same requirements of testing and registration as domestic products. The Secretary of the Treasury is required to notify the EPA and to provide samples upon request of pesticides that arrive in the US. The statute provides authority to bar the pesticide from admission into the United States if the pesticide is in violation of statutory standards.²⁶⁵

Exports of pesticides, however, are not regulated in the same way under FIFRA. Producers of exported pesticides are subject to recordkeeping requirements, certain procedural, labelling and data requirements related to the safe storage, disposal, handling and transportation of the pesticides, but producers are not subject to the registration requirements. If a pesticide is not registered in the United States, however, the exporter must obtain a statement from the foreign purchaser that acknowledges the pesticide is unregistered.²⁶⁶

Confidential business information. FIFRA provides for the protection of CBI by allowing applicants to mark and separately file data they believe to be ‘trade secrets or commercial or financial information’.²⁶⁷ The statute and regulations set out procedures that the EPA must follow if it seeks to disclose CBI under any of the exceptions set out in the statute.²⁶⁸ The statute requires that most environmental, health and safety data must be available to the

260 7 U.S.C. § 136d(a)(2); see also EPA, Adverse Effects Reporting: FIFRA 6(a)(2), available at <http://www.epa.gov/pesticides/fifra6a2/> (accessed 6 July 2009).

261 Bergeson and Hester (2008: 36–37).

262 7 U.S.C. § 136d(b).

263 Ibid. § 136d(c).

264 Ibid. § 136c.

265 Ibid. § 136o.

266 Ibid.; see also EPA (2007c).

267 15 U.S.C. § 136h(a); see also 40 C.F.R. §§ 158.33 (c), 161.33 (for each item, the submitter must cite the applicable portion of FIFRA on which the claim of confidentiality is based); *ibid.* § 172.46(d) (claims of confidentiality in experimental use permit notifications must be accompanied by ‘comments substantiating the claim and explaining why the submitter believes that the information should not be disclosed’).

268 15 U.S.C. § 136h(b); see also *ibid.* § 136h(c) (outlining the process EPA must follow prior to release of CBI).

public.²⁶⁹ It specifies, however, that the EPA may not disclose certain information related to manufacturing or quality control processes, methods for testing, detecting or measuring the quantity of deliberately added inert ingredients, and the identity or percentage quantity of such ingredients – *unless* it determines that ‘disclosure is necessary to protect against an unreasonable risk of injury to health or the environment.’²⁷⁰ In addition, CBI information concerning production, distribution, sale or inventories of a pesticide may be disclosed in connection with a public proceeding to determine whether a pesticide ‘causes unreasonable adverse effects on health or the environment, if the Administrator determines that such disclosure is necessary in the public interest.’²⁷¹

FIFRA does not specifically address sharing of information with foreign governments for purposes of regulatory coordination.²⁷² The regulations do, however, encourage submitters to include a statement that allows the EPA to share information with state and foreign governments and provides that it will inform the state or foreign government of any of the confidentiality claims associated with the information.²⁷³

4.2 EU chemicals regulation

4.2.1 REACH

(a) Background

European chemicals regulation has recently been consolidated and integrated with the creation of a single new EU Regulation on the Registration, Evaluation, Authorisation and Restriction of Chemicals (REACH).²⁷⁴ Having entered into force in June 2007, REACH is gradually replacing the patchwork of over 40 separate pieces of regulation that have hitherto covered different aspects of chemicals oversight in Europe. It has been described as the biggest piece of legislation the EU has ever undertaken,²⁷⁵ and its full impact will only be felt once all of its elements have been implemented in the coming years.

In addition, certain provisions relating to the classification and labelling of substances were previously covered by REACH but are now dealt with in a separate Regulation on Classification, Labelling and Packaging (CLP)²⁷⁶ of substances. The new CLP Regulation, which came into force in January 2009, will replace the current rules on classification, labelling and packaging of substances (Directive 67/548/EEC) and mixtures (Directive 1999/45/EC) after a transitional period. It aligns European regulation with the UN Globally Harmonized System (GHS) and will provide the general framework for the classification and labelling of substances, including nanomaterials, independently of their quantity of production.²⁷⁷

REACH and CLP are expected to play a critical role in addressing EHS risks of nanomaterials, not least because many such substances enter the market as chemical substances for use in a variety of industrial processes and products.²⁷⁸ Because of this, the application of REACH and CLP to nanomaterials, which we discuss further below, will have an important impact on the EU’s broader approach to nanotechnologies and the prospect for international coordination and convergence.

The overarching aim of REACH is to ‘ensure a high level of protection of human health and the environment including the promotion of alternative methods for assessment of hazards of substances, as well as the free circulation of substances on the internal market while enhancing competitiveness and innovation.’²⁷⁹ REACH explicitly states that it is based on the precautionary principle.²⁸⁰

269 Ibid. § 136h(d)(1) (stating ‘[a]ll information concerning the objectives, methodology, results, or significance of any test or experiment performed on or with a registered or previously registered pesticide ... and any information concerning the effects of such pesticide on any organism or the behavior of such pesticide in the environment ... shall be available for disclosure to the public’).

270 Ibid. § 136h(d)(1).

271 Ibid. § 136h(d)(2).

272 40 C.F.R. § 168.75 (regulations on the export of unregistered pesticides permit sharing of information claimed as CBI in ‘purchaser acknowledgment statements’ with the government of the importing country).

273 Ibid. § 158.33(c)(4).

274 European Commission (2006b).

275 See e.g. EurActiv, *EU environment legislation ‘slow or incomplete’, says review*, available at <http://www.euractiv.com/en/environment/eu-environment-legislation-slow-incomplete-review/article-173904> (accessed 3 August 2009).

276 European Commission (2006b); Regulation (EC) 1272/2008 of the European Parliament and of the Council.

277 The subsequent discussion focuses mainly on REACH, but the REACH and CLP regulations need to be seen as complementary in creating the overall framework for chemicals regulation in the EU.

278 The use of substances in applications covered by certain other legislations, such as cosmetics, pharmaceuticals or food, is excluded from certain REACH provisions.

279 European Commission (2006b: art. 1(1)). See also Environment Directorate-General (DG Environment), REACH, http://ec.europa.eu/environment/chemicals/reach/reach_intro.htm (accessed 3 August 2009).

280 European Commission (2006b: art. 1(3))([the] provisions [of this regulation] are underpinned by the precautionary principle).

REACH introduces several significant changes to previous regulations. These include: the scope of substances covered by the regulation has been expanded to include a wide range of substances that are manufactured, imported, used as intermediates or placed on the market, either on their own, in preparations or in articles;²⁸¹ responsibility for developing and assessing data and information on chemicals and specifying conditions needed for their safe use rests with industry – manufacturers, importers and downstream users²⁸² of chemicals – rather than regulatory authorities; and regulatory authorities are provided with a graduated approach to regulating chemicals, from the comprehensive classification and labelling system for hazardous substances to the staggered registration system of quantities of one tonne or more up to the more selective and interventionist authorization and restriction requirements for substances of very high concern. The notification of product and process oriented research and development (PPORD) to the European Chemicals Agency (ECHA) complements this system with basic information on substances in research and development.

In addition, certain implementation aspects of REACH have been centralized at the European level in an effort to promote greater consistency among Member States. The ECHA, which is located in Helsinki, Finland, was created in June 2007 to manage the registration and notification database and carry out technical, scientific and administrative roles in support of REACH. The agency's main role is to evaluate industry's data and testing submissions and to check compliance with registration requirements, but also to investigate in coordination with national authorities any chemicals with perceived risks. Furthermore, the ECHA is responsible for the dissemination and public access to information provided for in REACH and CLP, in addition to the protection of confidential business information.

The contrast between REACH and preceding EU regulations and directives is particularly evident with regard to the treatment of chemicals already on the market versus newly introduced substances. The previous system distinguished between 'existing' (on the market between 1 January 1971 and 18 September 1981)²⁸³ and 'new' chemicals (on the market after 18 September 1981)²⁸⁴ and required toxicological and ecotoxicological tests only for the latter.²⁸⁵ This meant that only limited hazard information existed for the large majority of chemicals in use, while the introduction of new, and potentially less dangerous, chemicals was often hampered by comparatively more burdensome regulatory requirements.²⁸⁶ As of today, over 100,000 chemicals are classified under the old rules as 'existing' in the European Chemical Substances Information System (ESIS), whereas only 4,381 substances are classified as 'new'.²⁸⁷ REACH seeks to address this imbalance by subjecting all chemicals to the same regulatory requirements, thereby attempting to create a more level playing field between existing and new products and to encourage greater technological innovation in chemicals.

Full implementation of REACH will take years to complete. Given the large volume of chemicals that need to be registered, REACH phases in the registration requirement over an eleven-year period, focusing initially on substances that are manufactured or imported in large quantities and those with potentially high toxicity. Substances in quantities over 1,000 tonnes per year, substances that cause cancer or mutation, or interfere with the body's reproductive function (CMRs), and substances in quantities over 100 tonnes per year that are 'very toxic' to aquatic organisms must be registered by 1 December 2010; all other relevant substances in quantities over 100 tonnes per year by 1 June 2013; and chemicals in quantities over one tonne per year by 1 June 2018. By that time, a total of 30,000 substances are expected to be registered.²⁸⁸

281 REACH applies to substances that are 'manufactured, imported, used as intermediates or placed on the market, either on their own, in preparations or in articles, unless they are radioactive, subject to customs supervision, or are non-isolated intermediates'. European Commission (2007c: 6). Exceptions include waste, substances necessary for defence purposes, polymers, substances covered by other specific legislation, such as those in food, medicinal products and biocides, and a few other substances that are considered to be either safe or inappropriate/unnecessary to register such as oxygen, glass or coal. Polymers may be subject to registration 'once a practicable and cost-effective way' to manage them has been established. EU Press Release (2007).

282 REACH imposes certain requirements on downstream users to consider the safety of their uses of substances and apply appropriate risk management measures. REACH also contains requirements for sharing of information relating to environmental, health, safety and risk management measures down and up the supply chain. A detailed description of these requirements is beyond the scope of this report.

283 Registered under their respective EINECS (European Inventory of Existing Commercial Chemical Substances) number.

284 Registered under their respective ELINCS (European List of Notified Chemical Substances) number.

285 The testing requirement for new substances applied to quantities of over ten kilograms. Exceptions existed only for so-called 'priority substances', that is, substances that were produced in very high volumes.

286 One of the important motivations behind the creation of REACH was the perception that the system of differentiating between new and existing chemicals 'did not produce sufficient information about the effects of the majority of existing chemicals on human health and the environment.' European Commission (2007c).

287 See also European Commission Joint Research Centre, European Chemical Substances Information System (ESIS), <http://ecb.jrc.ec.europa.eu/esis/> (accessed 3 August 2009).

288 Manufacturers and importers of phase-in substances had to pre-register their substances before 1 December 2008 to be able to benefit from the longer registration deadlines (2010, 2013 or 2018). Pre-registration requirements are intended, in part, to facilitate data-sharing and, therefore, reduce testing on vertebrate animals and reduce costs to industry. European Commission (2007c: 7). By 2018, a total of 30,000 substances are expected to be registered. To date, 2,750,000 pre-registrations have been filed by 65,000 companies. A total of approximately 146,000 separate substances have been pre-registered. Eva Sandberg Presentation, European Chemicals Agency, www.reach-usa.com/presentations2009/index.html (accessed 4 August 2009).

To facilitate implementation of REACH and CLP, the EU is conducting REACH Implementation Projects (RIP) in order to develop guidance documents and other materials. It has recently launched a new RIP for nanomaterials that will assess the potential need to amend existing guidance on substance identification, information requirements and chemical safety assessments for nanomaterials. The REACH Competent Authorities also created a subgroup on nanomaterials (CASG Nano) in March 2008 to address implementation issues, which is discussed in more detail below.

(b) Registration

REACH applies a 'no data, no market' principle to the commercialization of chemicals that reflects its stated aim that manufacturers, importers and downstream users 'should ensure that they manufacture, place on the market or use such substances that do not adversely affect human health or the environment'.²⁸⁹ Whereas in the past, public authorities held the primary responsibility for carrying out comprehensive risk assessment, industry now must provide data and, in many cases, assessments of chemical safety in order to register its chemical substances.²⁹⁰

Under REACH, in order to reduce the cost to industry and to reduce animal testing, data obtained by vertebrate animal testing must be shared among potential registrants of a substance, in exchange for payment. Other information must be shared upon request of a potential registrant. REACH establishes the Substance Information Exchange Forum (SIEF) to bring registrants together to share existing test data and information and agree on the generation of new test data.²⁹¹

The specific information requirements are set out in Annexes to REACH and vary according to the tonnage at which a substance is manufactured and its potential toxicity. The quantitative bands are set at 1 tonne, 10 tonnes, 100 tonnes, and 1,000 tonnes. The higher the band, or the more hazardous the substance, the more information is required. Information can be gathered through a variety of means, depending on factors detailed in REACH. These include use of existing data, modelling and testing. In order to reduce industry costs and avoid unnecessary animal testing, REACH only requires new tests when it is not possible to provide the information using a permissible alternative.²⁹²

In addition, manufacturers and importers who place a hazardous substance on the market, either on its own or contained in a hazardous mixture, or who place on the market a substance that is subject to registration under REACH are typically required to notify the ECHA of the identity, classification and labelling of the substance. The information provided must include the forms or physical states in which the substance will be placed on the market.²⁹³

REACH also applies to substances in *articles*²⁹⁴ that are produced or imported in an amount over one tonne per producer or importer per year, if those substances are intended to be released from the article during 'normal and reasonably foreseeable conditions of use'.²⁹⁵ In addition, substances of very high concern that are present in articles above a concentration limit of 0.1 per cent weight by weight and present above 1 tonne per year are covered by REACH, and safe use²⁹⁶ instructions are required, unless exposure to humans and environment can be excluded during normal conditions of use including disposal.²⁹⁷ The ECHA may require, however, the registration of a substance in an article at any time when it considers its release to pose a 'risk to human health or the environment'.²⁹⁸

Manufacturers or importers of chemical substances are required to produce a *technical dossier* that contains

289 European Commission (2006b: art. 1(3)).

290 The terms 'substance', 'preparation' and 'article' have a very specific meaning in the context of REACH. 'Substance' refers to 'a chemical element and its compounds in the natural state or obtained by any manufacturing process, including any additive necessary to preserve its stability and any impurity deriving from the process used, but excluding any solvent which may be separated without affecting the stability of the substance or changing its composition'. 'Preparation' refers to 'a mixture or solution composed of two or more substances' and 'article' refers to 'an object which during production is given a special shape, surface or design which determines its function to a greater degree than does its chemical composition'. In line with common usage and secondary literature on REACH by the European Commission, including 'REACH in Brief', European Commission (2007c), references to 'chemical substances' in this text acknowledge the above definition of a 'substance' in the REACH context.

291 European Commission (2007c: 7).

292 Denison (2007: IV-27 to IV-29) (noting that REACH allows for registrants to adapt standard testing regimes, including use of alternative methods of testing, and to waive higher-tier testing requirements without any independent evaluation of appropriateness, unless the substance is later selected by the ECHA or a Member State for evaluation, prior to which time it can be manufactured).

293 European Commission (2008i: art. 5); see also ECHA (2009a).

294 In an official publication on REACH titled *Questions and Answers on REACH*, the European Commission explains that, 'the [Chemical Safety Report] should also generically cover consumer use of substances as such, in preparations and in articles (e.g. plastics, textiles and toys) and subsequent waste handling.' European Commission (2007d).

295 European Commission (2006b: art. 7(1)).

296 A supplier of such articles 'shall provide the recipient [...] with sufficient information [...] to allow safe use of the article including, as a minimum, the name of that substance.' European Commission (2006b: art. 33(1)).

297 European Commission (2006b: art. 7(2)–(3)). See also European Chemicals Agency (ECHA), Guidance Fact Sheet: Requirements for Substances in Articles (2008), available at http://echa.europa.eu/doc/reach/echa_08_gf_03_articles_en_20080801.pdf (accessed 3 August 2009).

298 Decisions on whether a risk to human health or the environment exists and whether this risk is 'acceptable' or 'unacceptable' are taken in 'comitology' procedures, discussed further in footnote 316, where the Commission chairs a committee consisting of representatives of the Competent Authorities of the Member States. Scientific support can be provided by ECHA and may draw on EHS data collected through REACH.

information on the properties, uses and classifications of substances, in addition to guidance on safe use. With respect to determining the properties of a substance, REACH sets out in line with the Regulation on Test Methods (440/2008/EC) specific information requirements in its Annexes that vary in part according to the tonnage in which the substance is manufactured or imported.²⁹⁹

Manufacturers or importers of substances in quantities over 10 tonnes also are required to provide a chemical safety report together with the technical dossier.³⁰⁰ This must include a chemical safety assessment that considers not only the use of the substance on its own, but also its use in a preparation, in an article, and at all stages of the life-cycle of the substance.³⁰¹ REACH states that ‘risk management measures should be applied to ensure ... that exposure to these substances ... throughout the whole life-cycle is below the threshold level beyond which adverse effects may occur’.³⁰² Moreover, the chemical safety assessment should include: (a) a human health hazard assessment; (b) a human health hazard assessment of physicochemical properties; (c) an environmental hazard assessment; and (d) a PBT (persistent bio-accumulative and toxic) and a vPvB (very persistent and very bio-accumulative) assessment.³⁰³ However, the chemical safety report need not include consideration of human health risks from end uses of a chemical substance in food contact materials or cosmetic products, which are both covered by other regulations and directives.³⁰⁴

Information on hazardous properties and on substance classifications in the technical dossier must be submitted to the ECHA jointly by the lead registrant on behalf of other manufacturers and importers when a substance is first registered.³⁰⁵ Chemical safety reports may be, but are not required to be, submitted jointly. If the ECHA or a Member State seeks to obtain information in addition to that submitted in a registration, it must follow a specific process for requesting such information, as discussed below.

(c) Confidential business information

If manufacturers or importers of chemical substances declare some of the information they submit in their registrations to be confidential business information, they must include a justification explaining why the publication of this information might be harmful to their commercial interest.³⁰⁶ Article 118 of REACH specifically identifies the types of information the disclosure of which would normally be considered to undermine the protection of commercial interests, such as the full composition of a preparation and the precise tonnage of a substance or preparation manufactured or placed on the market.³⁰⁷ Article 118 also provides, however, that where ‘urgent action is essential to protect human health, safety or the environment’ the ECHA may disclose such information. REACH also sets out the types of information that must be made publicly available unless the party that submitted the information submits a justification that is accepted by the ECHA as to why publication would be potentially harmful to commercial interests.³⁰⁸

REACH also delineates a category of information that will be made available to the public free of charge over the Internet, which does not qualify for confidentiality protection. This includes information about classification and labelling, physicochemical data, results of toxicological and ecotoxicological studies, and guidance on safe use.³⁰⁹

Article 120 of REACH makes clear that confidential information received by the ECHA may be disclosed to another government or international organization pursuant to an agreement. The agreement must provide for any appropriate protection of the information and state that the purpose of the agreement is cooperation on the implementation or management of legislation concerning chemicals covered by REACH.³¹⁰

299 European Commission (2006b: Annex VI(5), (6)). See also European Commission (2007c: 7).

300 However, classification and labelling obligations as outlined in the ‘Dangerous Substances’ Directive (67/548/EEC) are not subject to the respective volume threshold. See Commission Directive 2001/59/EC.

301 European Commission (2006b: Annex I). Annex I further states that such a safety assessment ‘shall be based on a comparison of the potential adverse effects of a substance with the known or reasonably foreseeable exposure of man and/or the environment to that substance taking into account implemented and recommended risk management measures and operational conditions.’ Ibid., at §0.

302 European Commission (2006b: recital (70)).

303 Annex 1 of REACH on the ‘General Provisions for Assessing Substances and Preparing Chemical Safety Reports’ provides specific guidelines to all four areas of safety assessment. See European Commission (2006b: Annex I).

304 European Commission (2006b: art. 14(5)).

305 The costs for such joint registrations are shared among all registrants. Manufacturers and importers may opt out of the joint registration, however, if they face excessive costs by doing so, if they disagree with the lead registrant on the content of the registration, or if the disclosure of confidential information may lead to ‘substantial commercial damage.’ European Commission (2007c: 8). As noted, to facilitate the coordination of such joint registrations, ECHA has created the Substance Information Exchange Forum (SIEF) for use in the pre-registration phase. ECHA, SIEF, http://echa.europa.eu/sief_en.asp (accessed 3 August 2009).

306 European Commission (2006b: art. 10(a)(xi)).

307 Ibid., at art. 118.

308 Ibid., at art. 119(2).

309 European Commission (2006b: art. 119(1)).

310 Ibid., at art. 120.

(d) Evaluation

REACH provides for two types of regulatory evaluations. ECHA will perform *dossier evaluations* or completeness checks on registration materials that are submitted. It intends to conduct dossier evaluations for at least five per cent of the dossiers submitted in each tonnage band. In an effort to avoid unnecessary animal testing, it will also evaluate testing proposals from registrants.³¹¹

REACH also provides for *substance evaluation*. In coordination with Competent Authorities in Member States, the ECHA may conduct substance evaluations to clarify ‘suspicions of risks to human health or the environment’.³¹² To help implement these provisions, it will develop risk-based prioritization criteria for substance evaluation and use them to select substances for the Community Rolling Action Plan. Member States may then choose substances from the list to evaluate, but REACH does not specify the number or rate of evaluations that must be performed. Member State evaluations must be completed within twelve months. If a Member State does not prepare a draft decision that requests a registrant or downstream user to provide additional information during the twelve-month period, the evaluation is deemed closed.

Any draft decision prepared by a Competent Authority of a Member State requesting further information on a substance must either be accepted by all other Member States’ Competent Authorities, in which case the agency takes the decision, or if an agreement cannot be reached the Commission makes the decision.³¹³ The result of substance evaluations may be no action, a request to industry for further information on a substance and its safety or, as discussed further below, imposition of authorization or restriction procedures.

REACH also provides that manufacturers and importers may appeal against dossier and substance evaluation decisions to the ECHA’s Board of Appeals. REACH does not set a standard of review but states that the Board shall ‘examine whether the appeal is admissible’. In addition, any decision by the agency’s Board of Appeals or by the Commission can be appealed to the European Court of Justice.³¹⁴

(e) Authorization and restriction

Substances of ‘very high concern’ (SVHC), such as CMRs, PBTs or vPvBs, and substances posing potentially equivalent concern, may be subject to the additional process of *authorization*. Substances that are subject to authorization are listed in Annex XIV of REACH and producers or importers of such substances must apply for the authorization for ‘each use of the substance’.³¹⁵

The ‘comitology’ procedure³¹⁶ is used to determine which substances are listed and subject to authorization. The process begins with the preparation of dossiers by Member State Competent Authorities or the agency (on behalf of the European Commission); these are subject to public comment. The identified substances are considered candidates for prioritization. From the candidate list, the agency then recommends to the Commission the substances to be listed in Annex XIV.³¹⁷ In June 2009 it made its first recommendation for seven substances to be included.³¹⁸

Authorization applications must include an analysis of whether suitable alternatives to the substance exist and, if so, a substitution plan must also be provided. A substance still may be authorized if the applicant can demonstrate that risks can be adequately controlled, provided it is a substance for which a safe level can be defined. If adequate control measures are not available, or the substance is an SVHC for which no safe threshold can be assumed to exist, such substances can still be authorized if the applicant can show that the ‘socio-economic benefits of their use outweigh the risks and there are no suitable alternative substances or processes’.³¹⁹ Authorization decisions will be reviewed within a specified time period that will be set on a case-by-case basis. Furthermore, because substances of very high concern will be ‘fed into the authorization system as resources allow’, in some cases substances may be placed on the market until an authorization decision is made.³²⁰

311 European Commission (2007c: 11–12).

312 Ibid.: 12.

313 Ibid.

314 European Commission (2006b: art. 91) (decisions related to the following can be appealed to the Board: PPORD exemptions, rejections of incomplete registrations, data sharing with potential registrants and SIEF members, and dossier and substance evaluations).

315 If included in Annex XIV, specific uses of substances may, however, be exempted from authorization requirements if, for example, ‘sufficient controls established by other legislation are already in place.’ See *ibid.*, art. 58.

316 This describes the process whereby committees consisting of representatives from Member States enter a dialogue with the Commission to ‘assist’ it in implementing legislation. In some cases the European Parliament also has the right to scrutinize and oppose measures proposed by the Commission. See also Europa Glossary on Comitology, http://europa.eu/scadplus/glossary/comitology_en.htm (accessed 3 August 2009).

317 ECHA, Guidance on inclusion of substances in Annex XIV 22–27, available at http://guidance.echa.europa.eu/docs/guidance_document/annex_xiv_en.pdf (accessed 4 August 2009).

318 ECHA (2009b).

319 European Commission (2007c: 13).

320 The Commission has explained that ‘banning will not occur by default and a decision on such applications will always be taken by the Commission.... [w]here the time limit for a decision has been exceeded, article 56(1) (d) provisions apply – i.e. can be placed on the market until a decision is taken.’ European Commission (2007d).

The second regulatory intervention that REACH provides is *restriction* of chemical substances, which means that the use of the substance is either subject to conditions or prohibited. In contrast to the authorization process, the burden rests with the regulators to establish that the restrictions are needed. The ECHA or the Competent Authorities in Member States can propose restrictions by creating a dossier that demonstrates a risk to human health or the environment that must be addressed on a Community-wide basis. This dossier must be reviewed by the ECHA's Committee on Risk Assessment and its Committee on Socio-economic Analyses. If neither objects to a restriction, the Commission can, in coordination with Member States through the comitology procedure, restrict the manufacture, use and marketing of a chemical substance.³²¹

As noted, to facilitate implementation, the EU established numerous REACH implementation projects, each of which includes the development of guidance documents³²² and other materials. Its project on 'Guidance Documents for Industry' includes Guidance Documents on when and how to conduct a socio-economic analysis under REACH³²³ and on the process to be followed when applying for an authorization for manufacture and use of a substance of very high concern.³²⁴ Similarly, as part of its implementation project on 'Guidance Documents for Authorities', the Commission plans to develop a Guidance Document on the criteria for prioritization of substances for its evaluation process and for the preparation of dossiers for proposed restrictions.³²⁵

4.2.2 Pesticides

Pesticides are covered by the Plant Protection Products (PPP) Directive (91/414/EEC) and by the Biocidal Product Directive (BPD) (98/8/EC), both of which are currently being revised. They are regarded as registered under Article 15 of REACH, and will be exempt from registration requirements until 1 December 2010.³²⁶

All pesticides for use in plant protection, including agricultural production, fall under the PPP Directive, which includes a positive list of approved substances (Annex I). In order for a substance to be included on this list, it must be subject to toxicological and ecotoxicological tests. This occurs in four stages. The applying company first submits a dossier to a Member State, which in turn evaluates the application and produces a report for further consideration by the European Food Safety Authority. The EFSA assesses the report in consultation with all Member States and passes it on to the Commission. The Commission then produces a proposal for inclusion or non-inclusion.

Maximum residue levels (MRLs) of pesticides in food and feed are regulated by Regulation EC 396/2005. This regulation lists, for example, the products subject to MRLs and pesticides for which a default limit other than 0.01 mg/kg will apply.

The Biocidal Product Directive covers 23 biocidal product types, ranging from disinfectants to preservatives to pest controls. The active substances³²⁷ of biocidal products are subject to authorization in a positive list (Annex I). In order for a substance to be included on this list, applicants must submit a dossier that includes information on physical and chemical properties; methods of detection and identification; toxicological and ecotoxicological profiles; and measures necessary to protect humans, animals and the environment (Annex IIA). Once substances are included in Annex I according to the requirements outlined in Annex IIA, specific products in which these substances are used are also subject to authorization. For this second step, an applicant must submit a dossier with similar requirements (e.g. toxicological and ecotoxicological data), as discussed above and outlined in Annex IIB. The technical evaluation of these dossiers is carried out by Member States' Competent Authorities, and the inclusion of substances in Annex I and the authorization of biocidal products are decided by the Commission together with Member States. The Biocidal Product Directive is also currently under review to improve data protection and data-sharing, and to simplify procedures and data requirements.

321 European Commission (2006b: art. 68).

322 Most of the Guidance Documents already have been prepared, including guidance to aid local authorities in prioritizing substances for authorization. See European Chemicals Agency, *Guidance on inclusion of substances in Annex XIV* (2008), available at http://guidance.echa.europa.eu/docs/guidance_document/annex_xiv_en.pdf?vers=12_08_08 (accessed 3 August 2009); European Chemicals Agency, *Guidance on inclusion of substances in Annex XV* (2007), available at http://guidance.echa.europa.eu/docs/guidance_document/restriction_en.pdf?vers=19_09_08 (accessed 3 August 2009).

323 The EC states that this document will 'strive for making [socio-economic analysis or] SEA outputs as comprehensive, consistent and user-friendly for the SEA committee as possible taking into account the broad range of chemicals, uses, alternatives, etc. to be analysed and the various parties and processes to be covered by the guidance.' European Commission (2008b).

324 Ibid. Topics of additional documents under the implementation project include, but are not limited to: downstream user requirements, substances in articles, and substance identity.

325 See European Commission, REACH Implementation Project 4: Guidance Documents for Authorities, http://ec.europa.eu/environment/chemicals/reach/preparing/rip_4_en.htm (accessed 3 August 2009).

326 European Commission (2006b: art. 23).

327 An active substance in the Biocidal Product Directive is defined as '[a] substance or micro-organism including a virus or a fungus having general or specific action on or against harmful organisms.' European Commission (1998: art. 2).

4.2.3 REACH and nanoscale substances

Although REACH does not explicitly address nanoscale substances, it is clear from the above discussion that the new European chemicals regulation will play an important role in addressing nanotechnology-related EHS risks. What is less clear, however, is how specific REACH provisions will address existing and emerging nanoscale substances. Given existing scientific knowledge gaps and the fast-changing nature of nanotechnology research and commercialization, this will depend not least on how the EU's new chemicals regime will be implemented in the coming years. The development of guidance documentation for REACH implementation will therefore be an important factor,³²⁸ as will the future review of the regulation to close potential gaps in the regulatory oversight for nanoscale substances.

As discussed in more detail below, one of the problems in discussing how REACH applies to different nanomaterials³²⁹ – and especially how this compares with the situation in the United States – is the fact that REACH has been in force for just two years. It introduces new and innovative regulatory principles that differ in important ways from earlier regulations and from corresponding regulations in other countries, but we have only limited experience with its implementation and how its principles apply particularly to nanomaterials. The European Commission has published a number of documents to address some of these uncertainties, but existing ambiguities inevitably leave scope for interpretation and debate among experts and stakeholders, as we have discovered in our research interviews.

It is also important to note that, as is the case in most EU-level regulation, REACH contains general provisions that require detailed technical implementation guidelines. In order to develop preliminary advice in this regard, as noted earlier, the European Commission established in March 2008 the REACH Competent Authorities Subgroup on Nanomaterials (CASG Nano). The work programme of this subgroup extends until 2012, at which time it is expected to have resolved most of the remaining questions as to how exactly REACH will apply to nanomaterials.³³⁰ CASG Nano is to provide additional details on substance identification, on the preparation of registration dossiers for nanomaterials, and on general information and testing requirements. In addition, some industry groups have already issued their own guidelines on how to fulfil statutory requirements in REACH.³³¹

The discussion of how REACH applies to nanomaterials generally focuses on two questions: first, whether it covers nanomaterials from a legal point of view (i.e., whether any gaps exist); and second, whether and how it can be successfully implemented with regard to potential EHS risks associated with nanomaterials. These two questions can be separated for analytical purposes but are, of course, closely related. For in practice the question of regulatory coverage and gaps depends crucially on how existing legal provisions are being implemented, particularly in context of a rapidly evolving scientific field and uncertainties with regard to the identification of nanoscale substances and associated risks.

With regard to the first question, general agreement exists among experts that nanomaterials are broadly covered by REACH, despite the fact that it does not explicitly mention nanomaterials. The European Commission, in its 2008 regulatory review, states unambiguously that ‘nanomaterials are covered by the “substance” definition in REACH’ and are thus subject to the same regulations as other chemical substances.³³² This statement is supported by the broad definition of a substance, which is taken to mean ‘a chemical element and its compounds in the natural state or obtained by any manufacturing process.’³³³

REACH holds registrants responsible for updating the registration dossier whenever the composition, use, knowledge of risks or classification and labelling of a substance changes (Article 22). This, according to the European Commission, means that ‘when an existing chemical substance, already placed on the market as a bulk substance, is introduced on the market in a nanomaterial form (nanoform), the registration dossier will have to be updated to include specific properties of the nanoform of that substance’. The Commission further notes that ‘the risk management measures and operational conditions will have to be communicated to the supply chain.’³³⁴ Similarly, CLP (Article 15) typically requires a new evaluation of the classification of a substance when a manufacturer, importer or downstream user becomes aware of new scientific or technical information or makes a change in the composition of a hazardous mixture.

328 See European Commission (2008a: 9).

329 Following the terminology proposed by CASG Nano, the term ‘nanomaterial’ is used in this report to refer to all manufactured nano-sized and nanostructures materials and thereby also to substances and forms of substances at nanoscale as defined by REACH.

330 The most recent progress report on the work of the subgroup was published on 16 December 2008: Follow-up to the 6th Meeting of the REACH Competent Authorities for the implementation of Regulation. European Commission (2008c).

331 See e.g. German Chemical Industry Association (VCI), Responsible Production and Use of Nanomaterials (a collection of guidance documents), <http://www.vci.de/default2~cmd~shd~docnr~122306~rub~809~tma~1~nd~.htm#dwnldstbl> (accessed 3 August 2009).

332 European Commission (2008a: 4).

333 European Commission (2006b: art. 3(1)). The REACH Competent Authorities endorsed, on the basis of a proposal from CASG Nano, the first document concerning *Nanomaterials in REACH* on 15–16 December 2008. European Commission (2008c). It contains advice on how to deal with nanomaterials in each step of REACH.

334 European Commission (2008a: 4).

While the substance definition provides broad coverage of nanomaterials, the implementation of REACH and CLP will play a critical role in determining how comprehensive this coverage will be. Further work is needed on reviewing existing or creating new guidance documents with regard to nanomaterials. The Commission has acknowledged this, and the CASG Nano report of December 2008 states that

*further work is needed to provide guidance for substances at nanoscale. In particular, the question needs to be clarified in which cases a nanomaterial is to be considered as a separate substance and in which cases it should be considered as a particular form of a bulk substance. As part of the preparations for such guidance, the Commission services are currently preparing a separate document in co-operation with the REACH Competent Authorities and its subgroup on nanomaterials.*³³⁵

A further question that has arisen as REACH is being implemented is the quantitative threshold that serves as a trigger for the Regulation's registration requirement. This requirement applies to a chemical substance produced by a company only if the total production or import quantity is above 1 tonne per year. While relatively unproblematic for conventional chemicals, this quantitative threshold raises the possibility that producers of newly introduced nanoscale substances are not required to register the chemical in nanoform and provide information that would be relevant to risk assessment. Because REACH's data requirements increase with growing production or import quantity, there is concern that the minimal requirements for low-quantity chemicals may not provide sufficient information to adequately evaluate a nanomaterial's risks. Several of our interviewees have raised this question as an area of concern.

Similar questions have been raised in the CASG Nano by stakeholders as to whether the current 1 tonne threshold for registration, which was designed primarily for 'traditional' chemical substances, allows authorities to gather data adequately on certain nanomaterials.

In determining the quantity of a nanomaterial, however, the total quantity of the substance manufactured – in both bulk and nanoscale form – is counted for purposes of calculating whether the quantitative threshold is triggered.³³⁶ Industry representatives have pointed out that most nanomaterials currently on the market are also on the market in bulk form in quantities above critical thresholds, and would thus be covered by statutory requirements in REACH. Nevertheless, the European Commission acknowledged that it will need carefully to monitor the implementation of REACH and that current provisions such as quantitative triggers 'may have to be modified' in the light of experience with evolving implementation.³³⁷

The threshold question under REACH is of particular importance as it may affect the generation of relevant data that are to be used in other regulatory contexts, including cosmetics, environmental protection and worker safety. Because REACH will be an important first-step method of gathering relevant data that inform the risk assessment process throughout the life-cycle of nanomaterials, any gaps in its coverage of nanomaterials are likely to become an important issue in future regulatory review.

The importance of closing such knowledge gaps about the development and commercial use of nanomaterials has been recognized by European authorities, and has led to a number of national initiatives to provide a more comprehensive information base. In the UK, the Department for Environment, Food and Rural Affairs (DEFRA) introduced the Voluntary Reporting Scheme (VRS) for Engineered Nanoscale Materials³³⁸ in 2006, Europe's first such scheme. Since the end of the scheme's two-year pilot phase in September 2008, DEFRA has been considering how to develop a future reporting scheme, not least since the voluntary project received only twelve submissions, representing about a third of the companies currently manufacturing nanomaterials in the UK.³³⁹ Germany and Denmark have conducted targeted surveys of nanomaterials use that have obtained useful information, but against the background of the lack of comprehensive reporting requirements, the French government is considering taking steps to introduce a mandatory reporting scheme.³⁴⁰

Apart from the comprehensiveness of reporting requirements, the question of delays in producing relevant data has also raised concerns among some stakeholders about the appropriateness of REACH provisions for the purposes

335 European Commission (2008c: 10). On 15–16 June 2009 the Competent Authorities for REACH and CLP (CARACAL) launched a specific REACH implementation project (RIP) addressing issues related to substance identification, information supply and chemical safety assessment under CASG Nano. No documents for this RIP were publicly available at the time of writing (July 2009).

336 European Commission (2008c: 6).

337 European Commission (2008a: 3).

338 See DEFRA, Nanotechnology-policy activities, <http://www.defra.gov.uk/environment/nanotech/policy/index.htm> (accessed 3 August 2009).

339 See Advisory Committee on Hazardous Substances (ACHS), Draft Minutes of the 31st Meeting of the ACHS held on 25/11/08, available at <http://www.defra.gov.uk/environment/chemicals/achs/081125/minutes081125.pdf> (accessed 3 August 2009); see also DEFRA, *UK Voluntary Reporting Scheme for Engineered Nanoscalematerials*, available at <http://www.defra.gov.uk/environment/nanotech/policy/pdf/vrs-nanoscale.pdf> (accessed 3 August 2009).

340 See Mayer Brown, *EU Competition – Brussels Client Alert: France might take the lead on nanotechnology regulation*, available at <http://www.mayer-brown.com/publications/article.asp?id=6317&nid=6> (accessed 3 August 2009).

of nanotechnology oversight. Our research indicates that for at least some stakeholders, the question of *when* and in what *form* certain data will be available is a critical issue as well as *whether* it will be available. As mentioned above, REACH operates a graduated system of deadlines by which different types of chemical substances need to be registered. Substances that have been manufactured in large quantities and those with potentially high toxicity are given highest priority for registration by 1 December 2010, with chemicals in quantities over 100 tonnes requiring registration by 1 June 2013, and chemicals in quantities over one tonne needing to be ‘phased in’ by 1 June 2018.

The question of when nanoscale substances are due to be registered depends in part on whether there is an equivalent bulk substance and, if so, how it is categorized under REACH (i.e. as phase-in or non-phase-in substance).³⁴¹ As described earlier, REACH requires data-sharing and preparation of a joint registration which is submitted to ECHA by the lead registrant the first time a chemical is registered. Thus, when a nanoscale substance has a bulk counterpart that is produced in high quantities or is potentially of high toxicity, the registration materials that address the bulk and nanoscale versions of the substance will be due as early as December 2010.

With regard to reporting timelines, but also data requirements, an important question is, therefore, whether nanomaterials and their counterparts in bulk form should be considered one and the same substance. In terms of coverage under REACH, substances are defined according to their chemical structure, purity, name (IUPAC (International Union of Pure and Applied Chemistry) and CAS (Chemical Abstracts Service)) and the supporting spectral and analytical data. The European Commission, however, points out that ‘the fact that a substance has different properties can in itself not be used to decide if it is a new substance’³⁴² and leaves open the possibility of extending the identification of a substance to include parameters such as particle size or geometry.³⁴³ The introduction of particle size as a criterion may lead to a clearer distinction between nano-scale substances and bulk substances in some cases. However, further criteria may be needed if more complex nanomaterials are to be differentiated from chemically similar – but functionally different – bulk substances.

The Commission thus recognizes the need to clarify certain aspects of how REACH applies to nanomaterials. In its December 2008 report, CASG Nano reiterates a statement by the Commission Services and Member States Competent Authorities that ‘[n]anomaterials having specific properties may require a different classification and labelling compared to the bulk material, also when the nanoform is derived from a bulk substance’.³⁴⁴ Moreover, ‘the question needs to be clarified in which cases a nanomaterial is to be considered as a separate substance and in which cases it should be considered as a particular form of a bulk substance’.³⁴⁵

The question of substance identification is of course of great practical relevance. For instance, the Commission recently amended Annex IV of REACH (substances for which sufficient information is known to be considered to cause minimum risk) through Regulation EC 987/2008 to remove carbon and graphite from the list of substances that are exempted from registration ‘due to the fact that the concerned EINECS (European Inventory of Existing Commercial Chemical Substances) and/or CAS numbers in Annex IV are used to identify forms of carbon or graphite at the nano-scale, which do not meet the criteria for inclusion in this Annex VI’.³⁴⁶ This decision was taken against the background of rising concerns on the hazards associated with certain forms of carbon nanomaterials, and underlines the importance of distinguishing between chemical substances in nano and bulk form, with regard to potential hazards to human health and the environment.

A further, and widely discussed, concern that regulators face in the implementation of REACH and CLP is the need to adjust current testing methods or develop new ones in some cases to detect specific hazards associated with certain nanomaterials. The European Commission’s Scientific Committee on Emerging and Newly Identified Health Risks (SCENIHR) has raised this concern in a number of opinions published since 2005.³⁴⁷ In its most recent opinion of January 2009, SCENIHR concludes again that ‘[o]ne of the main limitations in the risk assessment of nanomaterials is the general lack of high quality exposure data both for humans and the environment ... [and that] knowledge on the methodology for both exposure estimations and hazard identification needs to be further developed, validated and standardised’.³⁴⁸ This, of course, is a more generic problem in nanotechnology risk assessment, which concerns regulators world-wide. SCENIHR did recognize, however, that ‘based on discussions in OECD and ISO working groups, a consensus is now emerging on the physical-chemical properties of nanoparticles that need to be addressed in the risk assessment process of nanomaterials’.³⁴⁹

CASG Nano recognized that the principles and approaches to risk assessment discussed in the REACH guidance on information requirements and chemicals safety assessment, although ‘considered to be applicable’, do not yet address

341 European Commission (2008c).

342 Ibid.: 7.

343 Ibid.

344 Ibid.: 8.

345 Ibid.: 11.

346 European Commission (2008d).

347 See e.g. SCENIHR (2006); SCENIHR (2007); and SCENIHR (2009).

348 SCENIHR (2009: 4).

349 Ibid.: 14.

specific properties of substances at nanoscale and ‘will need further adjustments to be able to fully assess the information related to substances at the nanoscale/nanoform, to assess their behaviour and effects on humans and the environment, and to develop relevant exposure scenarios and risk management measures’. It further recognized that to determine ‘specific hazards associated with substances at the nanoscale, current test guidelines may need to be modified’³⁵⁰ and that ‘current risk assessment procedures may require modification for nanomaterials both regarding test methods for hazardous identification and exposure assessment’.³⁵¹ Thus, until revised and specific test guidelines for substances at the nanoscale exist, registrants will need to carry out toxicity testing, ‘according to already existing guidelines unless they have been shown to be inadequate and/or by corresponding test methods complying with the conditions laid down in ... REACH’.³⁵²

4.3 Comparing US and EU approaches

This section provides a comparative analysis of the United States and EU approaches to nanoscale materials under their respective chemical regulatory frameworks. It begins by highlighting key factors that should be considered in comparing the two approaches. The comparative analysis is not comprehensive, but focuses on several important aspects of the regulatory programmes: registration/notification requirements, information and data collection, and regulatory controls.

To compare how the regulatory systems would work in practice, a simple hypothetical scenario is added to highlight the potential differences in regulatory approaches. A hypothetical scenario is particularly useful because REACH is in the early stages of implementation. This section focuses on the laws and regulations that apply to a range of industrial chemicals, as opposed to those specifically for pesticides, because TSCA and REACH are likely to govern a wider range of nanoscale materials. Furthermore, stakeholders interviewed for this project expressed significant interest in a comparative analysis of REACH and TSCA because of the perceived significance of the new but untested policies and regulatory tools embodied in the former.

4.3.1 Key factors

Clear differences exist between the REACH and TSCA regulatory schemes. These disparities, discussed below, are well recognized.³⁵³ Before examining these differences, it is important to view the comparative analysis of the two systems in a broad context.

First, REACH is new. Implementation of its policies and regulatory tools is only just beginning. Accordingly, any comparison between the two regulatory systems must recognize that there is a long track record of TSCA implementation that allows for a more thorough assessment of how that system works in practice, while such an evaluation is not yet possible with respect to REACH.³⁵⁴ At this stage, we rely primarily on legal authorities and stated policy objectives in analysing REACH. As with any new programme, many implementation challenges lie ahead, some of which could bear on the regulation of nanoscale materials. One example is the application of tonnage thresholds to nanoscale materials. Other implementation issues affect all chemicals regulated under REACH and will therefore also influence the regulation of nanoscale materials. These issues include how to conduct a socio-economic analysis in the context of reviewing substances of very high concern, prioritize substances for evaluation by the EC, and prepare dossiers for proposed restrictions.³⁵⁵

Second, although a track record exists under TSCA for regulating chemicals generally, it is far more limited for nanomaterials. Until recently, there was only minimal information available to the public about EPA regulatory action regarding specific nanomaterials, and that information is still limited because of claims of confidential business information. Furthermore, the EPA’s implementation approach could change in significant ways in coming years, particularly under the Obama administration, as regulators gain more experience in addressing nanoscale materials. For example, the EPA could continue to shift its emphasis from voluntary to mandatory reporting of EHS data under TSCA,³⁵⁶ or it could take action on the currently pending petition on nanosilver.³⁵⁷

350 European Commission (2008c: 11).

351 Ibid.

352 Ibid.

353 See e.g. GAO (2007); see also Farber (2008); Applegate (2008).

354 GAO (2007: 30).

355 See e.g. European Commission (2008b); see also European Commission, *REACH Implementation Project 4: Guidance Documents for Authorities*, http://ec.europa.eu/environment/chemicals/reach/preparing/rip_4_en.htm (accessed 7 July 2009).

356 EPA (2009a: 28).

357 See EPA, *Petition for Rulemaking Requesting EPA Regulate Nanoscale Silver Products as Pesticides; Extension of Comment Period*, <http://www.epa.gov/fedrgstr/EPA-PEST/2009/January/Day-14/p622.pdf> (accessed 7 July 2009).

Third, it is possible that TSCA will be amended just as REACH implementation is gearing up. Although legislative reform may not reach completion in the current Congress, the GAO has identified the chemicals programme as a high-risk area in need of reform³⁵⁸ and hearings are under way in key congressional committees.³⁵⁹ Legislation was introduced in the last Congress and will be re-introduced in the current one.³⁶⁰ The new EPA Administrator has identified toxic chemicals as a top priority for the President.³⁶¹ In addition, prominent non-governmental organizations have stepped up their repeated calls for reform. The confluence of these factors, as well as the enactment of REACH, coupled with the data gap challenges presented by nanoscale materials, may produce the political momentum needed to achieve legislative reform.³⁶² Some of these reforms could result in a statute that is more consistent with REACH, although the likelihood and substance of such reform are difficult to predict at this juncture.

Fourth, neither system is insular or completely independent. For example, multinational companies that operate in both the EU and US are subject to both regulatory systems and may choose to take similar approaches to the manufacture, use and distribution of their chemicals that contain nanomaterials.³⁶³ Furthermore, because EU importers are subject to REACH requirements, in some cases they may rely on their suppliers, including US exporters, to provide hazard data and safe use information required for registration.³⁶⁴

Furthermore, in addition to data generated through the projects of the OECD, data generated by companies under either system or by other entities, such as university laboratories, may ultimately be factored into regulatory requirements and decisions under both systems. For example, as discussed above, companies are required to report any 'reasonably ascertainable' information, including known EHS studies, as part of the TSCA pre-manufacture notice process, which presumably will include any publicly disclosed studies that are submitted pursuant to the REACH registration process.³⁶⁵ Dossiers prepared by industry for REACH registration similarly are required to incorporate 'available information from assessments carried out under other international and national programmes',³⁶⁶ which presumably includes any information publicly disclosed through the TSCA PMN process. In addition, data obtained through one regulatory system could influence reporting under another. For example, data submitted through the REACH registration process could inform a company's obligation under TSCA to notify the EPA when it obtains information that a chemical presents a substantial risk of injury to health or the environment. Similarly, data generated under REACH could be used by US regulators to support actions to require testing of chemicals, obtain information or subpoena documents from regulated entities.³⁶⁷

In addition, formal and informal consultations among regulators in the United States and EU will continue to inform regulatory decisions under both systems. As several interviewees pointed out, the more informal and formal coordination and sharing of information take place at this early stage in the regulation of nanomaterials, the more likely it is that the two approaches will result in similar regulatory decisions, despite differences in regulatory policies and authorities.

4.3.2 Comparative analysis

REACH and TSCA are typically viewed as very different regulatory regimes. REACH has been described as a response to the failings of TSCA.³⁶⁸ Perhaps the most frequently cited difference between the two regimes is the degree of precaution reflected in the regulatory approaches. REACH explicitly states in its first article that '[i]ts provisions are underpinned by the precautionary principle'.³⁶⁹ In contrast, TSCA is generally viewed as less precautionary in approach. For example, it has been characterized as containing a 'reverse precautionary

358 See GAO (2009a).

359 See e.g. Committee on Energy and Commerce, US House of Representatives (2009) (statement of J. Clarence (Terry) Davies).

360 See GovTrack, *Kid-Safe Chemicals Act of 2008*, <http://www.govtrack.us/congress/billtext.xpd?bill=s110-3040> (accessed 7 July 2009); Senator Lautenberg, *Press Release of 12 February 2009*, <http://lautenberg.senate.gov/newsroom/record.cfm?id=308177&> (accessed 7 July 2009); see also Environmental Defense Fund, *Main US Toxics Law Failing to Ensure Safety of Thousands of Chemicals*, <http://www.edf.org/pressrelease.cfm?contentID=9296> (accessed 7 July 2009).

361 See Committee on Environment and Public Works, US Senate (2009).

362 'Now that REACH exists, the US may be under pressure to change its own chemical regulations.' (Farber 2008:2); 'In short, American public policy is now, at least under some circumstances, the product of debates occurring in Brussels. US laws are, in a sense, being drafted overseas.' (Wirth 2007: 104).

363 Sachs (2009: 54) (discussing REACH's 'informational spill over effects' in the US).

364 See European Chemicals Agency (ECHA), *REACH, the New European Chemicals Legislation: Information for Exporters to the European Union*, http://ec.europa.eu/environment/chemicals/reach/pdf/reach_non_eu_countries.pdf (accessed 7 July 2009). In the alternative, US manufacturers may appoint a company established in the EU as its 'only representative' to carry out the registration on its behalf, in which case the importers of the substance are relieved of their duties as registrants under REACH but will be regarded as 'downstream users.' European Commission (2007d).

365 15 U.S.C. § 2604(d).

366 ECHA (2008a: 76).

367 Sachs (2009).

368 Applegate (2008: 723-34).

369 European Commission (2006b: Article 1(3))

principle' that allows information to be gathered only when a risk is already known to exist.³⁷⁰ Many interviewees echoed these perceptions, but some also pointed out that these differences are less pronounced when it comes to actual regulatory decisions in the EU and US.

Despite differences in the stated priority placed on precaution, both laws seek a balance between protection of health, environmental and economic concerns. TSCA states:

*Authority over chemical substances and mixtures should be exercised in such a manner as not to impede unduly or create unnecessary economic barriers to technological innovation while fulfilling the primary purpose of the Act to assure that such innovation and commerce in such chemical substances and mixtures do not present an unreasonable risk of injury to health or the environment.*³⁷¹

REACH seeks a similar balance: 'This Regulation should ensure a high level of protection of human health and the environment as well as the free movement of substances, on their own, in preparations and in articles, while enhancing competitiveness and innovation.'³⁷²

REACH and TSCA differ, however, with respect to the burden placed on industry to develop data, apply control measures to manage risks and in some cases to establish that the benefits of a particular chemical outweigh the costs. Because REACH places these burdens on industry and for other reasons discussed further below, key stakeholders clearly perceive it as considerably more precautionary in approach.³⁷³

Existing analyses provide useful comparisons of specific authorities and regulatory tools established under REACH and TSCA.³⁷⁴ This comparative analysis focuses on several important junctures in the regulatory process that are of particular importance to the oversight of nanoscale materials: registration and notification requirements, information and data collection, and regulatory controls. Accompanying the comparative overview of each regulatory component, we examine how the two regimes may apply in practice to a hypothetical nanoscale substance.

For our hypothetical scenario we assume the following: a large private firm has developed and plans to manufacture a nanoscale substance that is derived from and has the same molecular identity as a chemical that the company manufactures in conventional form. Although this may not be typical, it is the only company that manufactures the chemical in either form. The new nanoscale substance – which is manufactured as nanometre-scale particles – offers a number of functional advantages over the non-nanoscale form of the material: the smallness of the nanoparticles enables them to be incorporated into products with greater ease; the size of the particles allows functional products to be manufactured using significantly lower quantities of the substance; and changes in the reactivity of the substance when manufactured at the nanoscale allow the development of new uses.

This analysis is not intended to be a roadmap for how a particular nanoscale material will be regulated, but to demonstrate the differing approaches and types of questions raised at a few pivotal stages in the regulatory process. Accordingly, this analysis should not be used to inform any real-world decisions about the treatment or regulation of any actual nanoscale substance under either regulatory scheme, as that would require a more detailed analysis.

Pre-manufacture review and registration requirements

TSCA and REACH are fundamentally similar in that for the most part they both regulate chemicals at the source rather than in environmental media such as air and water. In addition, in theory they both seek to prevent harm from chemicals before it occurs.³⁷⁵ As a result, both require a company to determine prior to manufacturing a chemical whether it is subject to regulation. However, the factors that determine whether a particular chemical is subject to regulation differ considerably under TSCA and REACH.

370 Farber (2008: 9).

371 Toxic Substances Control Act, Pub. L. No. 94-469, § 2(b) (1976) (codified as 15 U.S.C. § 2601(b)(3)).

372 European Commission (2006b: Recital (1)).

373 This view is reflected in Cal Dooley's recent testimony before the US House of Representatives, Commerce Committee, in which the President of the American Chemistry Council stated: 'Appropriate enhancements to the US federal chemical management system should be cost and resource efficient, and should promote innovation. To be clear, ACC is NOT advocating the adoption of the European Union's REACH system.' (Emphasis in original). Committee on Energy and Commerce, US House of Representatives (2009).

374 See e.g. Denison (2007).

375 Applegate (2008: 723, 754–5).

Both EU and US regulators consider their regulatory authorities under REACH and TSCA to cover nanoscale materials, although both regulatory schemes contain exemptions that could apply to particular nanoscale materials, as outlined above. A principal difference, however, is that REACH eliminates the distinction between new and existing chemicals, in an effort to subject all chemicals to the same regulatory oversight. Although it does not distinguish between new and existing chemicals in terms of regulatory requirements, it does delineate between non-phase-in (new) and phase-in chemicals (existing)³⁷⁶ for purposes of registration time frames and in some cases data requirements imposed on manufacturers and importers (collectively referred to in this section as ‘manufacturers’).³⁷⁷ Furthermore, chemicals can be manufactured shortly after the registration is filed, regardless of whether the registration has been evaluated, unless the chemical is subject to authorization or restriction.

In contrast, TSCA distinguishes between new and existing chemicals for purposes of the pre-manufacture obligations imposed on manufacturers and the regulatory tools available to the EPA. The most important difference is that only ‘new’ chemicals are automatically subject to pre-manufacture notification and review, which allows the agency to determine whether restrictions should be imposed prior to allowing the chemical to be manufactured. A company may begin the manufacture of a chemical after 90 days in most cases, however, if the EPA does not take regulatory action. In addition, the agency can review a significant new use of an existing chemical, provided it has issued a significant new use rule or SNUR that applies to the chemical. Otherwise, if a chemical is an ‘existing’ chemical, a company may manufacture it without any prior regulatory review.

Hypothetical: Pre-manufacture review and registration requirements under TSCA and REACH

1. TSCA

To determine whether it has any pre-manufacture regulatory obligations under TSCA, the manufacturer would need to determine whether the nanoscale substance is a chemical substance that already is on the TSCA Inventory and thus is an ‘existing’ chemical for purposes of regulation. Under EPA policy³⁷⁸ (which, as discussed above, is controversial) the key question is whether the hypothetical nanoscale substance and bulk substance have the same molecular identity, which the EPA defines as the same chemical or compositional features, as opposed to the same physical attributes such as size. Thus it is likely that the EPA would consider our nanoscale substance an existing chemical. (If the manufacturer was uncertain, however, it could seek a consultation with the EPA³⁷⁹ to determine whether the nanoscale substance is a new chemical subject to PMN reporting requirements or an existing chemical already listed on the Inventory.)

Assuming the chemical is an existing one, no further action is required prior to manufacture, unless the EPA has previously taken a regulatory action that now applies to the nanoscale substance. For example, if it had issued a significant new use rule that applied to this particular nanoscale substance,³⁸⁰ the manufacturer would be required to file a SNUN that includes reasonably ascertainable information, such as any known environmental, health and safety studies. But the EPA has not issued a SNUR that specifically applies to the hypothetical nanoscale substance³⁸¹ or a categorical SNUR that would cover a broad range of nanoscale substances.³⁸² Accordingly, as an existing chemical, the nanoscale substance would not be subject to PMN reporting, and because it is not regulated by a SNUR it would not be subject to SNUN reporting requirements.

Note: If the nanoscale substance was considered a ‘new’ chemical, the manufacturer would need to file a PMN, unless the substance qualified for an exemption under TSCA. It could fall under one of several exemptions. Because it would not be manufactured in small quantities for purposes of scientific experimentation or analysis, but rather for commercial purposes, it would not qualify for

376 European Commission (2007c: 7).

377 See e.g. European Commission (2006b: art. 12(1)).

378 EPA (2008a) (although ‘a nanoscale substance that has the same molecular identity as a non-nanoscale substance listed on the Inventory differs in particle size and may differ in certain physical and/or chemical properties resulting from the difference in particle size, EPA considers the two forms to be the same chemical substance’); see also Toxic Substances Control Act Inventory Status of Carbon Nanotubes, 73 Fed. Reg. 64946, 64946 (31 October 2008) (carbon nanotubes ‘are not necessarily identical to graphite or other allotropes of carbon’ and if ‘a particular CNT is not on the TSCA Inventory, anyone who intends to manufacture or import that CNT is required to submit a PMN (or applicable exemption.)’).

379 EPA (2008a: 6–7).

380 Duvall and Wyatt (2009: 7) (discussing EPA’s authority to issue SNURs for nanomaterials).

381 The EPA has issued SNURs for several nanosubstances. See Significant New Use Rules on Certain Chemical Substances, 73 Fed. Reg. 65,743, 65,751–2 (5 November 2008) (for siloxane-modified silica and siloxane-modified alumina nanoparticles); Significant New Use Rules on Certain Chemical Substances, 74 Fed. Reg. 29,982, 29990–91, 29,998 (24 June 2009) (four new chemical SNURs issued for multi-walled and single-walled carbon nanotubes).

382 For a discussion of the SNUR authority as applied to nanoscale substances, see Duvall and Wyatt (2009).

the research and development exemption, which is self-executing and does not require application to the EPA for approval. Other exemptions that would require EPA approval include, but are not limited to, the low-volume exemption and the low-release/low-exposure exemption. Requests for these exemptions must be made in writing to the EPA. The agency has reported on its approval of low-release/low-exposure exemptions for nanomaterials in limited cases. It has not reported publicly that it has approved any low-volume exemptions for nanoscale materials. If none of the exemptions applied to the hypothetical nanoscale substance, the manufacturer would be required to file a PMN that included any known environmental, health and safety studies, which would provide the EPA with the opportunity for pre-manufacture regulatory review.

2. REACH

To determine whether the nanoscale substance is subject to REACH, the manufacturer would first decide whether any exemptions could apply to its nanoscale substance. For example, it could be exempt from REACH if it is adequately covered under other regulations (such as medicines), is a polymer, is listed in Annex V or is listed in Annex IV because sufficient information exists for it to be considered to cause minimum risk owing to its intrinsic properties.³⁸³ In addition, if the nanoscale substance was to be manufactured for purposes of product- and process-oriented research and development (PPORD), the manufacturer could qualify for a five-year exemption (with additional extensions possible in some cases), provided it notified the ECHA of the exemption.³⁸⁴

If no exemptions apply, the manufacturer must determine whether the nanoscale substance will be manufactured in a quantity of one tonne or more. The total quantity of the bulk chemical and the nanoscale counterpart are counted for the purposes of calculating whether the quantitative threshold is triggered.³⁸⁵ Thus the manufacturer must determine whether its nanoscale substance is the same as the bulk conventional substance it already manufactures (as is likely to be the case), by considering factors similar to those under TSCA.³⁸⁶

If the one tonne threshold is met, the manufacturer may produce the nanoscale substance in quantities of one tonne or more after it has submitted the registration information required, regardless of whether ECHA has reviewed the technical dossier, chemical safety report or any other information submitted as part of the registration process. Furthermore, the timing for submission of the registration materials could range from 2010 to 2018. For example, if the nanoscale substance is a phase-in chemical (which would be likely if the conventional form has already been manufactured) and is produced in a quantity of one tonne per year, the manufacturer may not be required to submit its full registration materials until 1 June 2018, but in the meantime could manufacture the nanoscale substance. However, if the nanoscale substance is a CMR, or is manufactured in quantities greater than or equal to 1 tonne per year, or is classified as 'very toxic to aquatic organisms' and produced in a quantity greater than 10 tonnes per year, it would need to be registered much earlier – by 2010. If the nanoscale material is not produced in sufficient quantities to trigger REACH jurisdiction when considered alone or with its conventional counterpart, it still could be regulated under REACH if it is listed as a substance of very high concern subject to authorization or restrictions, as substances can be regulated under the authorization and restriction processes, discussed above, regardless of quantity.³⁸⁷

In sum, if the nanoscale substance is manufactured in quantities of less than one tonne (when counted with its conventional counterpart) and is not a SVHC, it would not be subject to the REACH registration requirements. The manufacturer would not be required to submit registration materials and could manufacture it in amounts below the threshold, unless regulatory action was taken under the restriction or authorization process. If the nanoscale substance is covered by REACH registration requirements, following submission of the registration materials and a brief waiting period, the company could manufacture the substance.

Information and data-collection requirements

The approaches and authorities granted to regulators to require manufacturers to produce information, including EHS data, differ significantly under the two systems. Nevertheless, in theory both are science-based approaches that seek to assess the risk of chemicals based on data of some type.³⁸⁸ As a result, although the two systems employ

383 European Commission (2007c: 6).

384 ECHA (2008b).

385 European Commission (2008c: 6).

386 A 'decisive criterion' is whether the nanoscale substance is on the European Inventory of Existing Commercial Substances or EINECS. European Commission (2008c: 7); cf. European Commission (2008c: 10–11) (stating 'the question needs to be clarified in which cases a nanomaterial is to be considered as a separate substance and in which cases it should be considered as a particular form of a bulk substance').

387 Authorization and restriction schemes apply regardless of quantities manufactured or placed on the market. See ECHA (2008a); see also European Commission, REACH and nanomaterials, http://ec.europa.eu/enterprise/reach/reach/more_info/nanomaterials/ (accessed 7 July 2009).

388 Applegate (2008: 729, 759).

very different data standards and requirements, US and EU regulators face fundamentally similar challenges in regulating nanomaterials. Specifically, both US and EU regulators are faced with limited knowledge of the human health and ecotoxicological effects of nanoscale substances throughout their entire life-cycle. Furthermore, both need in some cases to adjust existing test methods or develop new ones to assess and evaluate these effects for regulatory purposes.

The key difference is that manufacturers and others subject to REACH are required to provide certain information – without action by a regulator – regardless of whether the information is already available or instead has to be generated. The scope of the information and data required and the time frame for submission vary considerably, however, depending on the quantity manufactured and potential toxicity of the chemical. Under TSCA, manufacturers only are required to provide information automatically – without action by a regulator – if a chemical is ‘new’ and, therefore, subject to pre-manufacture review. In addition, a manufacturer must provide information about ‘significant new uses’ of existing chemicals, but only if the EPA has issued a SNUR that applies to the chemical. Furthermore, the information that must be submitted in both cases is generally information that already exists and is reasonably ascertainable, as opposed to new information generated for the purposes of regulatory review.

Both TSCA and REACH provide additional information-gathering authorities. For example, in order ‘to clarify a suspicion of risk’, ECHA may seek additional information beyond the minimum data set that is required to be submitted as part of the registration process. This process must follow an established procedure that involves notice and comment, as discussed above. Several factors will influence how this new process will work in practice, including the resources available to ECHA and Member States to conduct dossier and substance evaluation; the extent of the need for additional information about nanoscale substances; and the efficiency of procedures required to ensure coordination among regulatory entities.

Similarly, the EPA has information-gathering authorities in addition to those associated with the pre-manufacture review process, but these tools must be used on a case-by-case basis, often imposing a considerable burden on the agency, and in some cases the scope of information that can be obtained is limited. For example, the US Government Accountability Office has characterized the EPA’s authority to require additional testing of chemicals under TSCA Section 4 as ‘costly and time-consuming’ because the statute requires the agency to demonstrate that certain health or environmental ‘risks are likely’; this leads the GAO to observe that the EPA does not opt to ‘routinely test existing chemicals.’³⁸⁹ Although the EPA could and does use consent orders, which are less burdensome, to obtain data about chemicals, the agency is still required to take affirmative action to obtain data, which it has done for only 60 chemicals. As a result of these constraints, the EPA relies on structure activity relationships when it does evaluate chemicals, as discussed above, and also seeks considerable amounts of data through a range of voluntary reporting programmes.

REACH and TSCA also differ in terms of the obligations imposed on manufacturers to provide updated information to regulators. For chemicals produced in quantities above 25,000 pounds in the reporting year, TSCA requires the submission of manufacturing information once every five years under its Inventory Update Rule. For chemicals produced in quantities above 300,000 pounds in the reporting year, some limited downstream processing and use information is also required.³⁹⁰ In contrast, REACH does not require regular reporting (except as chemicals move to the next highest production quantity tier), but it does require that manufacturers notify regulatory authorities about changes in use, production quantity, and new information on risks to human health and environment and to update their registrations as appropriate. As discussed below, both systems impose certain requirements with respect to reporting information about health and safety risks as it is learned.

Confidential business information is protected under both REACH and TSCA, and both allow for its disclosure when necessary to protect human health or the environment. As outlined earlier, however, the systems vary considerably in their treatment of CBI. Under TSCA, manufacturers claim substantial amounts of the information they submit as CBI and are not always required to provide upfront justification for their claims. Furthermore, the EPA must review CBI claims on a case-by-case basis and, partly because of resource constraints, does not review or challenge large numbers of such claims. REACH takes a different approach by delineating among types of information that: 1) normally is considered CBI; 2) must be made publicly available unless an acceptable justification is provided; and 3) will be made available to the public free of charge. Finally, another notable difference is that REACH allows for the disclosure of CBI to foreign governments pursuant to agreements that provide for appropriate protection of the information. TSCA does not allow CBI to be disclosed to foreign governments, except in the very limited context of notices of regulatory actions taken against exported chemicals.

389 GAO (2009a: 23).

390 See Denison (2007: III-8) (discussing Inventory Update Rule limitations).

In addition to the differing regulatory authorities and tools, numerous factors will influence the breadth and depth of information that manufacturers are required to provide on nanoscale materials under each system. These factors include, for example, the extent to which the EPA uses its SNUR, test-rule and information-gathering authorities to compel disclosure of information; how many nanoscale materials constitute new as opposed to existing chemicals under TSCA; the number of nanoscale materials covered by REACH (e.g., that meet the quantitative threshold); how often chemical safety reports, in addition to technical dossiers, are required for nanoscale substances; and the extent to which the ECHA uses its authority to seek data on such substances, in addition to information that is required as part of the registration process.

Nevertheless, information collection is a key area in which TSCA and REACH differ. As the US Government Accountability Office has concluded, REACH 'generally places the burden on companies to provide data on the chemicals they produce'. In contrast, 'EPA's assessments of industrial chemicals under TSCA provide limited information on health and environmental risks'.³⁹¹

Hypothetical: Information and data-collection requirements under TSCA and REACH

1. TSCA

Under TSCA, the hypothetical manufacturer would not be required to provide any information to the EPA prior to manufacturing the nanoscale substance because the substance is considered an existing chemical – unless the EPA had issued a SNUR that applied to the nanoscale substance. If a SNUR applied to the nanoscale substance, it would typically require the manufacturer to file a SNUN that included any known EHS studies. In addition, the manufacturer would be required to comply with reporting requirements that govern existing chemicals under TSCA, such as submitting upon request records of 'adverse reactions to health or the environment' caused by the hypothetical nanoscale substance³⁹² and notifying the EPA if it obtained any information that the nanoscale substance 'presents a substantial risk of injury to health or the environment'.³⁹³ If it manufactured the nanoscale substance in large enough quantities, it also could be required to comply with the Inventory Update Rule and provide certain information to the EPA every five years.³⁹⁴ Finally, unless it is exempt as a small manufacturer, it would be required to provide information about the nanoscale substance that is requested by the EPA under Section 8(a) but only 'insofar as known' or 'reasonably ascertainable'.³⁹⁵

The manufacturer would not be required to submit any additional information or data about the nanoscale substance unless the EPA took regulatory action under its test-rule, information-gathering, SNUR or subpoena authorities.³⁹⁶ As discussed above, the use and scope of some of these regulatory tools may be limited. For example, the scope of information that the EPA could compel the manufacturer to produce under several information-gathering authorities would be limited for the most part to information that is known or reasonably ascertainable, as opposed to new information generated by the manufacturer.

The manufacturer also could opt to participate in the EPA's voluntary reporting programme, the NMSP, discussed above, and submit information on its nanoscale substance to the agency. The manufacturer could participate in the Basic Program by providing information on current use of the nanoscale material or in the In-Depth Program by partnering with the EPA to identify data gaps, engage in testing, and develop new data.³⁹⁷ The manufacturer could claim the information submitted to the EPA as confidential business information, in which case public access to it would be restricted.

Note: If a SNUR applied or if the nanoscale substance instead was considered a new chemical, the manufacturer would be required to file a SNUN (or PMN for a new chemical) that included information that is 'reasonably ascertainable', including known environmental, health and safety studies. It would not be required to conduct any new studies, unless the EPA took action to require the manufacturer to develop and produce additional data, on a case-by-case basis.³⁹⁸

391 See GAO (2009a: 24) (recommending 'both statutory and regulatory changes to, among other things, strengthen EPA's authority to obtain additional information from the chemical industry, shift more of the burden to chemical companies for demonstrating the safety of their chemicals, and enhance the public's understanding of the risks of chemicals to which they may be exposed').

392 15 U.S.C. § 2607(c).

393 Ibid. § 2607(e).

394 40 C.F.R. § 710.52.

395 15 U.S.C. § 2607(a)(2); EPA (2009d) (explaining that 'Section 8(a) regulations can be tailored to meet unique information needs (e.g., via chemical-specific rules) or information can be obtained via use of "model" or standardized reporting rules such as a "Preliminary Assessment Information Rule" (or PAIR)').

396 See e.g. Denison (2007: III-7 to III-9).

397 EPA (2008c).

398 If information in pre-manufacture notice is inadequate, EPA may ban or limit use of a chemical; however, while 85 per cent of pre-manufacture notices lack any health or safety test data, it 'rarely uses its authority to obtain this information.' (GAO 2005: 4, 11).

2. REACH

Under REACH, the manufacturer would automatically be required to submit certain information as part of the registration process. Because the nanoscale substance would be manufactured in conventional form by the manufacturer, the two would be considered together for purposes of determining the information requirements for registration. The extent of information required could vary considerably depending on the quantity manufactured and potential toxicity. To take just two of the many possible scenarios, if the nanoscale is a phase-in substance that with its conventional counterpart will be manufactured in quantities of one tonne or more per year, physico-chemical property data would be required. Additional data would be required if the substance is a SVHC or is potentially dangerous to health or the environment and used in a dispersive manner.³⁹⁹ If it is manufactured in quantities over ten tonnes, the manufacturer would also be required to provide a chemical safety report that includes a wider range of toxicological and ecotoxicological information. Regardless of the scope of the information required, the manufacturer would need to include information specific to the properties of the nanoform if they differ from the conventional form, including, for example, any different classification and labelling, safety assessment, identified uses and exposure scenarios.⁴⁰⁰

Until specific test guidelines for nanoscale substances are developed, the manufacturer would need to carry out toxicity testing, according to existing guidelines, unless they are shown to be inadequate, and/or by corresponding test methods that comply with the conditions set out in REACH.⁴⁰¹ Furthermore, it could rely on ECHA guidance on information requirements and chemicals safety assessment; however, it is recognized that the guidance will need to be adjusted to enable assessment of the behaviour of nanoscale substances and their effects on humans and the environment, and to develop relevant exposure scenarios and risk management measures.⁴⁰²

Although the manufacturer would have an affirmative obligation to provide information, it may not need to file a full registration that addresses the nanoscale substance until the conventional substance is required to be fully registered, which could be as late as 2018. It is possible, however, that the production of the nanoscale substance could in some manner change the registration requirements and time frame that apply to the conventional substance by, for example, increasing the tonnage manufactured.⁴⁰³

The manufacturer would have no other reporting obligations unless there were significant changes in use or production quantity, or unless ECHA, in coordination with the Competent Authorities of Member States, requested additional information in order to 'clarify suspicions of risks to human health or the environment'. As discussed, such requests must be made pursuant to an involved process and it is unknown how frequently this process will be used.⁴⁰⁴

Finally, the manufacturer could submit data on the nanoscale substance even if it is not required by regulation. The Commission encourages companies to consider voluntary options such as registering substances before the applicable relevant deadline, registering substances even if they are manufactured below the 1 tonne threshold, and generating further information beyond what is required to demonstrate that the risks of a nanoscale substance are controlled.⁴⁰⁵

Regulatory controls

TSCA and REACH take differing approaches to regulating the manufacture, use and distribution of chemicals. One of the most notable differences is the REACH authorization process, which provides for regulators to develop a list of substances of very high concern that are then subject to a prioritization process to determine which chemicals will be subject to authorization. Once a substance is subject to authorization, manufacturers must apply for authorization for each use and bear the burden of demonstrating that the risks associated with the use of the substance are adequately controlled or that the socio-economic benefits outweigh the risks.⁴⁰⁶ Manufacturers must also analyse whether a safer alternative exists and, if so, must prepare a substitution plan.⁴⁰⁷

TSCA does not prioritize chemicals in this manner and does not require manufacturers to perform substitution analyses. Although the REACH approach is markedly different from the approach taken under TSCA, several factors will influence how the prioritization process works in practice. These include the efficiency and effectiveness of the process for identifying SVHCs and subjecting them to authorization; the extent to which SVHCs ultimately

399 European Commission (2007c: 7).

400 European Commission (2008c: 7).

401 Ibid.: 11 (explaining that 'in order to address the specific hazards associated with substances at nanoscale, additional testing or information may be required ... and current test guidelines may need to be modified').

402 Ibid.

403 European Commission (2007c: 7); European Commission (2008c: 13).

404 European Commission (2007c: 12).

405 European Commission (2008c: 14).

406 Ibid.: 17.

407 European Commission (2007c: 13).

will be allowed on the market owing to the required consideration, in some cases, of adequate control measures and socio-economic factors; and whether industry-performed substitution analyses result in a substantial number of replacements. Nevertheless, the authorization process represents a significant departure from the approach taken under TSCA to prioritizing chemicals and addressing their risks.

Another key method under REACH for regulating chemicals is the restriction process, which bears some similarity to the TSCA chemical review and regulatory process. Both require regulators to examine chemicals on a case-by-case basis and determine whether controls are needed. As discussed, the substantive and procedural burdens placed on the EPA before it can impose restrictions vary depending on whether the substance is considered a new or an existing chemical. There is a long history of efforts to restrict chemicals under TSCA, and many argue this suggests the need for reform, particularly with respect to existing chemicals.⁴⁰⁸ Under REACH, regulators may also seek to impose similar restrictions on chemicals, but the standards and process for doing so differ.

Under REACH, the same standard applies to all chemicals. Restrictions may be imposed when a Member State or ECHA demonstrates an ‘unacceptable risk to health or the environment’ that must be addressed on an EU-wide basis. It is difficult to determine at present how burdensome this procedure will be and, therefore, how it will compare to the TSCA standards for imposing restrictions on new and existing chemicals. It also is unknown whether the involved procedures for imposing such restrictions under REACH will work effectively and efficiently, as restrictions can only be imposed if proposed in a dossier that is reviewed by the ECHA’s Committee for Risk Assessment and Committee for Socio-Economic Analysis. The committees, in turn, must prepare and submit opinions on the proposed restrictions to the Commission, after obtaining public comment. It is only then that the latter can compose a draft amendment to REACH and decide on the restriction.⁴⁰⁹ Furthermore, as many proposed restrictions will be based on dossier and substance evaluation, the use of the restriction process will depend in part on the resources available to regulators. Despite these considerations, however, in seeking to impose restrictions EU regulators will have substantial information and data available to them as a result of the registration process.

Finally, in addition to the authorization and restriction process, REACH requires through the registration process that manufacturers apply ‘appropriate measures to control risks’ that they identify in their chemical safety assessments. It is difficult to determine the practical effects of this requirement, in addition to public disclosure of at least some of the required information, on the identification and implementation of control measures. For example, it is unclear how far resource constraints will influence regulators’ ability to evaluate the appropriateness of the control measures identified and whether they have been applied. Nevertheless, it is notable that REACH imposes on manufacturers an affirmative duty to assess risks, identify control measures and implement them. TSCA does not have a corresponding requirement. Control measures may be imposed by regulators under Sections 5 and 6 of the statute under certain circumstances, discussed above. In addition, manufacturers may apply such measures voluntarily and report them as part of the PMN or SNUN process in order to inform the EPA’s review, but TSCA does not impose an affirmative duty on manufacturers with respect to such measures.

Hypothetical: Regulatory controls under REACH and TSCA

1. TSCA

For a nanoscale substance that is an existing chemical on the TSCA Inventory, the EPA could in theory impose a wide range of restrictions including, for example, prohibiting or limiting the amount manufactured or distributed.⁴¹⁰ As discussed above, however, the procedural and substantive requirements imposed on the EPA under the law mean it would find it difficult to regulate the nanoscale substance under this authority, which it has used only five times since the statute was enacted in 1976.⁴¹¹ In addition, the EPA could in theory seize the nanoscale substance or products containing it if it determined that it was an ‘imminently hazardous’ chemical. Again, the agency does not regularly use this authority and would be required to file a civil action in district court to do so.⁴¹²

Finally, the EPA could review the nanoscale substance using its authority to regulate ‘significant new uses’ of existing chemicals. If it issued, prior to manufacture of the nanoscale substance, a chemical-specific SNUR or a SNUR that applied more broadly to certain categories of nanoscale substances, the manufacturer would be required

408 See e.g. Committee on Energy and Commerce, US House of Representatives (2009) (Statement of J. Clarence (Terry) Davies).

409 European Commission (2006b: Articles 69(6), 72, 73); ECHA (2008a) (EC Guidance on the preparation of dossiers by Member States, including a detailed outline of the process of creating a ‘justification that the substance poses a risk to human health or the environment’).

410 15 U.S.C. § 2605(a).

411 GAO (2005: 58–60) (the five existing chemicals/chemical categories are polychlorinated biphenyls (PCB), fully halogenated chlorofluoroalkanes, dioxin, asbestos and hexavalent chromium).

412 15 U.S.C. § 2606(a).

to file a SNUN that contains information about the chemical, including 'reasonably ascertainable' information about known environmental and health effects, its expected uses, and expected exposure.⁴¹³ The EPA would have to use notice and comment rulemaking, rather than the expedited procedures that can be used in conjunction with the review of a new chemical, because the manufacturer is the only company that produces the chemical and therefore a new chemical SNUR would not already have been issued.

2. REACH

Under REACH, the nanoscale material could in theory be regulated through either the restriction or authorization process. The substance would only be subject to the authorization process if it is specifically included in Annex XIV, because it is a CMR (category 1 or 2), a PBT, a vPvB or a chemical identified from scientific evidence as causing equivalent probable serious effects to humans or the environment.⁴¹⁴ Whether the manufacturer would ultimately be allowed to make the nanoscale substance could depend on several factors, including the availability of safer substitutes. The substance still could be manufactured if the manufacturer demonstrates that it is adequately controlled, but this would not be permitted if it is a PBT or a vPvB, or a CMR substance for which a safe level could not be defined. Such a substance could only be manufactured for a specific use if there are no substitutes for that use and its socio-economic benefits outweigh the risks. Furthermore, SVHCs are 'fed into the authorization system as resources allow'.⁴¹⁵ Thus, even if the nanoscale substance is a SVHC, it may not immediately be subject to regulatory action under REACH and could be placed on the market with controls determined to be adequate by the manufacturer until a decision is made through the authorization process.⁴¹⁶

In addition, either a Member State or the ECHA could propose restrictions on the nanoscale substance, as discussed above. However, this process requires a demonstration of 'an unacceptable risk to health or the environment' that must be addressed at an EU-wide level and in most cases can only be imposed through a multi-stage process.⁴¹⁷

4.4 Conclusion

In summary, TSCA and REACH differ considerably in their approach to regulation of chemicals generally and nanoscale materials in particular, including differences in policies, authorities and requirements. Nevertheless, many factors will influence the extent and manner to which these differences in approach result in disparate regulatory actions. These factors include implementation resources, interpretation of regulatory authorities, subsequent legislative reforms and, perhaps most importantly (as discussed in Chapter 7), the extent to which regulators coordinate and share information at this critical juncture in the regulation of nanoscale materials.

413 Ibid. § 2604(d).

414 European Commission (2007c: 12–13).

415 Ibid.

416 European Commission (2007d).

417 European Commission (2007c: 13–14).

5 Food Regulation

5.1 US food regulations

Food safety in the US is controlled by multiple laws that are implemented by several agencies.⁴¹⁸ The FDA, and, to a lesser extent, the USDA and EPA, are primarily responsible for food safety in the US. These agencies implement separate legal authorities governing food, food ingredients and dietary supplements.

The FDA regulates food, including food additives and dietary supplements, under the FFDCA. Section 201(f) of the FFDCA defines ‘food’ broadly to include ‘(1) articles used for food or drink for man or animals, (2) chewing gum, and (3) articles used as components of any such article.’⁴¹⁹ Examples of FDA-regulated food include meat and meat products not subject to exclusive USDA jurisdiction,⁴²⁰ fruits and vegetables, fish and seafood, dairy products, canned, frozen and prepared foods, candy and baked goods, beverages, dietary supplements and ingredients, and direct and indirect food additives. The FFDCA prohibits the sale of food into which drugs or biologics have been added.⁴²¹

Section 301 of the FFDCA prohibits the introduction or delivery of any ‘adulterated’ or ‘misbranded’ food into interstate commerce.⁴²² In general, food is ‘adulterated’ if it contains a poisonous or deleterious substance or was prepared under unsanitary conditions that may render it injurious to health.⁴²³ Food is ‘misbranded’ if its labelling is false or misleading in any particular or if it fails to contain certain specified information.⁴²⁴ Specific requirements apply to dietary supplements, direct and indirect food additives, pesticide residues and colour additives. Each of these categories is discussed separately below.

5.1.1 Whole foods

In general, the FFDCA provides the FDA with limited pre-market oversight of whole foods.⁴²⁵ As a result, the FDA’s authorities are largely centred on post-market response to adulterated or misbranded foods. However, under the Public Health Security and Bioterrorism Preparedness and Response Act of 2002 (Bioterrorism Act),⁴²⁶ owners and operators of domestic or foreign facilities that manufacture, process, pack, or hold food for consumption in the US must register their facilities with the FDA.⁴²⁷ Facilities that manufacture, prepare, pack or hold food are also subject to the FDA’s current good manufacturing practice (cGMP) regulations. The cGMP regulations, promulgated pursuant to the FFDCA, set forth the criteria and conditions for determining whether a food is adulterated.⁴²⁸ The FDA may also review food packages and labels to determine whether they contain all required information and to ensure that they do not contain false or misleading statements. In addition, with certain limited exceptions, food labelling may not include claims that the product cures, mitigates, treats or prevents any disease. Foods that make such ‘drug’ claims are considered by the FDA to be unregistered new drugs and are subject to additional regulation (see US Cosmetics Regulation, below).

418 The total number of federal agencies with food safety responsibilities is far larger, encompassing ‘at least a dozen’ agencies in total (Institute of Medicine and National Research Council 1998).

419 21 U.S.C. § 321.

420 The USDA has jurisdiction over specified meats, poultry and egg products and certain foods produced from them under the Meat Inspection Act (Pub.L. 90–201, 81 Stat. 584 (1967)), the Poultry Products Inspection Act (Pub.L. 85–172, 71 Stat. 441 (1957), and the Egg Products Inspection Act (Pub.L. 91–597, 84 Stat. 1620 (1970)).

421 21 U.S.C. § 331(ii). This provision was added by section 912(a) of the Food and Drug Administration Amendments Act of 2007, Pub. L. 110–85, 121 Stat. 952 (2007).

422 21 U.S.C. § 331(a); see also Anderson et al. (2001).

423 21 U.S.C. § 342.

424 21 U.S.C. § 343.

425 Pre-market review is available for some food products, such as food additives and the grey area of genetically modified foods. Genetic modifications that cause a significant compositional change in the resultant food are regulated as food additives. The FDA has issued a series of guidance documents that provide additional detail on the treatment of genetic changes and has established a voluntary pre-market consultation process. See FDA (2006b).

426 Pub. L. 107–88, 116 Stat. 594 (2002).

427 21 U.S.C. § 350d.

428 21 C.F.R. Part 110.

Foods (or drugs) that are determined to be adulterated or misbranded are subject to recall, seizure or withdrawal from the marketplace. The FDA can remove from the market products containing naturally occurring hazardous substances only if the substances ‘ordinarily render [the product] injurious to health.’⁴²⁹ ‘Poisonous or deleterious substances’ that are added to foods unintentionally as the result of human activity (e.g. mercury) are considered adulterants⁴³⁰ and the FDA may remove foods containing these substances from the market if the substance is in the food at a level that ‘may render it “injurious to human health”’.⁴³¹

5.1.2 Food additives

The FDA regulates food additives under the FFDCA, as amended by the Food Additive Amendments of 1958. These amendments were enacted to ensure public acceptance of the growing use of chemicals for food processing.⁴³² They were intended to balance the need for determining the safety of new additives against the benefits of promoting innovation in food science, without exposing to pre-market approval the majority of ingredients that had already been sanctioned for use or that were generally recognized as safe.

Section 201(s) of the FFDCA defines the term ‘food additive’ to include, with certain limited exceptions,⁴³³ ‘any substance the intended use of which results or may reasonably be expected to result, directly or indirectly, in its becoming a component or otherwise affecting the characteristics of any food.’⁴³⁴ The term ‘food additive’ does not include any substance that is either ‘generally recognized as safe’ (GRAS) or subject to a prior sanction, under the conditions of its intended use.

The definition of food additive includes both direct and indirect additives. Direct food additives include any substance intentionally added to food, including spices, preservatives, vitamins and minerals, emulsifiers, stabilizers and flavourings. Indirect additives are substances that are not intentionally added to food but that are nonetheless present in food owing to their intended use ‘in producing, manufacturing, packing, processing, preparing, treating, packaging, transporting, or holding food; and including any source of radiation intended for any such use.’⁴³⁵ Colour additives, animal drug residues and pesticide residues are excluded from the definition of food additive but are separately regulated by the FDA and/or EPA.

Ingredients with a history of safe use in food before 1958 and substances approved for specific uses by the FDA or USDA before 1959 are excluded from the definition of ‘food additive’ under the FFDCA and are therefore exempt from pre-market review. The FDA has issued regulations listing most ingredients for which it or the USDA issued a sanction or approval prior to 1958.⁴³⁶ These substances are considered to have a history of safe use and are not subject to the food additive regulations. The FDA takes the position that any ingredient not listed by chemical identity for a sanctioned use cannot meet the requirements for this exception.

Substances used in food contact articles are food additives if they are reasonably expected to migrate into food.⁴³⁷ However, such substances may be exempted from listing as food additives if they migrate into food in very small amounts and their use poses ‘negligible safety concerns.’⁴³⁸ The FDA has established a process to enable determination of when the ‘likelihood or extent of migration to food’ by such substances does not require them to be regulated as food additives.⁴³⁹ On the basis of toxicological data from representative compounds, it set the ‘threshold level below which dietary exposures to substances used in food-contact articles are so negligible as to pose no public health or safety concerns.’⁴⁴⁰ Producers can request the FDA to exempt from listing as food additives substances that are

429 21 U.S.C. § 342(a)(1) (‘[I]n case the substance is not an added substance such food shall not be considered adulterated ... if the quantity of such substance in such food does not ordinarily render it injurious to health.’)

430 The FFDCA describes additional ways in which foods may be adulterated. 21 U.S.C. § 342.

431 21 U.S.C. § 342(a)(1). Note that this ‘poisonous or deleterious substance’ authority is distinct from that for product categories that are specifically regulated, including a ‘pesticide chemical residue in or on a raw agricultural commodity or processed food, a food additive, a color additive, or a new animal drug.’ 21 U.S.C. § 342(a)(2).

432 See Taylor (2006: 19–20).

433 The term ‘food additive’ does not include ‘(1) a pesticide chemical residue in or on a raw agricultural commodity or processed food; or (2) a pesticide chemical; or (3) a color additive; or (4) any substance used in accordance with a sanction or approval granted prior to the enactment of this paragraph 4 pursuant to this Act [enacted 6 September 1958], the Poultry Products Inspection Act (21 U.S.C. 451 and the following) or the Meat Inspection Act of March 4, 1907 (34 Stat. 1260), as amended and extended (21 U.S.C. 71 and the following) or (5) a new animal drug; or (6) an ingredient described in paragraph (ff) in, or intended for use in, a dietary supplement.’ 21 U.S.C. § 321(s).

434 21 U.S.C. § 321(s).

435 21 U.S.C. § 321(s).

436 21 C.F.R. §§ 181.22–181.34.

437 21 U.S.C. § 321(s).

438 FDA (1995). See also *Monsanto v. Kennedy*, 613 F.2d 947, 955 (D.C. Cir. 1979).

439 Ibid.

440 Ibid.

not carcinogenic, present no other safety concern, and result in dietary concentrations of less than 0.5 ppb.⁴⁴¹ This rule has been little used since the FDA developed abbreviated notification procedures for food contact materials.⁴⁴²

The definition of food additive does not include substances that are GRAS. Substances are considered to be GRAS only for specific intended uses. A substance considered to be GRAS for one use may not be considered safe for use in other applications.⁴⁴³ To qualify as GRAS, experts, qualified by their scientific training and experience, must evaluate an ingredient's safety for its intended use on the basis of objective scientific evidence and procedures – the same level of evidence required to demonstrate food additive safety.⁴⁴⁴ GRAS determinations 'ordinarily' must be based on published studies, which may be corroborated by unpublished studies and other data or information.⁴⁴⁵ Substances used in food prior to 1 January 1958 may, however, be listed as GRAS through either scientific procedures or experience, on the basis of a history of safe use in food.⁴⁴⁶

Once a producer determines that an ingredient is GRAS for its intended purpose, it may notify the FDA of that determination but is not required to do so.⁴⁴⁷ Producers may market products containing GRAS ingredients without informing or seeking review by the FDA. The FDA has published detailed lists of GRAS ingredients, including chemical specifications, through its notice inventory.⁴⁴⁸ The FDA can challenge independent GRAS determinations by showing that there is a dispute over the safety of the ingredient. In addition, observers have noted that industry norms 'typically require guarantees and other forms of assurance that a packaging material or other food substance can be lawfully marketed.'⁴⁴⁹ Such assurance may include FDA notification.

Food additives that are not GRAS are subject to FDA pre-market review and approval. All food ingredient manufacturers must also comply with the FDA's cGMP requirements,⁴⁵⁰ and the agency can inspect manufacturer facilities and records. Under the FFDCA, any food containing a non-approved food additive is considered adulterated.⁴⁵¹ To obtain approval of a new food additive, a producer must submit a petition supported by data based on FDA testing requirements. The petition must demonstrate that there is a 'reasonable certainty' that the additive 'is not harmful under the intended conditions of use.'⁴⁵² In evaluating the safety of an additive, the FDA considers the composition and properties of the substances, the amount typically consumed, immediate and long-term health effects and various safety factors. If it determines that there is a reasonable certainty of no harm, it will approve the additive and issue a regulation that sets limits and conditions on its lawful use.⁴⁵³ The food additive petition process does not currently explicitly consider particle size, although the FDA does evaluate the composition and properties of the material. This particle-size ambiguity creates uncertainty over how the FDA will treat petitions for approval of nanomaterials as food additives. The FDA Task Force Report recommends that the FDA issue guidance to help clarify what different or additional testing, data and information may be required to support approval of petitions for nanoscale additives.⁴⁵⁴

Some indirect food additives – most notably food packaging materials – qualify for a streamlined approvals process. 'Food contact substances',⁴⁵⁵ including most packaging materials, typically migrate into food in low levels and are believed to present low toxicological concern. Historically, as noted above, food packaging was regulated

441 21 C.F.R. § 170.39. Producers can also seek exemption for regulated direct food additives used in food contact articles at levels resulting in a dietary exposure of less than 1% of the acceptable daily intake level. See FDA (2009a).

442 Many food contact substances are probably marketed on the basis of manufacturer self-determinations of GRAS rather than food contact notifications.

443 21 U.S.C. § 321(s).

444 21 U.S.C. § 321(s); 21 C.F.R. § 170.3; 21 C.F.R. § 170.30(b).

445 21 C.F.R. § 170.30.

446 Ibid.

447 FDA (1997) (proposed rule to establish notification procedure).

448 FDA, GRAS Notification Program, <http://www.cfsan.fda.gov/~dms/opa-noti.html> (accessed 7 July 2009). FDA regulations also list some specific ingredients that are GRAS, but acknowledge that a complete list of GRAS ingredients is not feasible. 21 C.F.R. § 182.1; 21 C.F.R. § 170.30. The FDA may also affirm the safety of GRAS ingredients through notice-and-comment rulemaking pursuant to 21 C.F.R. § 170.30. Ingredients affirmed to be GRAS are listed in 21 C.F.R. Part 184 and food contact substances affirmed as GRAS are listed in 21 C.F.R. Part 186. The FDA's 1997 proposed rule would supersede the affirmation process and replace it with guidance that would create a notification process (FDA 1997). The proposed rule has not been finalized to date, but the FDA has implemented the notification process, which is now the primary means for FDA consideration of whether ingredients are GRAS (Burrows and Brougher 2008).

449 Taylor (2008: 20).

450 21 C.F.R. § 172.5 (direct additives), 21 C.F.R. § 174.5 (indirect additives), 21 C.F.R. § 174.6 (food contact substances).

451 21 U.S.C. § 348(a).

452 21 C.F.R. § 170.3(i).

453 See FDA, Food Ingredients and Colors, <http://www.cfsan.fda.gov/~dms/foodic.html> (accessed 7 July 2009).

454 FDA (2007a).

455 'Food contact substance' is defined as 'any substance intended for use as a component of materials used in manufacturing, packing, packaging, transporting, or holding food if such use is not intended to have any technical effect in such food'. 21 U.S.C. § 348(h)(6).

under the food additive petition process for non-GRAS substances.⁴⁵⁶ Over time, however, the FDA and industry determined that requiring the full additive review and approval process for food contact substances was an unnecessary use of agency and industry resources.⁴⁵⁷ As a result, Congress created a more streamlined administrative process for such substances in the FDA Modernization Act of 1997. In lieu of a food additive petition, which can take 2–4 years, producers may submit a food contact notification (FCN) containing certain safety information prescribed by the FDA.⁴⁵⁸ Without FDA consent, an FCN cannot be submitted for a food contact substance that will increase the cumulative dietary concentration above 1 ppm (200 ppb for antimicrobials) in the daily diet or for a food contact substance for which there exists a bioassay that the FDA has not reviewed and that is ‘not clearly negative for carcinogenic effects’.⁴⁵⁹ If the agency does not object within 120 days, the FCN is ‘effective’ and the producer can market the packaging. If at any time the FDA determines that the packaging is unsafe, it can deny or revoke the FCN. To date, at least two FCNs for nanoscale materials – titanium nitride and titanium aluminium nitride – appear to be effective.⁴⁶⁰

5.1.3 Colour additives

Colour additives are excluded from the definition of food additive⁴⁶¹ and have been separately regulated by the FDA since 1902;⁴⁶² the agency is responsible for regulating all colour additives used in foods, cosmetics, drugs, and medical devices. All colour additives are subject to rigorous safety standards prior to their approval and listing for use in food; unlike food additives, there is no GRAS exemption for colours.⁴⁶³ Before marketing a new colour additive the manufacturer must petition the FDA for approval. The petition and approval process includes pre-market review analogous to that applicable to food additives. During its review of a petition for listing, the FDA classifies colour additives either as ‘subject to certification’ or ‘exempt from certification’ based on whether the composition of the colour requires controls to protect public health. Certification refers to the process whereby the FDA assures that newly manufactured batches of colour meet the identity and specification requirements laid out in its regulations. Nine certified colour additives are currently approved for use in food in the US.⁴⁶⁴ In addition to certification, every manufacturer producing colour additives for use in food must register with the FDA pursuant to the Bioterrorism Act.⁴⁶⁵

5.1.4 Residues

The FDA, EPA and USDA have varying responsibility for governing and monitoring residues in food. The FDA sets tolerances for animal drug residues in food, and the EPA sets tolerances for pesticide residues in food (see chapter 4).⁴⁶⁶ The USDA monitors these residue tolerances in meat, poultry, and egg products through its Food Safety and Inspection Service (FSIS). The FSIS administers the National Residue Program (NRP) for veterinary drug, pesticide and environmental contaminant residues in these products pursuant to authority provided by the Federal Meat Inspection Act, the Poultry Products Inspection Act, and the Egg Products Inspection Act.⁴⁶⁷ The FDA monitors residues, including pesticide residues, in all other types of food products pursuant to the FFDCA.

456 FDA authority over food packaging is supplemented by EPA authority over antimicrobial products pursuant to FIFRA, as modified by the Food Quality Protection Act (FQPA) (Taylor 2008).

457 Taylor (2008).

458 21 C.F.R. § 170.101.

459 21 C.F.R. § 170.100.

460 FDA (2009b: 302, 818). The original FCN for titanium nitride, FCN 716, has since been replaced by FCN 818. See Duvall (2008). Determination of application of this and other FCNs to nanoscale ingredients is difficult because the FCN inventory does not reference particle size. See generally FDA (2009b).

461 Dyes and pigments used in food contact materials that do not migrate into food are considered colorants and are regulated as food additives. 21 C.F.R. § 178.3297(a).

462 The term ‘color additive’ means a material which: (A) is a dye, pigment, or other substance made by a process of synthesis or similar artifice, or extracted, isolated, or otherwise derived, with or without intermediate or final change of identity, from a vegetable, animal, mineral, or other source, and (B) when added or applied to a food, drug, or cosmetic, or to the human body or any part thereof, is capable (alone or through reaction with other substance) of imparting color thereto; except that such term does not include any material which the Secretary, by regulation, determines is used (or intended to be used) solely for a purpose or purposes other than coloring.

463 GRAS substances, however, may also be listed as colour additives. See FDA/CFRAN, Color Additives: FDA’s Regulatory Process and Historical Perspectives, available at <http://www.fda.gov/ForIndustry/ColorAdditives/RegulatoryProcessHistoricalPerspectives/default.htm> (accessed 7 July 2009).

464 21 C.F.R. § 74, subpart A.

465 21 U.S.C. § 350d.

466 21 U.S.C. § 346a. EPA’s authority is modified by the Food Quality Protection Act. FDA also sets action levels for cancelled pesticides – those no longer approved for use by EPA.

467 See US Department of Agriculture (2007).

5.1.5 Dietary supplements

The FDA separately regulates dietary supplements in addition to foods, food additives, colour additives and residues. Prior to the enactment of the Dietary Supplement Health and Education Act (DSHEA) in 1994, the agency regulated dietary supplements as conventional foods and food additives. The DSHEA established a unique framework for dietary supplement regulation, so that supplements are now subject to a different set of regulations from those governing conventional food products. Under the statute, the dietary supplement manufacturer, rather than the FDA, has the primary responsibility for determining that a dietary supplement is safe before it enters the market.⁴⁶⁸ Generally, manufacturers are not required to register their products with the FDA, and dietary supplements are not required to undergo FDA review or obtain FDA approval prior to marketing. The FDA is responsible for monitoring the safety of dietary supplements once they are on the market and has the authority to take action against an unsafe dietary supplement only after it has entered commerce. It also regulates dietary supplement labelling and claims.⁴⁶⁹

The DSHEA includes a wide range of products in its definition of dietary supplements. As a result, its reach extends beyond the traditional category of essential nutrients such as vitamins, minerals and proteins. Under the DSHEA, the definition of a 'dietary supplement' includes:

- *a product (other than tobacco) that is intended to supplement the diet that bears or contains one or more of the following dietary ingredients: a vitamin, a mineral, an herb or other botanical, an amino acid, a dietary substance for use by man to supplement the diet by increasing the total daily intake, or a concentrate, metabolite, constituent, extract, or combinations of these ingredients.*
- *a product that is intended for ingestion in pill, capsule, tablet, or liquid form.*
- *a product that is not represented for use as a conventional food or as the sole item of a meal or diet.*
- *a product that is labeled as a 'dietary supplement.'*
- *an article such as an approved new drug, certified antibiotic, or licensed biologic that was marketed as a dietary supplement or food before approval, certification, or license (unless the Secretary of Health and Human Services waives this provision).⁴⁷⁰*

The DSHEA limited the oversight of dietary supplements by the FDA, which lacks full pre-market review and approval authority and cannot remove dietary supplements from the market unless it can prove that they 'present a significant or unreasonable risk of illness or injury'.⁴⁷¹ However, when it determines that a supplement poses an imminent hazard, the FDA can summarily remove that substance from the market. The identification of unsafe supplements has presented a challenge to the FDA, and the Task Force Report noted that 'to date FDA has received only voluntarily submitted adverse events' for dietary supplements.⁴⁷² The Dietary Supplement and Non-prescription Drug Consumer Protection Act (DSNDCPA) of 2006 restored some of the FDA's authority by requiring responsible parties to report 'serious adverse events' to the FDA.⁴⁷³ This mandatory adverse event reporting for dietary supplements is based on the existing system that applies to drugs. Adverse event reports are not required to indicate whether the material is being used in nanoscale form. The FDA expects this authority to strengthen its ability to engage in post-market monitoring of dietary supplement safety.⁴⁷⁴

The FDA retains some authority over 'new' dietary supplement ingredients (NDIs) under the DSHEA. New supplements include substances that have not been used in supplements previously and are not present in the food supply in the same chemical form. Without exception, producers must notify the FDA before marketing supplements that contain new ingredients – no GRAS exclusion applies to NDIs. In its notification, the producer must include information showing that the supplement 'will reasonably be expected to be safe'.⁴⁷⁵ However, the nature of the safety information on which the manufacturer may rely is not specified in the law, and there is no requirement that a manufacturer wait for a safety determination from the FDA before marketing the product.⁴⁷⁶ This authority may require notification of new nanoscale ingredients that may be incorporated into dietary supplements. The Task Force has recommended issuance of guidance on the issue. A January 2009 report from the Government Accountability Office indicated that the FDA has begun to develop such guidance but could not provide a time frame for its finalization.⁴⁷⁷

468 See Dietary Supplement Health and Education Act of 1994, Pub.L. 103–417, 108 Stat. 4325, (1994), available at <http://vm.cfsan.fda.gov/~dms/dietsupp.html> (accessed on 7 July 2009). The Federal Trade Commission regulates dietary supplement advertising.

469 Ibid.

470 Ibid. 21 U.S.C. § 321(ff).

471 21 U.S.C. § 342(f).

472 FDA (2007a: 15).

473 Covington & Burling LLP (2006: 2).

474 FDA (2007a).

475 21 U.S.C. § 350(b).

476 FDA (2007a).

477 GAO (2009a).

5.1.6 Labelling

The FFDCA (as amended by the Nutrition Labeling and Education Act⁴⁷⁸) and the Fair Packaging and Labeling Act⁴⁷⁹ govern food labelling. Under the FFDCA, a product is misbranded if its label fails to comply with FFDCA requirements. Labels must be truthful and not misleading and must include information required by the FDA (such as ingredients), among other requirements.⁴⁸⁰ Determination of whether a label is misleading is based both on representations made or suggested on the label and by failure to disclose material facts.⁴⁸¹ A fact may be material in the light of representations on the label or ‘with respect to consequences which may result from the use of the product under the conditions of use prescribed in the labeling or under customary or usual conditions of use.’⁴⁸² With respect to food labels, material information may relate to organoleptic, nutritional, or functional properties of the food.⁴⁸³ For products subject to pre-market authorization, FDA generally reviews labelling on a case-by-case basis. However, the agency does not review labels for products not subject to pre-market review – including food products.⁴⁸⁴ As a result, food manufacturers market products without receiving FDA pre-approval for their labels.

The FDA has not issued explicit guidance on the disclosure of nanomaterial use in labelling for any product category. However, the Task Force directly considered both permissible and mandatory labelling. Under the FFDCA, labelling of nanomaterials hypothetically could result in misbranding either by including misleading representations about either the benefits or the risks of nanomaterials. The Task Force focused on risks, in response to a stakeholder suggestion that the FDA require all products containing nanomaterials to disclose that use on their label. The Task Force concluded that the agency could determine that ‘a particular use of a particular nanoscale material, or the use of nanoscale materials more generally, was a material fact for a category of products’ and require labels to include information on the use of such materials.⁴⁸⁵ However, the Task Force recommended against such action by the FDA, noting that ‘the current science does not support finding that classes of products with nanoscale materials necessarily present greater safety concerns than classes of products without nanoscale materials.’⁴⁸⁶ Instead, the Task Force recommended that the agency consider whether labelling must or may include disclosure of nanomaterial use on a case-by-case basis across all product categories.

5.1.7 Confidential business information

The FDA, like other agencies, must balance the competing incentives for retention of private data and disclosure of information to the public. In general, the Freedom of Information Act (FOIA) establishes that most types of agency records are subject to disclosure unless they fall into one of nine exempt categories, including business confidential information.⁴⁸⁷ The FDA has promulgated regulations on disclosure to implement the FOIA.⁴⁸⁸ The FFDCA independently limits the FDA’s ability to disclose information. In general,⁴⁸⁹ section 301(j) of the FFDCA specifically prohibits the agency from revealing information it has acquired pursuant to certain authorities – including but not limited to inspections and food additive petitions – concerning ‘any method or process which as a trade secret is entitled to protection.’⁴⁹⁰ The Federal Trade Secrets Act also protects trade secrets against disclosure.⁴⁹¹

Confidential business information exempt from disclosure is defined in the FOIA as ‘trade secrets and commercial or financial information obtained from a person and privileged or confidential.’⁴⁹² Following this statute, the FDA divides confidential business information into trade secrets and ‘commercial or financial information which is

478 Pub.L. 101–535, 104 Stat. 2353 (1990).

479 15 U.S.C. §§ 1451–61. This Act is related to accurate description of food quantity rather than safety. A number of specific limitations and requirements apply to food and nutrition labelling, as well as to dietary supplement labelling. The specifics of these systems are beyond the scope of this report.

480 21 U.S.C. § 343.

481 21 U.S.C. § 321(n).

482 Ibid.

483 FDA (2007a: 34).

484 See FDA (2008a).

485 FDA (2007a: 35).

486 Ibid.

487 5 U.S.C. § 552(b).

488 21 C.F.R. Part 20. See also FDA (1974). FDA is also subject to FOIA regulations promulgated by the Department of Health and Human Services (HHS). See 45 C.F.R. Part 5.

489 The FDA can disclose trade secret information to persons outside the agency if the Secretary of HHS determines that such person needs the information ‘in connection with an activity which is undertaken under contract with the Secretary, which relates to the administration of this chapter, and with respect to which the Secretary (or an officer or employee of the Department) is not prohibited from using such information.’ The Secretary must require that the person receiving the information take security precautions as prescribed by regulation. 21 U.S.C. § 379.

490 21 U.S.C. § 331(j). This restriction applies to information obtained pursuant to 21 U.S.C. §§ 344, 348, 350a, 350c, 355, 360, 360b, 360c, 360d, 360e, 360f, 360h, 360i, 360j, 360ccc, 360ccc–1, 360ccc–2, 374, 379, or 379e.

491 18 U.S.C. § 1905.

492 5 U.S.C. § 552(b)(4). See also 21 U.S.C. § 379 (referencing 5 U.S.C. §§ 552(a) & (b)(4)).

privileged or confidential' (confidential commercial information).⁴⁹³ Trade secrets are defined with reference to tort law and cannot be disclosed, as established in section 301(j) of the FFDCa.⁴⁹⁴ By contrast, confidential commercial information is defined as 'valuable data or information which is used in one's business and is of a type customarily held in strict confidence or regarded as privileged and not disclosed to any member of the public by the person to whom it belongs'.⁴⁹⁵ Confidential commercial information does not fall under section 301(j) or the Federal Trade Secrets Act, but FDA regulations state that both categories are exempt from disclosure.⁴⁹⁶ However, specific disclosure requirements may contravene that exemption. For example, FDA regulations require that certain data and information in food additive and colour additive petitions be available for public disclosure prior to approval 'unless extraordinary circumstances are shown'.⁴⁹⁷

FDA regulations allow the agency to share 'confidential commercial information submitted to [the FDA], or incorporated into agency-prepared records' with foreign officials 'who perform counterpart functions to the [FDA] as part of cooperative law enforcement or regulatory purposes'.⁴⁹⁸ Prior to disclosure, a foreign agency must provide written assurance that it can and will protect the confidentiality of the information, and the FDA Commissioner must make at least one of three determinations: that the sponsor of the product application approves the disclosure; that it 'would be in the interest of public health by reason of the foreign government's possessing information concerning the safety, efficacy, or quality of a product or information concerning an investigation'; or that the disclosure is to a foreign scientist who is visiting the FDA 'as part of a joint review or long-term cooperative training effort'.⁴⁹⁹ Except in the case of visiting foreign scientists, however, no information relating to 'manufacturing methods and processes' protected by section 301(j) may be disclosed to foreign governments.⁵⁰⁰

The FDA also may disclose to or receive from a foreign government official any 'nonpublic, predecisional documents concerning the Food and Drug Administration's or the other government agency's regulations or other regulatory requirements, or other nonpublic information relevant to either agency's activities' on behalf of 'cooperative efforts to facilitate global harmonization of regulatory requirements, cooperative regulatory activities, or implementation of international agreements'.⁵⁰¹ Prior to disclosure, the foreign government must certify that it has the authority to and will in fact protect the information from public disclosure, and the FDA must make a determination that the disclosure is 'reasonably necessary to facilitate' the global harmonization of other efforts listed above.⁵⁰²

The term 'official of a foreign government' is defined to include, but is not limited to, 'employees (whether temporary or permanent) of and agents contracted by the foreign government, or by an international organization established by law, treaty, or other governmental action and having responsibility to facilitate global or regional harmonization of standards and requirements in the FDA's areas of responsibility or to promote and coordinate public health efforts'.⁵⁰³ The FDA has established confidentiality agreements with the EU for sharing information on a number of topics.⁵⁰⁴ These notably include commitments with the European Food Safety Authority (EFSA) regarding information-sharing for food and feed⁵⁰⁵ and with DG SANCO regarding food safety.⁵⁰⁶

5.1.8 *Nanospecific regulatory actions*

The FDA has considered how nanotechnology will affect its regulatory programmes, focusing on food as part of its larger mandate. In particular, as noted above, it created a Nanotechnology Task Force to investigate 'regulatory

493 21 C.F.R. § 20.61.

494 21 C.F.R. § 20.61(a), stating 'A trade secret may consist of any commercially valuable plan, formula, process, or device that is used for the making, preparing, compounding, or processing of trade commodities and that can be said to be the end product of either innovation or substantial effort. There must be a direct relationship between the trade secret and the productive process.' See also FDA (1974: 44,612, quoting Restatement of Torts § 757, comment b (1938)).

495 21 C.F.R. § 20.61(b).

496 21 C.F.R. § 20.61(c).

497 21 C.F.R. §§ 171.1(h)(1), 71.15(a). Other disclosure requirements may also apply. With respect to index files for unapproved new animal drugs for minor species, for example, FDA may disclose 'brief summar[ies] of ...selected portions of the safety and effectiveness data as are appropriate for public consideration of a specific pending issue, e.g., ... pursuant to an exchange of important regulatory information with a foreign government'. 21 C.F.R. § 516.171(d). See also 21 C.F.R. § 601.51(d)(1) (biologics licences); 21 C.F.R. § 514.11 (unapproved new animal drug applications).

498 21 C.F.R. § 20.89(c)(1). Section 20.89 also allows sharing of confidential investigatory files between governments without disclosure. 21 C.F.R. §§ 20.89(a) & (b).

499 21 C.F.R. § 20.89(c)(1).

500 21 C.F.R. § 20.89(c)(2).

501 21 C.F.R. § 20.89(d)(1).

502 Ibid.

503 21 C.F.R. § 20.89(e).

504 See FDA, International Arrangements, at <http://www.fda.gov/oia/> (accessed 7 July 2009).

505 FDA (2007c).

506 FDA (2005).

approaches that encourage the continued development of innovative, safe, and effective FDA-regulated products that use nanotechnology materials.⁵⁰⁷ The Task Force issued its final report in 2007.

The FDA recognizes that nanoscale materials may present unique health risks and benefits, but considers those risks to be uncertain. It has also acknowledged limitations in its ability to gather data to make risk determinations to support rule-making.⁵⁰⁸ As a result, the agency appears unlikely to regulate nanomaterials as a class. Instead, it will continue to apply its existing regulatory framework, considering nanomaterial risks as necessary to evaluate the safety of particular products. The agency's policy is thus likely to follow historical precedent for other emerging technologies as well as its standing practice for review of products that contain natural (as opposed to engineered) nanoscale materials.⁵⁰⁹ In addition, it is likely to issue guidance on particular subjects, as recommended by the Task Force report.

5.2 EU food regulations

EU food and feed legislation has changed significantly over the past decade in the wake of a series of health and safety scandals, such as bovine spongiform encephalopathy (BSE), infected blood products for transfusions, and dioxin contamination of feedstock for chicken. These changes have brought about a strengthening of EU authority in food regulation, which covers food products and food production, packaging and labelling, as well as the creation of the European Food Safety Authority (EFSA) as an independent European agency. Food regulation is now largely determined at EU level, and national food laws in EU Member States generally implement decisions taken by EU authorities. General risk management authority rests with DG SANCO, the European Commission's Directorate-General for Health and Consumers. Working closely with national authorities, the EFSA performs two main functions, which are the provision of independent scientific advice to risk managers and the communication of food-related risks to stakeholders and the wider public.

The new EU food safety regime is based on Regulation EC 178/2002, which was adopted in 2002. This regulation establishes the general principles and requirements of food law and sets forth food safety procedures. Its primary aim is to provide 'a strong science base, efficient organisational arrangements and procedures to underpin decision-making in matters of food and feed safety'. The legal responsibility for ensuring food safety lies with food business operators, but EU law authorizes regulators to use oversight mechanisms such as pre-market review, positive and negative lists, and post-market surveillance, depending on whether 'regular' food and feed, 'novel' foods, food contact materials, additives or supplements are concerned.

In its review of regulatory aspects of nanomaterials, the Commission argues that in general, EU food and feed legislation contains the necessary provisions to adequately address safety concerns related to nanomaterials in all relevant food and feed sectors. At the same time, however, EU institutions are considering necessary adjustments to existing regulations in order to close potential gaps in the regulatory coverage of nanotechnology. Furthermore, the first scientific assessments of nanomaterials in food have revealed certain gaps with regard to scientific data on health and environmental effects.

The regulatory tools employed in each area of EU food regulation differ to some extent, in terms of the use of positive lists of authorized substances (e.g. food contact materials, additives, supplements, etc.), but also with regard to explicit or implicit references to nanotechnology and nanomaterials. To address potential differences between authorized substances in nanoform and in bulk form, for instance, some statutes have recently been adjusted to take into account factors such as particle size or the use of nanotechnology (e.g. regulations on enzymes and additives). More such adjustments can be expected in the coming years (e.g. for novel foods).

5.2.1 Novel Foods

The Novel Foods Regulation (EC 258/97) applies to foods and food ingredients (except food enzymes, additives, flavourings, and extraction solvents) not consumed in the EU before 15 May 1997. It establishes a legal requirement for all novel foods to be approved before they are introduced to the market. Food producers need to submit a safety assessment for novel foods and, once they have received regulatory approval, are obliged to inform customers through labelling of any food characteristics or properties that 'render a novel food or food ingredient no longer equivalent to an existing food or food ingredient'. The label must also describe the method by which this characteristic or property was obtained. Although the Novel Foods Regulation was originally drafted to address genetically modified foods and feeds, which are today covered by Regulation 1839/2003, it was worded to apply to a broad variety of food products, and is thus considered to be of central importance to the regulation of newly emerging nanomaterials in food products.

507 FDA (2006a).

508 Marchant et al. (2007); FDA (2007a: 18) ('... ability to detect nanoscale materials in the body or in products regulated by FDA is limited, and development of appropriate analytical methods for classes of products and of nanoscale materials may require substantial effort').

509 Marchant et al. (2007: 196) (citing Sadrieh 2005).

The definition of 'novel food' is of critical importance to the question of whether nanomaterials are fully covered. Article 1(2) of the Novel Food Regulation lists several categories under which a food or food ingredient can be considered as 'novel'. In its existing formulation, which is currently under review, the Regulation does not explicitly mention nanotechnology or particle size as a relevant criterion. Two categories listed in Article 1(2) have been considered as fall-back provisions to capture nanomaterials under the novel food definition:

(c) foods and food ingredients with a new or intentionally modified primary molecular structure; [...]

(f) foods and food ingredients to which has been applied a production process not currently used, where that process gives rise to significant changes in the composition or structure of the foods or food ingredients which affect their nutritional value, metabolism or level of undesirable substances.

The extent to which these definitions of 'novel food' comprehensively capture all forms of nanotechnology use in food products remains a matter of debate in expert circles. The applicability of category (c) has been questioned recently as the molecular structure of nano-structured food products does not necessarily differ from that of conventional food products. By contrast, category (f), which focuses on novel processes, is more likely to capture a wider range of nanotechnological uses in food. Even so, category (f) adds the qualifying requirement that the use of nanotechnologies needs to result in significant changes that affect the food product's nutritional value, metabolism or level of undesirable substances if such products are to be considered 'novel'.⁵¹⁰ Because the decision to identify nanofoods as 'novel' under EU law lies with food producers, any ambiguities with regard to the applicability of the above 'novel foods' criteria may therefore prevent a comprehensive regulatory coverage of nanotechnology use in food products.

It is this uncertainty in the definition of novel foods that is to be addressed through a revision of the Regulation on Novel Foods. In January 2008, the European Commission adopted a proposal that would rewrite the scope of the Novel Foods legislation to include new technologies derived from nanosciences and to centralize the assessment and approval procedure at EU level. By specifically mentioning nanotechnology in the definition of 'novel food',⁵¹¹ the proposed reform provides an opportunity to remove any ambiguity from the existing Regulation. In a 25 March 2009 vote, the European Parliament endorsed the principles behind the European Commission's proposal and urged the Commission to introduce mandatory labelling of nanomaterials in the list of ingredients, and to include a definition of nanomaterials.⁵¹² It also approved the inclusion of a new category for defining novel foods that includes an explicit reference to 'food containing or consisting of engineered nanomaterials not used for food production within the Community before 15 May 1997', which would provide a firmer basis for covering nanomaterials under the Novel Foods Regulation. The European Parliament proposal also defines 'engineered nanomaterial' to mean 'any intentionally produced material that has one or more dimensions of the order of 100 nm or less or is composed of discrete functional parts, either internally or at the surface, many of which have one or more dimensions of the order of 100 nm or less, including structures, agglomerates or aggregates, which may have a size above the order of 100 nm but retain properties that are characteristic to the nanoscale'.⁵¹³ 'Properties characteristic to the nanoscale' include 'those related to the large specific surface area of the materials considered'; and 'specific physico-chemical properties that are different from those of the non-nanoform of the same material'.⁵¹⁴ The proposal requires the Commission to adjust these definitions in the light of technical and scientific progress and the emergence of agreed definitions at the international level.

The European Parliament proposal also includes several specific requirements relevant to nanomaterials that will have far-reaching consequences if adopted in its current version.⁵¹⁵ It states that '[t]est methods currently available are not adequate for assessing the risks associated with nanomaterials. Nano-specific non-animal test methods should be

⁵¹⁰ Gergeley et al. (2009).

⁵¹¹ 'Novel food should include ... foods modified by new production processes, such as nanotechnology and nanoscience' (European Commission (2008e: 10)).

⁵¹² See European Parliament, Press Release, Novel foods, MEPs set new rules (2009), available at http://www.europarl.europa.eu/news/expert/infopress_page/067-52498-082-03-13-911-20090324IPR52497-23-03-2009-2009-false/default_en.htm (accessed 7 July 2009).

⁵¹³ Under the ongoing revision of the novel food legislation, a draft definition of 'engineered nanomaterials' was introduced and preliminarily endorsed by the Council and the European Parliament in March 2009. European Parliament (2009a: amdt. 92, 35, art. 3(cc)); European Council (2009: art. 3(2) (c)). If adopted, this definition would clarify when a pre-market authorization is required.

⁵¹⁴ Ibid.

⁵¹⁵ The proposal would also alter the food products subject to the Novel Foods Regulation, which currently does not apply to additives, enzymes, flavourings and solvents. The proposal would add 'vitamins and minerals' and genetically modified foods to the list of food products excluded from the regulation. These products may nonetheless be subject to the Novel Foods Regulation, however, if they are produced via novel processes that change their structure or characteristics – including the use of 'engineered nanomaterials'. European Parliament (2009a: amdt. 91, art. 2a). This statement was excised from the version reported by the European Council (2009: art. 2).

developed as a matter of urgency.’⁵¹⁶ Thus, under Article 6, ‘foods to which production processes have been applied that require specific risk assessment methods (e.g. foods produced using nanotechnologies) may not be included in the community list until such specific methods have been approved for use, and an adequate safety assessment on the basis of those methods has shown that the use of the respective foods is safe.’⁵¹⁷ Thus an amended Novel Foods regulation may require approval of nano-specific test methods before foods produced with nanotechnologies can be assessed or authorized for sale. This regulation could thus slow the commercialization of nano-enabled foods in the EU.

Uncertainty remains, of course, about the precise wording of the new Novel Foods Regulation, as European institutions seek a compromise between different legislative proposals put forward so far. The European Council’s own version, which was agreed in June 2009, also mentions that ‘there is inadequate information on the risks associated with engineered nanomaterials’, and, accordingly, new test methodologies need to be developed. However, it does not explicitly make the authorization of foods produced using nanotechnologies conditional upon the development of such test methodologies.⁵¹⁸

5.2.2 Food enzymes, additives and flavourings

In December 2008, the EU published a set of new regulations for food enzymes (EC 1332/2008), food additives (EC 1333/2008) and food flavourings (EC 1334/2008), as well as a regulation on a common authorization procedure for these substances (EC 1331/2008).⁵¹⁹ Similar to preceding regulations and directives on additives and flavourings, the new regulation on a common authorization procedure stipulates that enzymes, additives and flavourings ‘must not be placed on the market or used in foodstuff [...] unless they are included on a Community list of authorised substances’.

Moreover, Regulation 1331/2008 establishes a common Community assessment and authorization procedure, subject to an opinion by the EFSA when necessary, that ‘must be preceded by an independent scientific assessment, of the highest possible standard, of the risks that [enzymes, additives and flavouring substances] pose to human health’.⁵²⁰ Information relating to the safety of a substance should ‘under no circumstances’ be confidential. The regulation furthermore states:

*It is recognised that, in some cases, scientific risk assessment alone cannot provide all the information on which a risk management decision should be based, and that other legitimate factors relevant to the matter under consideration may be taken into account, including societal, economic, traditional, ethical and environmental factors and the feasibility of controls.*⁵²¹

Food enzymes were not regulated at EU level prior to Regulation EC 1332/2008. The new regulation covers only enzymes that are added to food to perform a technological function in the manufacturing, processing, preparation, treatment, packaging, transport or storage of such food but does not cover enzymes for nutritional or digestive purposes. In general, food enzymes should only be approved if they are safe and if they fulfil a ‘technological need’. As mentioned above, a safety assessment has to be carried out before the authorization of a specific enzyme. Enzymes that are already authorized but are produced by a ‘significantly different’ method that involves, for instance, a ‘change in particle size’ are subject to an additional evaluation.

Food additives are defined as

*any substance not normally consumed as a food in itself and not normally used as a characteristic ingredient of food, whether or not it has nutritive value, the intentional addition of which to food for a technological purpose in the manufacture, processing, preparation, treatment, packaging, transport or storage of such food results, or may be reasonably expected to result, in it or its by-products becoming directly or indirectly a component of such foods.*⁵²²

The new food additive regulation covers only food additives falling within this definition, and does not apply to food enzymes, flavourings or certain other substances.⁵²³ Similar to other food legislation, the food additive regulation

516 European Parliament (2009a: amdt. 11, recital 6c). The June 2009 version indicates that test methods should be created ‘as a matter of urgency’ (European Council 2009: recital 16(a)).

517 European Parliament (2009a: amdt. 50, art. 6(1a)).

518 European Council (2009: recital 16a).

519 European Commission (2008f).

520 Ibid.

521 European Commission (2008f: recital 14).

522 European Commission (2008f: art. 3).

523 Ibid. art. 2.

stipulates that food additives must be safe when used, there must be a technological need for their use, they must be of benefit to the consumer, and they must not mislead the consumer.

The new food additive regulation is of particular interest in the context of this report, as it is the first EU regulation that explicitly mentions nanotechnology. Article 12 on 'Changes in the production process or starting material of a food additive already included in a Community list' states:

When a food additive is already included in a Community list and there is a significant change in its production methods or in the starting materials used, or there is a change in particle size, for example through nanotechnology, the food additive prepared by those new methods or materials shall be considered as a different additive and a new entry in the Community list or a change in the specifications shall be required before it can be placed on the market. (Emphasis added)

By way of background, in July 2006, the European Commission first presented a proposal to turn the food additives directive into a regulation.⁵²⁴ This proposal did not include any explicit reference to particle size of a food additive or to nanotechnology as such. A subsequent April 2007 legislative report by the European Parliament recommended an amendment to Article 10(1a) to include a statement that 'if the use of nanotechnology is authorised, separate limit values for that purpose shall be laid down'.⁵²⁵ As a justification for this amendment, the legislative report argues that 'it is not certain that the limit value for traditional use of an additive and the limit value for nanoparticles of an additive should be the same'. It also argues, more generally, that 'nanoparticles should be regulated separately [from other substances used as additives] in the Community list'.⁵²⁶

In a subsequent Communication, the Commission stated that the amendment on limit values for nanoscale food additives is not necessary, 'as specific restrictions could already be allocated under the conditions of use if these are deemed necessary' (p. 7). It suggested amending its initial proposal for a regulation to 'reiterate and clarify that nanoscale additives would need to be evaluated by EFSA before they could be used as they may behave in a different manner which could affect their safety' (p. 7). This, according to the Communication, is incorporated in Article 11 of the Commission proposal.⁵²⁷

The new regulation on food flavourings covers flavourings, source materials for flavourings and foods containing flavourings, which it defines as 'products that are not intended to be consumed as such, which are added to food in order to impart or modify odour and/or taste'. It stipulates that flavourings can only be used when they are safe and do not mislead consumers. The regulation further outlines which types of flavourings are subject to risk assessment and must be included in a Community list before being used in food. Similar to other food legislation, the flavourings regulation stipulates that the approval of flavourings should also consider a range of societal and economic factors and also includes a specific reference to the precautionary principle. In contrast to the new regulations on additives and enzymes, however, it does not make any specific reference to particle size or nanotechnology as criteria for safety assessments.

5.2.3 Food supplements

Food supplements, such as vitamins and minerals,⁵²⁸ are regulated by Directive 2002/46/EC. Only those supplements that are listed on so-called positive lists are allowed to be marketed in Europe. Listing requires a prior safety assessment by the EFSA, which issues guidelines on the application process for safety evaluation. The Directive stipulates that authorized food supplements be labelled so that consumers can make informed choices. Member States' Competent Authorities are responsible for the monitoring of this Directive, and are entitled temporarily to suspend or restrict authorizations of supplements, in cases where new information or a reassessment of existing information points to threats to human health.

The Directive does not explicitly mention nanotechnologies or nanomaterials. The European Commission points out that the authorization procedures as well as the safeguard provisions of the Directive ensure that 'risks associated with the use of vitamins and minerals in "nano" forms ... be dealt with in an appropriate way'. However, it also acknowledges ambiguity in the existing rules that may need to be addressed in future revisions of the Directive, particularly in the form of an explicit requirement to provide information on the particle form and production process of supplements. The Commission also points out that EFSA guidelines on the application process for safety assessment may 'need to be adapted to require identifications of possible compounds present in "nano form"', and that risk assessment 'would need to be adapted to take into account specific risk arising from the use of substances in "nano-form", if any'.⁵²⁹

524 European Commission (2006c).

525 European Parliament (2007: amdt. 35, art. 10(1a)).

526 European Parliament (2007: Explanatory Statement).

527 European Commission (2007e).

528 Defined in European Commission (2002: Article 2) as concentrated sources of nutrients to supplement the normal diet.

529 European Commission (2008a: 24).

A recent example of how existing regulations affect the introduction of nanotechnology-based food supplements is provided by the EFSA's scientific opinion on the safety of silver nanoparticles, published in November 2008.⁵³⁰ After reviewing an application to include silver hydrosols, a nutrient already in use in Europe and the US, in the positive list in Annex II of the Food Supplements Directive, the EFSA declared that there was not enough evidence to determine the safety of nanosilver for use in food supplements. In its conclusion, the agency stated that the toxicological data were insufficient 'to allow hazard characterization of silver hydrosol'. As in other cases, knowledge gaps regarding EHS risks have prevented a definite regulatory decision, illustrating the importance of implementation to the question of how well the existing regulatory framework covers nanotechnology-related risks.

5.2.4 Food contact materials

All food contact materials and articles, including food-packaging but also cooking utensils, food processing and transport equipment, are regulated by framework regulation EC 1935/2004. In principle, manufacturers are responsible for ensuring that food contact materials are safe and that they do not transfer constituent substances to foodstuffs under normal or foreseeable conditions of use in a way that endangers human health, or bring about an unacceptable change in the composition of the food, or cause a deterioration in the organoleptic characteristics of the food (i.e. taste, colour, odour and texture). In certain cases, however, the EFSA is required to give a positive evaluation of food contact materials before they can be included in positive lists and introduced to the market. Furthermore, some groups of materials such as glass, plastics and silicones, but also 'active and intelligent materials and articles',⁵³¹ may be subject to specific measures such as migration limits⁵³² or additional labelling requirements.⁵³³ As with food additives, Member States' Competent Authorities have the power temporarily to suspend or restrict authorizations of food contact materials, in cases where new information or a reassessment of existing information points to threats to human health.

The Food Contact Material Regulation establishes special restrictions on 'active' and 'intelligent' food contact materials and articles. 'Active' materials 'are intended to extend the shelf-life or to maintain or improve the condition of packaged food' and 'are designed to deliberately incorporate components that would release or absorb substances into or from the packaged food or the environment surrounding the food'. 'Intelligent' materials are those that 'monitor the condition of packaged food or the environment surrounding the food'.⁵³⁴ While food contact materials must be manufactured to prevent migration to food that would cause an unacceptable change in food composition or a deterioration of the food's organoleptic characteristics,⁵³⁵ Article 4 of the Regulation allows for active and intelligent materials and articles to change a food's composition and organoleptic conditions so long as the resultant changes comply with other applicable community food provisions.⁵³⁶ Thus, for example, if a component released by an active material changes the composition of food so that the component is a food additive as defined in the Food Additive Regulation, that component cannot be used unless it is included on the EU's list of approved additives. More generally, components of active or intelligent materials can be subject to mandatory authorization and a safety evaluation under other regulations, such as the Novel Food, Flavouring, or Additive Regulations, if they fall within the scope of those regulations.

As in the case of food supplements, the European Commission has pointed out that EFSA guidelines for safety testing of food contact materials 'would need to be adapted to require identifications of possible compounds present in "nano form"', and that risk assessment 'would need to be adapted to take into account specific risk arising from the use of substances in "nano-form", if any'.⁵³⁷ In general, however, and given the authority of Member States to suspend EU authorizations of food contact materials to protect against threats to human health, the Commission concludes that 'the requirements and mechanisms contained in Framework Regulation (EC) No 1935/2004 allow risks associated with nanomaterials to be dealt with in an appropriate way'.⁵³⁸

The EFSA's case-by-case assessment of individual nanomaterials used as a protective barrier in polyethylene terephthalate (PET) articles has produced two recent scientific opinions. In February 2007, the EFSA decided that silicon dioxide coating (SiO₂) can be used as a surface treatment agent on PET materials, and in November 2008

530 EFSA (2008), on a request from the commission on silver hydrosol as a source of silver added for nutritional purposes to food supplements.

531 See European Commission (2004: Annex I) for a complete list. According to European Commission (2004: art. 2), 'active materials and articles' means 'materials and articles that are intended to extend shelf-life or to maintain or improve the condition of packaged food. They are designed to deliberately incorporate components that would release or absorb substances into or from the packaged food or the environment surrounding the food.' 'Intelligent materials and articles' means 'materials and articles which monitor the condition of packaged food or the environment surrounding the food'.

532 European Commission (2004: art. 5(e)).

533 Ibid., art. 5(l).

534 Ibid., art. 2(2)).

535 Ibid., art. 3.

536 Ibid., art. 4.

537 European Commission (2008g: 23).

538 Ibid.: 24.

the EFSA decided that titanium nitride (TiN) can be used in PET bottles up to 20mg/kg.⁵³⁹ EFSA scientific opinions on the inclusion into positive lists for food contact materials thus focus on specific food contact materials in the context of specific applications and procedures. It remains to be seen how this approach will evolve in the light of a growing number of new and potentially more complex applications. The current Food Contact Materials Regulation does not require food contact material suppliers to inform their customers about the nature and amount of potential migration.⁵⁴⁰

5.2.5 Labelling

The presentation, advertising, and labelling of foodstuffs⁵⁴¹ is regulated by Directive 2000/13/EC, which requires labelling information of a variety of information, including ingredients, durability, net quantity and storage condition. Article 4, Section 3 of the Directive also stipulates that the food product should include information on 'the physical condition of the foodstuff or the specific treatment which it has undergone (e.g. powdered, freeze-dried, deep-frozen, concentrated, smoked) in all cases where omission of such information could create confusion in the mind of the purchaser'. Additional, more specific labelling requirements apply to products making health and nutrition claims, mineral waters, dietetic and weight reduction foods, foods for special medical purposes, vitamins and minerals, and food supplements. For food supplements, for example, additional labelling regulations require guidelines for use and forbid food supplements to claim the property of 'preventing, treating or curing a human disease, or refer to such property'.⁵⁴²

While there is no general labelling requirement for nanomaterials in food, specific requirements may apply to certain categories of food products, e.g. where nanomaterials in food are considered to be novel foods. Current regulatory rules and practice in the EU thus point to a selective approach to labelling, but the European Parliament issued a call for a more comprehensive labelling system in its 25 March 2009 vote on the Commission proposal for a revised Novel Foods Regulation. It remains to be seen whether the final compromise between the European Council and European Parliament adopts the latter's preference for a general nanomaterials labelling regime for food.

5.2.6 General concluding remarks on EU food regulation

EU food and feed legislation places the responsibility for ensuring product safety on manufacturers, but allows for specific regulatory measures in the form of pre-market approval, post-market monitoring and labelling in certain product categories. As in other regulatory contexts, the question of whether nanomaterials are adequately covered depends on both the regulatory provisions and implementation praxis. Recent developments in the EU suggest that European institutions apply a case-by-case analysis of nanomaterials that are entering the market and are seeking to deal with any regulatory gaps or uncertainties through amendments to existing laws.

Questions relating to the implementation of EU food law have thus emerged as a key factor in determining the effectiveness of nanotechnology food oversight. In its general opinion on the Potential Risks Arising from Nanoscience and Nanotechnologies on Food and Feed Safety, the EFSA states that knowledge on the characterization, detection, measuring, toxokinetics, toxicology, exposure pathways and current use of nanomaterials in food is limited.⁵⁴³ It concludes that risk assessment of engineered nanomaterials should therefore consider the specific properties of nanomaterials and should be 'performed on a case-by-case basis', but cautions that under present circumstances, 'any individual risk assessment is likely to be subject to a high degree of uncertainty'.⁵⁴⁴ This conclusion is echoed in the finding of the UK's Food Standards Agency (FSA), which stated in its regulatory review of August 2008 that it had 'not identified any major gaps in regulations' but pointed out that 'there is uncertainty in some areas whether applications of nanotechnologies would be picked up consistently'.⁵⁴⁵

5.3 Comparing US and EU approaches

The US and the EU take a similar approach to food regulation, basing regulatory authority on product categories, each of which is regulated according to its perceived risk level. The US and the EU apply a similar suite of regulatory tools to these product categories, ranging from pre-market review to labelling. Despite broad similarities between them, however,

539 EFSA (2007: 3). For the opinion on titanium nitride nanoparticles, see EFSA, *Scientific Opinion: 21st list of substances for food contact materials* (2008), at http://www.efsa.europa.eu/cs/BlobServer/Scientific_Opinion/cef_op_ej888-890_21stlist_en,3.pdf?ssbinary=true (accessed 8 July 2009).

540 See also Food and Drug Federation, *FDf response to FSA draft report of regulatory review of the use of nanotechnologies in relation to food*, at http://www.fdf.org.uk/responses/fdf_response_nano.pdf (accessed 8 July 2009).

541 All foodstuff with the exception of fresh fruit and vegetables, some dairy products and products comprising a single ingredient.

542 European Commission (2002: art. 6(2)).

543 EFSA (2009).

544 EFSA (2009: 2); see also Food Safety Authority of Ireland (2008).

545 FSA (2008: 2).

the specific elements of food regulation and implementation differ. Moreover, the regulatory system for food in the EU has changed dramatically in the past decade and will continue to evolve in coming years as a result of the maturation of regulatory practice. In contrast, the FDA has a long history of food regulation and previously has considered emerging technologies in other contexts. However, even though its general practices are established, specific regulatory developments are likely in coming years to address nanomaterials. By necessity, we therefore examine only existing legal authorities and stated policy objectives; we cannot predict how these developing policies and regulatory tools will be applied in practice.

The following discussion identifies similarities and differences between EU and US regulatory systems for food products in several areas. These areas include both how these systems regulate in general and their responses to issues of significance to nanotechnologies and nanomaterials in particular.

5.3.1 Nano-specific regulation

The US and the EU use two general approaches to regulating food products containing or made with nanotechnologies or nanomaterials. The first approach to nanomaterial regulation is to use a case-by-case assessment under existing regulatory processes. The FDA's approach to food product regulation exemplifies this strategy. In its review of food products as required by the FFDCA, the agency will consider particle size where relevant to health or safety risks, but it does not consider particle size by default in all cases. The EU also commonly follows a case-by-case approach. For example, its supplement regulation does not specifically reference nanotechnologies or nanomaterials, but the use of these technologies or materials is evaluated as necessary, as seen in the silver hydrosol risk assessment determination noted above.⁵⁴⁶

The second approach to regulation of nanomaterials in food products is to refer explicitly to nanotechnologies and/or nanomaterials and to establish specific safeguards for their use in food products or production processes. This approach is exemplified by the EC's proposed amendment of the novel foods regulation, which would specifically require pre-market safety assessment and mandate labelling of food products produced with new technologies derived from nanosciences. The EU appears more willing than the US to create such default rules; the US regulatory system will favour case-by-case analysis of products unless evidence emerges that indicates that all nanomaterials (or a subset of nanomaterials, such as fullerenes or nanotubes) may be potentially injurious to health and, therefore, require regulation as a group.

5.3.2 Definitions and product categories

Food products are regulated on the basis of product categories in both the EU and US. For example, food additives and colour additives are subject to different regulations in the US, and the EU has established specific separate regulations to govern food enzymes and food contact materials. The regulatory standards that apply to any particular product therefore depend on the categorization of that product. Categorization of products depends upon the definition of each product type. Food regulations in the US and EU differ in some respects with regard to both the product categories and the definitions that apply to those categories.

First, the US and the EU have not established identical product categories. In this chapter, we have introduced the product categories used by each entity. Many of them are analogous on both sides of the Atlantic. For example, both jurisdictions identify as product categories food, food additives and (dietary) supplements. Others are not shared. For example, the US does not separately regulate novel foods or food enzymes, while the EU does not uniquely regulate residues in its food authorities.

Second, the definitions that delineate the scope of each product category may differ. For example, the definition of 'food additive' in the US appears to be broader than in the EU. Food contact materials fall under the definition of food additives in the US, but the EU controls them under a specific framework regulation. Similarly, food enzymes and food flavourings are subject to specific regulations in the EU, whereas these products may be food additives or GRAS ingredients in the US, depending on their specific regulatory history.

The differences between product categories and definitions in the US and the EU preclude generalization as to how a particular nano-enabled food ingredient will be regulated; instead, determination of the regulatory status for a particular product requires case-by-case analysis.

5.3.3 Pre-market regulatory tools

The EU and the US share similar suites of regulatory tools to govern the production and marketing of food products. These tools can be divided into two groups: those that apply before a product can be marketed, and those that are used for products already on the market. Pre-market tools include requirements for safety assessment and agency approval of products, while post-market tools include product monitoring and recall powers, as well as labelling requirements.

⁵⁴⁶ Ingredients in food supplements placed on the market after June 1997 are also novel foods and thus are subject to risk assessment by means of the Novel Foods Regulation, as amended.

This section discusses the similarities and differences among the pre-market and post-market tools that apply in the US and EU for different product categories. A comprehensive comparison of how each regulatory system governs each specific product category is beyond the scope of this report. By necessity, therefore, we generalize across categories, while selecting specific examples where appropriate. We recognize the inherent loss of nuance accompanying this approach and refer the reader to the preceding sections for the in-depth analysis of the systems governing each product category.

Pre-market review and approval powers are among the most powerful tools available to regulators for governing the development and sale of food products and for generating health and safety data. In both the US and the EU, some categories of food products require pre-market review and approval, while others can be marketed without agency review. In the US, for example, the FDA must review and approve new food and colour additives before they can be marketed, but dietary supplements are not subject to FDA approval. The EU requires pre-market review and approval in a larger number of product categories. For example, supplements must be approved prior to marketing, as must new food additives, enzymes and flavourings. On the other hand, ‘food as such’ or whole foods need not be approved.

Table 5.1: Comparison of US and EU pre-market review requirements

Product category	US	EU
Food and feed	No	No
Food additive	Yes	Yes
GRAS ingredient/prior sanction	No*	N/A
Food enzyme	N/A	Yes
Food flavouring	N/A	Yes
Supplement	No	Yes
Food contact material	Yes**	Yes
Colour additive	Yes	N/A***
Novel Food	N/A	Yes

* Subject to same level of safety as food additives.

** Food contact notification requires notice to but not explicit approval from FDA.

*** Colours are regulated as additives in the EU and are subject to pre-market review pursuant to the Food Additive Regulation.

Pre-market review and approved products

Pre-market review and approval applies to newly developed products proposed for use in food for the first time. These pre-market tools can also apply to new forms or uses of existing, approved products. Rules for reconsideration of existing products, whether based on the development of a new process for developing the products or on changes to product characteristics, may differ among product categories and between the US and EU. Nanotechnologies and nanomaterials may produce new uses of existing approved products, new nanoscale forms of approved products, or new production processes.

In the US, products subject to pre-market approval generally are identified and regulated on the basis of their chemical identity or molecular composition and their proposed use, but the FDA may also seek information on the physical characteristics of food products, including particle size, as part of review processes. The regulations for specific products (for example, GRAS ingredients or food additives) set forth conditions for safe use and may limit the types of foods in which a given product can be used and the maximum amount to be used, as well as setting labelling requirements. Where the FDA has determined a need to regulate physical and chemical properties of the product (including particle size), it includes these limitations in the regulation. Thus, determination of whether a new pre-market approval is needed depends on the following factors:

- *New uses:* Companies seeking to use existing products for uses that are not allowed by an existing regulation must seek approval, just as for a new product.
- *New nanoforms:* Determination of whether a nanoscale form of an approved product can legally be marketed depends on whether the regulation for that product includes a limitation on physical or chemical properties,

including particle size. Most regulations do not limit particle size, and the FDA could be required to amend its regulations to limit the use of nanoscale forms of those products.⁵⁴⁷

- *New processes:* Most product approval regulations do not specify the production process required to be used for particular products. The use of a new production process (without changes to the end product or its use) generally would not require a new review process unless the applicable regulation states otherwise.

The risk assessment process in the EU roughly echoes that used in the US. Products are primarily identified by molecular structure, but product approvals can also be limited by use and other physical properties, including particle size. The EFSA's scientific opinions are carried out on a case-by-case basis and may be tailored to particular molecular sizes and uses as needed. For example, as requested by the applicant, its scientific opinion for nanoscale silicon dioxide coating (for food contact material) covers only coatings less than 100nm in thickness in surface treatments on PET bottles. Thus, as in the US, the requirement for product re-approval based on the use of nanotechnologies or nanomaterials generally depends on the restrictions in the applicable existing product approval:

- *New uses:* Re-approval requirements for existing products desired to be used in a new way depend on the language of the original approval and require new review unless the product has been approved for general use.
- *New nanoforms:* For some product categories, including novel foods and food additives, a change in the particle size of an approved substance automatically triggers a new approvals requirement. For others, approval requirements are based on the language approving use of the bulk substance.
- *New processes:* The Novel Foods Regulation applies not only to novel food products but also to foods 'to which has been applied a production process not currently used [i.e. before 1997], where that process gives rise to significant changes in the composition or structure of the foods or food ingredients ...'. Nanotechnology-enabled processes are likely to fall under this definition if they change the resultant food product.

5.3.4 Post-market regulatory tools

Similar types of post-market authorities are available to regulators in both the US and the EU. These authorities include, but are not limited to, monitoring, inspection and recall powers, and mandatory labelling requirements. In general, the FDA may remove adulterated and misbranded food products from the US market. Its authority may differ for specific product categories, however. For example, its ability to remove from the market naturally occurring hazardous substances is narrower than its authority to remove poisonous or deleterious substances added to food as the result of human activity. In the EU, Article 17 of the general food law requires Member States to enforce and monitor compliance with the law, including surveillance for unsafe products and those with misleading presentation. The specific elements of these monitoring and enforcement protocols are not spelled out in the Regulation and may differ among Member States. Similarly, under Article 12 of the Novel Foods Regulation, Member States may restrict or suspend the trade in and use of novel food products that endanger human health or the environment. Thus, the post-market tools available to regulators may differ in the EU according to both Member State authority and product category. The post-market tools available in the US and EU are likely to differ for particular products, particularly given the different product categories that apply in each jurisdiction.

Labelling

Both the US and the EU contain mandatory labelling requirements for food products, including disclosure of product ingredients. These requirements may differ by product category; for example, the EU food contact regulation contains a specific symbol that must be included on food contact material products. In general the EU requires more information disclosure on food product labels than the FDA. For example, product labels for food contact materials in the EU must contain sufficient information to permit traceability of the product, whereas such information is generally not required in the US. In addition, the proposed Novel Foods Regulation requires the ingredient list to disclose ingredients that are present in nano-form. Thus, regulatory requirements for labelling of nano-enabled food products may differ substantially between the US and EU, particularly for Novel Foods.

5.3.5 Data collection and sharing

Both the US and the EU recognize that information limitations complicate determination of the health and safety risks of nanomaterials in food products. The FDA concluded in its Nanotechnology Task Force report that insufficient data are available to enable generalization about the risks of nanomaterials. Similarly, the EFSA has concluded

⁵⁴⁷ This discussion presupposes application of pre-market review processes. We note uncertainty, however, with respect to some product categories; for example, the FDA has recommended issuance of guidance on whether nanoscale forms of ingredients constitute 'new dietary ingredients' (FDA 2007a: 20, 30).

that the risks presented by nanoscience and nanomaterials are uncertain ‘due to presently limited information.’⁵⁴⁸ In particular, the EFSA identified information limitations with respect to the characterization, detection and measurement, limited information on toxicokinetics and toxicology for these materials, and limited knowledge about ‘current usage levels and (likely) exposure from possible applications and products in the food and feed area.’⁵⁴⁹ These limitations have played out in practice in the EU, as the EFSA concluded in its silver hydrosol opinion that toxicological data was insufficient for it to characterize the hazards presented by that particular product. Production and collection of information on the risks of nano-enabled food products is thus an area of focus for regulators on both sides of the Atlantic. Both FDA and EFSA have concluded that these information limitations require the use of a case-by-case assessment process.

Food laws and regulations impact on information availability. Legal authorities, most notably pre-market review requirements, may enable agencies to require producers to disclose existing, but not publicly available, information and to develop additional information to enable effective risk assessment, as necessary to meet product approval requirements. In addition, pre-market review or notice authorities may provide regulatory agencies with needed information on the commercial applications of nanomaterials in food. Information disclosure requirements may differ by category of food product and between the US and the EU. For example, the FDA has acknowledged that it faces hurdles to information-gathering for products that do not require pre-market review or notification, as compared to products subject to pre-market review.

The US and EU also may differ with respect to the public disclosure of information used for product assessment. In some cases, the submission of such information to regulatory agencies may be considered confidential business information and not available for subsequent disclosure by the agency. For example, the FDA is prohibited by statute from disclosing trade secrets, and confidential information may be withheld under EU authorities such as the Food Contact Material Regulation. In other cases, information submitted for use in product approval may be public; indeed, under the same EU Food Contact Material Regulation, all information not confidential is available to the public. However, the relevant regulatory agencies may have the ability to share even confidential information through bilateral links and agreements to hold such information as confidential. The FDA has established such agreements with EU bodies such as DG SANCO, providing for information exchange between the US and the EU.

548 EFSA (2009: 1).

549 Ibid.: 2.

6 Cosmetics Regulation

6.1 US cosmetics regulations

The FDA regulates cosmetics under the FFDCA. As a result, although the specifics of cosmetics regulation are unique, the agency structures and processes governing it are analogous to those previously discussed for food, and the challenges of regulating nanomaterials are similar in the food and cosmetic contexts. Repetitive issues are not duplicated here. This chapter includes an expanded consideration of the FDA's treatment of drugs, however, as some products regulated as drugs in the US are considered cosmetics in the EU and an understanding of drug regulation is therefore necessary to understand the interaction of US and EU cosmetics regulations.

The FFDCA defines cosmetics by use to include all 'articles intended to be rubbed, poured, sprinkled, or sprayed on, introduced into, or otherwise applied to the human body ... for cleansing, beautifying, promoting attractiveness, or altering the appearance.'⁵⁵⁰ The Act distinguishes cosmetics from drugs based on the manufacturer's intent: cosmetics may not claim to treat, cure or prevent disease or affect the 'structure or function' of the body.⁵⁵¹ Products may meet the definition of both a drug and a cosmetic. Examples of such products include anti-dandruff shampoos, fluoride toothpaste, antiperspirant deodorants, moisturizing skin protectants, and sunscreen containing makeup and moisturizers.⁵⁵² Such products must comply with the regulations applicable to cosmetics as well as the much more extensive regulatory requirements applicable to drugs (see box 6.1).

Box 6.1: FDA regulation of drug products

Drugs, including non-prescription or over-the-counter (OTC) drugs, are subject to more rigorous FDA oversight than cosmetics. Section 202(g)(1) of the FFDCA defines drugs, in part, as 'articles intended for use in the diagnosis, cure, mitigation, treatment or prevention of disease' and 'articles (other than food) intended to affect the structure or any function of the body'.

Unlike cosmetics, drugs are subject to FDA pre-market review and approval. Generally, drugs must either be approved by the FDA or, for certain OTC drugs, must comply with specific FDA regulations, called OTC monographs, that very specifically identify the conditions under which they are generally recognized as safe, effective and not misbranded.

OTC drugs for which the FDA has issued final monographs include acne treatments,^a skin protectant drugs,^b antiperspirants,^c sunscreens,^d and dandruff and psoriasis treatments.^e Although individual OTC drug products do not undergo FDA pre-market review and approval, every such product must strictly comply with the terms of the applicable OTC monograph, each of which specifies the composition, concentration and combinations of active ingredients and the indications, claims, dosage, warning and other information that must appear on the labelling.

Unlike cosmetics, OTC drugs are subject to the FDA's current Good Management Practices (cGMP) regulations, registration and listing requirements, and adverse event reporting. OTC drugs that do not strictly comply with the monograph requirements are considered to be new drugs for which an approved new drug application may be required.

a 21 C.F.R. Part 333 Subpart D.

b 21 C.F.R. Part 347.

c 21 C.F.R. Part 350.

d 21 C.F.R. Part 352.

e 21 C.F.R. Part 358 Subpart H.

550 21 U.S.C. § 321(i). Soap is excluded from the definition of cosmetics if it meets certain regulatory requirements. In this case, it is subject to EPA regulation under TSCA. In addition, cosmetics include only products applied to the human body – thus there are no animal cosmetics. Products such as pet shampoos and grooming products, which are intended to cleanse, beautify or promote the attractiveness of animals, are not regulated by FDA but may be subject to EPA jurisdiction under TSCA. Products that are intended to treat, cure or prevent disease or to affect structure or function in animals are veterinary drugs. 21 U.S.C. § 321; 21 C.F.R. § 701.20; see also ch. 4.

551 The 'Doctrine of Intended Use' governs this determination and the FDA has applied it repeatedly since 1938, noting that intent may be gleaned from labelling, promotional material, advertising or any other relevant source, including the consumer's intent in using the product (Milstein et al. 2001: 5, 7); see also FDA, Is it a Cosmetic, a Drug, or Both? (or Is It Soap?), <http://www.cfsan.fda.gov/~dms/cos-218.html> (accessed 8 July 2009); see also FDA (1993).

552 See FDA, Is it a Cosmetic, a Drug, or Both? (or Is It Soap?), <http://www.cfsan.fed.gov/~dms/cos-218.html> (accessed 8 July 2009).

The FFDCA grants the FDA more limited oversight authority for cosmetics than for drugs. The FDA's cosmetics authority does not include pre-market notification or review and is limited to labelling and post-market monitoring, with the exception of colour additives (see food).⁵⁵³ The FFDCA's authority permits the FDA to remove adulterated, unsafe or unlawfully labelled products from the market through judicial action. In general, standards for cosmetic adulteration and labelling echo those for food.

Cosmetics may be adulterated if they contain a poisonous or deleterious substance that renders them injurious to users under normal or customary conditions of use; if they contain a filthy, putrid or decomposing substance; if they are packed and held under insanitary conditions in which they may have become injurious; if their container is composed of a poisonous or deleterious substance; or if they contain unapproved colour additives.⁵⁵⁴ The FDA has used the inherent toxicity of some cosmetics ingredients to declare that products containing those ingredients will be considered adulterated.⁵⁵⁵

The FDA's cosmetic labelling requirements focus on both the inclusion of material information and the avoidance of false or misleading information.⁵⁵⁶ FDA regulations require cosmetics to bear a list of ingredients and include all relevant warnings.⁵⁵⁷ Manufacturers conduct safety substantiation prior to marketing and are not required to submit safety information to the FDA.⁵⁵⁸ Products that have not been 'adequately substantiated for safety prior to marketing' must bear a warning label to that effect. Few cosmetic products bear this warning label, suggesting that cosmetics companies are substantiating the safety of their ingredients and products. The FDA generally lacks the authority to inspect records, however, and does not systematically gauge compliance with this regulation.⁵⁵⁹

In 1976, the Personal Care Products Council (PCPC)⁵⁶⁰ established the Cosmetic Ingredient Review (CIR), with support from the FDA and the Consumer Federation of America.⁵⁶¹ The CIR reviews and publishes information on the safety of cosmetic ingredients. Ingredients that pass CIR review are generally agreed to be substantiated. As of 2006, the CIR had substantiated 1,298 ingredients,⁵⁶² comprising approximately two-thirds of all ingredients used in cosmetics.⁵⁶³

The FDA's post-market authorities allow the agency to enter cosmetics establishments and inspect them and 'all pertinent equipment, finished and unfinished materials, containers, and labeling therein'.⁵⁶⁴ The FDA has not promulgated regulations establishing good manufacturing practices for cosmetics, although it has issued relevant guidance.⁵⁶⁵ It has no mandatory recall authority but can request a voluntary recall and can take legal action to remove adulterated or misbranded products from the market.⁵⁶⁶ In general, it receives less data on cosmetics products safety than on products subject to pre-market review. In its Nanotechnology Task Force Report, the agency notes that for 'products not subject to premarket authorization by FDA, such as cosmetics ..., the agency generally does not receive data, including safety data, before the products are marketed. Furthermore, there are no post-marketing reporting requirements for adverse events associated with cosmetics. Therefore, FDA receives only cosmetic adverse event reports that are submitted voluntarily'.⁵⁶⁷

Voluntary initiatives assist the FDA with information-gathering. The FDA established the Voluntary Cosmetic Registration Program (VCRP) in response to cosmetic industry petitions. The VCRP is used by companies manufacturing, packing and distributing cosmetic products (other than samples and products marketed only to professionals) for commercial distribution in the US. It consists of two aspects. First, cosmetic manufacturers and packers of products in commercial distribution in the US can register each of their manufacturing establishments.⁵⁶⁸ 'FDA places the registration information in a computer database and uses the information to generate mailing lists

553 Colour additives are an exception and are subject to pre-market review (see Box 6.1).

554 21 U.S.C. § 361. Coal-tar hair dyes meeting the requirements of section [361] (including a warning label) are not considered 'adulterated' for containing a poisonous or deleterious substance. *Ibid.*

555 See 21 C.F.R. § 700.13.

556 See 21 C.F.R. Part 701.

557 21 C.F.R. § 701.3.

558 21 C.F.R. § 740.10.

559 21 U.S.C. § 374 (authorizing inspections but not including reference to records except for specified types of records, not including cosmetics). See also Moore (2007). The FDA has authority to inspect records of carriers and receivers of shipments of cosmetics in interstate transport. 21 U.S.C. § 373(a).

560 Formerly known as the Cosmetic, Toiletry, and Fragrance Association. The PCPC counts more than 600 member companies. PCPC, About the Personal Care Products Council, at http://www.personalcarecouncil.org/Template.cfm?Section=About_Us (accessed 23 July 2009).

561 Cosmetic Ingredient Review, Cosmetic Ingredient Review – Homepage, at <http://www.cir-safety.org/> (accessed 23 July 2009).

562 Cosmetic Ingredient Review, Cosmetic Ingredient Review Agenda, at <http://www.cir-safety.org/agenda.shtml> (accessed 8 July 2009).

563 Taylor (2006: 29).

564 21 U.S.C. § 374.

565 It has published GMP guidance: FDA, Good Manufacturing Practice (GMP) Guidelines/Inspection Checklist, at <http://www.fda.gov/cosmetics/GuidanceComplianceRegulatoryInformation/GoodManufacturingPracticeGMPGuidelinesInspectionChecklist/default.htm> (accessed 29 July 2009).

566 See FDA, FDA/CFRAN Recall Policies, at <http://vm.cfsan.fda.gov/~lrd/recall2.html> (accessed 8 July 2009).

567 FDA (2007a: 15).

568 21 C.F.R. Part 710.

for distributing regulatory information and for inviting firms to participate in workshops on topics in which they may be interested. FDA also uses the information for estimating the size of the cosmetic industry and for conducting onsite establishment inspections.⁵⁶⁹ Second, manufacturers, packers and distributors are asked to file a Cosmetic Product Ingredient Statement (CPIS) for each product they have brought into commercial distribution in the US.⁵⁷⁰ ‘This information assists FDA scientists in evaluating reports of alleged injuries and adverse reactions from the use of cosmetics. The information also is used in defining and planning analytical and toxicological studies pertaining to cosmetics.’⁵⁷¹ In 2007, the PCPC issued a voluntary ‘Consumer Commitment Code’, which requires participants to allow FDA access to substantiation and safety records, to comply with VCRP requirements, and to notify the FDA when adverse events occur.⁵⁷²

6.1.1 Labelling

As for food, cosmetic labelling is largely governed by the FFDCA and by the Fair Packaging and Labeling Act (FPLA), which prohibit misbranding. As noted above, a cosmetic product is misbranded if the label is false or misleading or fails to include required information, among other reasons.⁵⁷³ Identification of specific material information for inclusion on cosmetic product labels is determined by FDA regulation. The FDA does not review or approve cosmetics labels before marketing.

6.1.2 Confidential business information

In general, the CBI requirements in the FFDCA and FOIA apply equally in the food and cosmetic contexts. With respect to information-sharing with the European Union, the FDA has reached a confidentiality commitment with DG Enterprise to enable information-sharing related to cosmetics, including OTC drugs classified as cosmetics in the EU.⁵⁷⁴ This commitment specifically enables information-sharing on ‘ongoing and emerging regulatory issues of health and safety in the field of cosmetics in the US or the EU, such as nanotechnology’.⁵⁷⁵ Information subject to sharing includes but is not limited to confidential commercial information and trade secret information.⁵⁷⁶

6.1.3 Cosmetics and nanotechnologies

To date, the FDA has considered nanotechnologies in cosmetics primarily in the context of the Task Force report discussed previously. As for other product categories, the FDA recognizes that nanoscale materials may present unique health risks, but considers those risks to be uncertain. As a result, it is unlikely to regulate nanomaterials categorically. However, as noted above, the Nanotechnology Task Force report acknowledges that it receives adverse event reports for cosmetics only when they are submitted voluntarily.⁵⁷⁷ Moreover, an FDA representative has noted that the FDA ‘may be unaware that nanotechnology is employed’ in certain products, that the agency ‘has only limited authority for potentially high risk nano-products [including] cosmetics’, and that ‘for new nano-materials, new ‘tools’ may be needed’.⁵⁷⁸ Recognizing these difficulties, the FDA is likely to follow task force recommendations for cosmetics, including, for example, evaluating testing methodologies to assess product safety and quality, requesting submission of data addressing the effects of nanomaterials on product safety and the issuance of guidance describing safety issues that manufacturers should consider.

In addition to undertaking regulatory action for cosmetics, the FDA has responded to a specific request for regulatory action with respect to sunscreens, which are considered drugs in the US but may be considered cosmetics in the EU. In 2006, the International Center for Technology Assessment (ICTA) and several other NGOs⁵⁷⁹ petitioned the FDA to amend its regulations to address nano-engineered particles in products over

569 FDA (2007d).

570 21 C.F.R. Part 720.

571 FDA (2008b) Note that the data are not directly attached to formal adverse event reports.

572 Personal Care Products Council, The Personal Care Products Council Consumer Commitment Code, at http://www.personalcarecouncil.org/Content/NavigationMenu/About_Us/Consumer_Commitment_Code1/Consumer_Commitment_Code.htm (accessed 29 July 2009).

573 21 U.S.C. § 362. If the product is a colour additive, its label must be in conformity with colour additive labelling requirements in addition to those applicable for cosmetic products, unless it is a hair dye. 21 U.S.C. § 362(e).

574 FDA (2007b).

575 Ibid.

576 Ibid.

577 FDA (2007a: 15).

578 Alderson (2004: 8); Kuzma (2005: 18).

579 Friends of the Earth, Greenpeace, Action Group on Erosion, Technology and Concentrations, Clean Production Action, Center for Environmental Health, Our Bodies Ourselves, Silicon Valley Toxics Coalition.

which it has jurisdiction, with a particular emphasis on sunscreens.⁵⁸⁰ The FDA has not issued a final response to this petition, but on 27 August 2007 it proposed a rule to amend the OTC monograph for sunscreen, in which it solicited comments on the safety and efficacy of nanoscale particles in sunscreens.⁵⁸¹

6.2 EU cosmetics regulations

EU regulation of cosmetics is based on the 1976 Cosmetics Directive (76/768/EEC) and a patchwork of nearly 50 amendments that have been added over the past three decades.⁵⁸² Because of perceived legal uncertainties and inconsistencies⁵⁸³ in the existing framework and a general desire to strengthen and harmonize cosmetics regulation, the EU is in the process of replacing the current Directive with a new Regulation. Given the uncertainty about the legal changes currently under way – the European Parliament passed an amended version of the proposed Regulation in first reading on 24 March 2009, but further changes are likely before the new Regulation is adopted⁵⁸⁴ – this section describes both the existing framework and the provisions contained in the current version of the proposed Regulation.

The adoption of the new Regulation would bring in important changes to the way in which nanomaterials in cosmetics are regulated in Europe. For one, a Regulation would centralize regulatory authority over cosmetics at the EU level. Under EU law, a Regulation is directly applicable and legally binding in Member States. In contrast, the current Directive establishes the European Commission's overall regulatory responsibility but leaves some discretion to Member States in implementing the Directive and transposing it into national law. Moreover, the current version of the new Regulation is set to introduce explicit references to nanomaterials, including strengthened reporting and labelling requirements. If adopted, it would introduce stringent regulatory provisions for nanomaterial use.

6.2.1 The 1976 Cosmetics Directive and amendments

The Cosmetics Directive, which together with its amendments provides the main framework for the safety of cosmetic products, regulates product composition, labelling and packaging. It does so by requiring manufacturers to carry out risk assessment and by establishing positive and negative lists for certain permitted and prohibited substances. The European Commission's DG Enterprise and Industry is responsible for administering and supervising the implementation of the Cosmetics Directive, and DG SANCO's Scientific Committee on Consumer Products (SCCP) provides scientific assessments of the safety of cosmetic products.

A cosmetic product that falls under the Cosmetics Directive is defined as

*any substance or preparation intended to be placed in contact with the various external parts of the human body (epidermis, hair system, nails, lips and external genital organs) or with the teeth and the mucous membranes of the oral cavity with a view exclusively or mainly to cleaning them, perfuming them, changing their appearance and/or correcting body odours and/or protecting them or keeping them in good condition.*⁵⁸⁵

Annex I of the Cosmetics Directive lists 20 cosmetic product categories, ranging from face masks to external intimate hygiene. Under EU law, a substance is to be classified either as a cosmetic or as a medicinal product. Most facial creams, for example, are regulated under the Cosmetics Directive, while anti-acne creams fall under the medicinal products regulations. But the Directive's perceived legal uncertainty over borderline products and lack of precise legal definitions were among the factors behind the European Commission's proposal to recast the Directive in the form of a new Regulation.⁵⁸⁶

The Directive is based on the premise that cosmetic products 'must not cause damage to human health when applied under normal or reasonably foreseeable conditions of use' (Article 2). If substances are found to pose a health risk under the intended use conditions, they cannot be used in cosmetic products. Manufacturers must assess

580 International Center for Technology Assessment, *Citizen Petition to the United States Food and Drug Administration* (2006), at <http://www.icta.org/doc/Nano%20FDA%20petition%20final.pdf> (accessed 29 July 2009).

581 FDA (2007e).

582 An overview is available at http://ec.europa.eu/enterprise/cosmetics/html/consolidated_dir.htm (accessed 8 July 2009). A distinction is to be made between ingredients of cosmetic products, which are regulated by REACH (though not with regard to associated risks for human health), and cosmetic products themselves, which fall under the Cosmetics Directive.

583 See European Parliament, MEPs Approve New Rules on Safer Cosmetics, at http://www.europarl.europa.eu/news/expert/infopress_page/066-52333-082-03-13-911-20090323IPR52331-23-03-2009-2009-true/default_en.htm (accessed 8 July 2009).

584 European Parliament (2009b).

585 European Commission (1976: art. 1). The definition of a cosmetic product in the proposed regulation differs only slightly from the above definition, replacing for example 'any substance or preparation' with 'any substance or mixture'.

586 The Commission has argued that, 'until now, the Cosmetics Directive contains practically no legal definitions. This increases legal uncertainty and renders compliance more costly and burdensome than necessary.' European Commission (2008h: Explanatory Memorandum 6.1.1).

the safety of their products before marketing them, and in doing so, they must consider 'the general toxicological profile of the ingredients, their chemical structure and their level of exposure'. They are also required to notify the Competent Authorities in Member States when they place a cosmetic product on the market (Article 7a).

Under the current Cosmetics Directive, pre-market approval for produced or imported cosmetic products is not generally required, except for certain substances used in cosmetic products such as colorants, UV filters and preservatives. The Cosmetics Directive uses a series of lists of prohibited, restricted and permitted substances to identify which ingredients can, or cannot, be used in certain products. Annex II lists over 1,000 substances that are banned from use in cosmetics including, for example, gold salts, chloroform or chlorine. Annex III lists substances whose use may be permitted only for certain types of cosmetics, or which are subject to special labelling requirements, such as hydrogen peroxide, formaldehyde or aluminium fluoride. Annexes IV, VI and VII list approved colorants, preservatives and UV filters, respectively. Only colorants, preservatives and UV filters listed in the Annexes may be used in cosmetic products.⁵⁸⁷

The Cosmetics Directive provides post-market tools to supplement its targeted pre-market review of cosmetic ingredients. Cosmetic product manufacturers are required to retain information on the physico-chemical properties of ingredients and final products, manufacturing methods, and the product's safety assessment. Manufacturers must make this information accessible to the Member States' Competent Authorities upon request.⁵⁸⁸

While the Cosmetics Directive does not contain any explicit reference to particle size or nanomaterials, the European Commission argues that it broadly covers health-related risks of nanomaterials in cosmetic products. In its regulatory review of 2008, the Commission states that

*On the basis of the obligation to carry out a risk assessment and the possibility to lay down through implementing legislation detailed conditions of use for certain ingredients, risks in relation to nanomaterials and nanotechnologies can, therefore, in principle be dealt with in an appropriate way.*⁵⁸⁹

At the same time, however, the Commission acknowledges that a revision of the current framework may be necessary. In its proposal for a new Cosmetics Regulation, the Commission seeks to establish minimum requirements for cosmetic safety assessments, closer administrative cooperation of Competent Authorities and a system of coordination of Member States in risk assessment, the obligation for industry to report serious undesirable effects to Competent Authorities, and a centralized notification requirement. Although nanomaterials were not explicitly mentioned in the Commission's original draft, amendments by the European Parliament have now introduced such explicit references in the latest version of the proposed Regulation.

6.2.2 The proposed Cosmetics Regulation

The current draft of the new Cosmetics Regulation was approved by the European Parliament in first reading on 24 March 2009.⁵⁹⁰ It includes important changes with regard to the regulation of nanomaterials in cosmetic products, and seeks to strengthen and centralize regulatory oversight of cosmetics in Europe. It also seeks to create greater legal certainty with regard to the coverage of nanomaterials by explicitly mentioning them in the draft text.⁵⁹¹ It defines such materials and requires them to be appropriately labelled on cosmetic products. In this, it differs markedly from other recent amendments to existing European regulations. Revisions to food regulation, for example, refer more generally to 'nanotechnology' and 'changes due to particle size' (see chapter 5 on additives and enzymes).

The proposed Regulation defines a nanomaterial as 'an insoluble or biopersistent and intentionally manufactured material with one or more external dimensions, or an internal structure, on the scale from 1 to 100 nm' (Article 2 Paragraph 1(k)). Reflecting the continuing uncertainty about the precise definition of nano-scale substances, Article 2 Paragraph 3 goes on to qualify the definition by stating that, '[i]n view of the various definitions of nanomaterials published by different bodies and the constant technical and scientific developments in the field of nanotechnologies, the Commission shall adjust and adapt point (k) of paragraph 1 [quote above] to technical and scientific progress and with definitions subsequently agreed at international level'.⁵⁹²

The new Regulation contains specific guidelines on safety assessments and the cosmetic product safety report, which are obligatory for all manufacturers. The safety assessment has to include information on 'the anticipated systemic exposure to

587 These lists are far from exhaustive and the majority of substances used in cosmetic products do not appear in them but are instead subject to the general safety requirements of the Cosmetics Directive. See also Bowman and van Calster (2008).

588 See European Commission (1976).

589 European Commission (2008g: 17).

590 European Parliament (2009b).

591 The current version of March 2008 contains 28 such references. European Commission (2008h).

592 European Parliament (2009b). Moreover, a Commission statement accompanying the recast regulation explicitly states that, '[o]n definition of nanomaterials the Commission notes that work towards a common definition of nanomaterials is still evolving. The Commission therefore confirms that in future Community legislation progress on the common definition should be taken into account and notes that the comitology procedures contained within this proposal also allow for the updating of the definition within this proposal.' Ibid. On comitology procedures, see chapter 4, footnote 316.

individual ingredients in a final formulation' and the safety report has to be kept up to date even if additional information is generated after the cosmetic product is placed on the market (Article 10, Paragraph 1(a) and (c)). In addition, when evaluating exposure to a cosmetic product, the manufacturer must pay particular consideration to 'any possible impacts on exposure due to particle size' and, with regard to the toxicological profile of a product, particular consideration must be given to particle sizes and nanomaterials, as well as to the interaction of substances (Annex I, Paragraphs 6 and 8).

Moreover, the responsible person placing a cosmetic product on the market⁵⁹³ has to maintain a product file, readily accessible to Competent Authorities in Member States, which describes among others the method of manufacturing and includes the product safety report. In addition to these requirements, the regulation stipulates that prior to placing a cosmetic product on the market, the responsible person must notify the Commission of 'the presence of substances in the form of nanomaterials and (i) their identification including the chemical name (IUPAC) and other descriptors as specified in paragraph 2 of the Preamble to Annexes II to VI; [and] (ii) the reasonably foreseeable exposure conditions' (Article 13, Paragraph 1(f)). This information will be made available to Member States and national poison control centres for the purpose of market surveillance.

The proposed Cosmetics Regulation is the first EU legislation that devotes an entire Article (16) to nanomaterials. Paragraph 1 of Article 16 explicitly states that for every product that contains nanomaterials, 'a high level of protection of human health shall be ensured'. Moreover, cosmetic products containing nanomaterials have to be reported to the Commission six months before being placed on the market,⁵⁹⁴ with the following information to be provided:⁵⁹⁵

a) the identification of the nanomaterial including its chemical name (IUPAC) and other descriptors as specified in paragraph 2 of the Preamble to Annexes II to VI; b) the specification of the nanomaterial including size of particles, physical and chemical properties; c) an estimate of the quantity intended to be placed on the market per year; d) the toxicological profile of the nanomaterial; e) its safety data related to the category of cosmetic product as used in it; f) the reasonably foreseeable exposure conditions. (Article 16, Paragraph 3(a)-(f)).

The proposed Regulation also contains new provisions that would strengthen market surveillance and consumer labelling of nanomaterials in cosmetics. It stipulates that the European Commission shall make publicly available 'a catalogue of all nanomaterials used in cosmetic products, including those used as colorants, UV filters and preservatives in a separate section, placed on the market, indicating the categories of cosmetic products and the reasonably foreseeable exposure conditions' (Article 16 Paragraph 10(a)). Furthermore, Article 19 establishes a general labelling requirement for nanomaterials: 'All ingredients present in the form of nanomaterials shall be clearly indicated in the list of ingredients. The names of such ingredients shall be followed by the word "nano" in brackets.'

6.2.3 Nanomaterials and EU cosmetics regulation

Assessing the effectiveness of the EU's current cosmetics regulations and their treatment of nanomaterials is complicated by the fact that the legal basis for the regulatory system is currently being rewritten. Limited experience exists with regard to how the current Cosmetics Directive applies to nanomaterials, but the application of the future Cosmetics Regulation, which is yet to be finalized, remains uncertain at this point.

As in other regulatory contexts, the EU has adopted an approach based on case-by-case risk assessment of nanomaterials. The SCCP⁵⁹⁶ has already evaluated a small number of ingredients used in nanoform, primarily for use in sunscreens. The SCCP delivered an opinion on titanium dioxide (TiO₂) in 2000 and on zinc oxide (ZnO) in 2003. While permitting the use of titanium dioxide in sunscreen products, the SCCP concluded that more information was needed to enable a proper safety evaluation of nanoscale zinc oxide for use as a UV filter.⁵⁹⁷ In its general opinion

593 The term 'responsible person' as defined in Article 4 generally refers to the importer or manufacturer of a cosmetic product. European Commission (2008h).

594 The timeframe for notification of cosmetic products containing nanomaterials that are currently on the market has not yet been fully determined in the present version of the Regulation. Moreover, an exemption from these requirements exists for cosmetic products containing nanomaterials in conformity with requirements set out in Annex III (restricted substances) and for those products where nanomaterials are used as colorants, UV filters or preservatives, which are subject to specific safety testing requirements as outlined in Article 14 and the respective annexes. European Commission (2008h).

595 The regulation explicitly allows the Commission to add requirements due to technical and scientific progress. European Commission (2008h: art. 16).

596 Under the Cosmetics Directive, the responsibility for evaluating the safety of substances included in the Annexes of the Cosmetics Directive lies with DG SANCO's SCCP, formerly SCCNFP, which provides the Commission with scientific advice on non-food consumer products. The SCCP formulates scientific opinions based on a review by experts in the relevant fields. SCCP then formulates an opinion that is used for further evaluations in a 'comitology' procedure whereby the EC, in consultation with Member States, decides whether a substance should be prohibited, restricted or permitted for use in cosmetic products. Industry can propose substances to be evaluated under this process. European Commission (1976).

597 The initial decision referred to a lack of reliable data on absorption by the skin. See SCCP, Statement on Zinc Oxide Used in Sunscreens, at http://ec.europa.eu/health/ph_risk/committees/04_sccp/docs/sccp_o_00m.pdf (accessed 8 July 2009)). These data have apparently been made available and the SCCP is currently re-evaluating its decision. See European Parliament, *Parliamentary Questions, Answer given by Mr Verheugen on behalf of the Commission*, at <http://www.europarl.europa.eu/sides/getAllAnswers.do?reference=E-2006-2811&language=EN> (accessed 8 July 2009).

on the safety of nanomaterials in cosmetic products, published in 2007, the SCCP pointed to significant knowledge gaps and uncertainties in risk assessment. It stated, for example, that, for insoluble nanoparticles, conventional risk methodologies based on mass metrics are not sufficient to evaluate the toxicity and ecotoxicity of such particles and identified ‘large data gaps in the risk assessment methodologies and in regard to data on the nanoparticles in cosmetic products via inhalation and ingestion.’⁵⁹⁸ In the light of new scientific data, the SCCP considered it necessary to re-review the safety of nanosized titanium dioxide.⁵⁹⁹

The new Regulation, once adopted, is set to continue the principle of case-by-case risk assessment of nanomaterials in cosmetics, but is likely to provide a firmer legal basis for establishing a system of market surveillance and consumer labelling. These provisions would turn cosmetics regulation into an advanced regulatory approach for nanomaterials in consumer products. As the new rules are not likely to enter into force before 2012, the current system under the Cosmetics Directive and evolving implementation guidelines will continue to set the relevant regulatory framework over the next three years.

6.3 Comparative analysis

6.3.1 Limitations of scope of comparison

Cosmetics regulation in the US and the EU follows similar pathways and uses similar regulatory tools. However, specific elements of these regulatory systems differ, with significant implications for how cosmetic products containing nanomaterials may be regulated in each location. In addition, the ongoing reframing of the Cosmetics Directive in the EU promises to significantly affect the relative treatment of cosmetic products.

The implementation of the existing FDCA and Cosmetics Directive, as well as the future implementation of the Cosmetic Regulation, are likely to play a significant role in how cosmetics products are regulated in practice. In particular, the enactment of the Cosmetics Regulation will shift the European cosmetics regulatory system from a system primarily implemented by Member States to one regulated centrally across the EU. This change will necessarily result in a shift in the nature, and particularly the uniformity, of cosmetics regulation in the EU. While we note the importance of this shift, evaluating both the current and potential future implementation of cosmetics regulation is beyond the scope of this report. In addition, while the contents of particular Member State cosmetics authorities are likely to differ significantly, this report cannot comprehensively address each of these statutes and regulations. As a result, this comparison is limited to the contents of existing and potential future authorities at the EU and US level.

6.3.2 Incorporation of nano-specific regulatory language

A comparison of how nanomaterials are considered in the US and EU most obviously begins with the overt reference to nanomaterials in relevant regulatory language. Neither the FDCA nor the Cosmetics Directive explicitly refers to nanomaterials, either in statutory language or (for the FDA) in regulations. The proposed EU Cosmetics Regulation, however, includes specific reference to nanomaterials used in these products. In particular, it is the first binding legal authority to explicitly define ‘nanomaterial’, while noting the need for an evolving definition of the term in accordance with developing practice.⁶⁰⁰ In addition, it includes specific regulatory requirements that apply only to products meeting the definition of nanomaterial, including on submission of information and labelling. If adopted, these nano-specific requirements will mark a significant deviation from existing practice in the US, which regulates nanomaterials under its existing regulatory mechanisms, as it has for other emerging technologies.

6.3.3 Definition of cosmetics

The US and EU share a similar system for determining which products are subject to cosmetics regulation; however, the categorization of products is different between the regulatory systems. In particular, different criteria are employed in determining whether a product is a cosmetic or a drug.

In the US, the FDCA defines cosmetics as products used externally and intended ‘for cleansing, beautifying, promoting attractiveness, or altering the appearance.’⁶⁰¹ Products that are represented to alter the structure or function of the body, however, are regulated as drugs. Under both the EU Cosmetics Directive and proposed Regulation, cosmetics are defined as substances or mixtures intended to be used externally ‘with a view exclusively or mainly to cleaning them, perfuming them, changing their appearance and/or correcting body odours and/or protecting them or keeping them in good condition.’⁶⁰²

598 SCCP (2007: 5–6).

599 Ibid.: 6.

600 European Commission (2008h: art. 2 §§ (1)(k); 2(3)).

601 21 U.S.C. § 321(i).

602 European Commission (1976: art. 1.1).

The different definitions in use in each jurisdiction affect the regulatory treatment of specific product types. In particular, products such as antiperspirants, anti-cavity toothpaste, anti-dandruff shampoos, and sunscreens are considered drugs in the US, and must comply with OTC monographs or go through a new drug pre-market approval process. Certain of these products are considered cosmetics in the EU, rather than medicinal products.⁶⁰³ For example, sunscreens have an ‘important “protective” function against UV radiation’ and are therefore cosmetics under the Directive.⁶⁰⁴ The EU has issued guidance to clarify the treatment of products as cosmetics rather than as products regulated under other sectoral legislation addressing medicinal products, biocidal products, food, and general product safety.⁶⁰⁵ A case-by-case approach is required to determine the correct classification of products in the US and EU.

6.3.4 Pre-market tools

As for other types of products such as food or drugs, both the US and EU authorities can be divided into pre-market and post-market application. In general, both the US and EU have established less stringent pre-market review requirements for cosmetics than for other product types. Thus, cosmetic products are not required to obtain approval from regulators in either jurisdiction prior to being placed on the market. However, other pre-market tools are used to limit what may be placed on the market.

Few limitations apply to products in the US, as the FDCA requires neither product approval nor submission of information to the FDA. That agency, however, can bar the use of specific ingredients in cosmetics in interstate commerce by declaring them adulterants. FDA regulations set forth nine such ingredients that are considered adulterants. Products containing these ingredients cannot be marketed legally. Unless particle size is explicitly included as an element in these regulations, nanoform and bulk substances are treated equally. The FDCA, however, does not bar the FDA from restricting the marketing of nanoscale cosmetic ingredients separately from their bulk counterparts. In particular, if the FDA determines that a particular nanomaterial renders products injurious to users under prescribed conditions of use while the bulk form of that ingredient does not, the agency can declare that nanomaterial in particular to be an adulterant.

The EU Cosmetics Directive includes more substantial pre-market requirements. First, producers must conduct a ‘cosmetic product safety assessment’ for each product. The contents of the safety assessment are established in Annex I to the Directive and proposed Regulation. Second, under Article 13 of the Directive, producers must provide the Commission with certain information when they place a new cosmetic product on the market (not including the safety assessment). Third, like the US, the Commission may limit the inclusion of specific materials in cosmetic products as permitted, prohibited or restricted by including them on an Annex to the Directive (or proposed Regulation). The Commission has included more than 1,100 substances on the prohibited and restricted lists.

To date, products containing nanomaterials are treated in the same way as other cosmetics, and particle size would be considered in the safety assessment as needed to ensure that the product is ‘safe for human use’ and would require no special notification provisions. However, the proposed Regulation would expand pre-market regulation of products containing nanomaterials to include notification, but not authorization. Although no special consideration is due for nanomaterials in product safety assessments, the Regulation would enhance notification requirements, requiring disclosure of ‘the presence of substances in the form of nanomaterials’, their chemical identification, and their reasonably foreseeable exposure conditions. The proposed new Article 16 would further require producers to file the notification six months *before* a product is placed on the market, converting notification to a pre-market tool. Moreover, Article 16 would further enhance the notification requirements by requiring the submission of additional data, as noted previously. The six-month prior notification is intended to provide the Commission with time to request safety assessment from the SCCS, which must provide its opinion within six months. This opinion provides the basis for requiring submission of additional information needed to determine ‘the safety of these nanomaterials’ for the proposed use and for the Commission to permit, restrict, or prohibit use of the nanomaterial by listing in Annex II or III, as appropriate. The proposed Regulation explicitly enables listing based on lack of information.

The EU and US regulatory systems share the ability to restrict the use of specific nanomaterials in cosmetic products, although the requirements for such a determination differ and are likely to shift further if the proposed Regulation is approved. Beyond this initial similarity, the EU system incorporates additional notice and safety assessment requirements. These additional requirements do not currently require explicit disclosure of nanomaterials, but the enhanced disclosure requirements for nanomaterials included in the proposed EU Cosmetics Regulation promise to substantially increase the amount of information available to regulators on the presence of nanomaterials in cosmetics products.

603 European Commission (1976: Annex I) (listing illustrative cosmetic products). See also DG Enterprise and Industry, ‘Borderline Products’ – Guidance, at http://ec.europa.eu/enterprise/cosmetics/html/cosm_borderline_docs.htm (accessed 8 July 2009).

604 See European Commission *Sunscreen products* website, at http://ec.europa.eu/enterprise/cosmetics/sunscreens/index_en.htm (accessed 8 July 2009).

605 See Working Group on Cosmetic Products for Consultation, Manual on the Scope of Application of the Cosmetics Directive 76/768/EEC (non-binding guidance for resolving borderline cases), at http://ec.europa.eu/enterprise/cosmetics/doc/manual_borderlines_version40.pdf (accessed 8 July 2009).

6.3.5 Post-market regulatory tools

Both the US and the EU enable post-market monitoring of cosmetic products and have established a similar suite of post-market tools for regulation of products, as noted in the food section. However, the US and the EU deploy these post-market regulatory tools in different ways in the cosmetics context. Key tools include recalls, adverse event reporting, inspection of records, good manufacturing practices and labelling.

Product recalls

Product recalls are subject to complex authorities. In the US, the FDA has limited recall authority, as the FDCA authorizes the agency to request a voluntary recall of particular cosmetic products or to remove adulterated or misbranded products from the market through court order. In the EU, Article 12 of the EU Cosmetics Directive allows Member States to provisionally prohibit or condition the marketing of a particular product, even if that product is in compliance with the requirements of the Directive. To use this authority, the state must have a substantial justification to believe that the product ‘represents a hazard to health’. The Directive does not explicitly address corrective actions that can be undertaken in the event of non-compliance with the Directive or Member State authorities, although marketing of non-compliant products is unlawful. However, the proposed regulation does address non-compliance, and it allows the Commission to prescribe all required corrective actions, or to require withdrawal of the product from the market or its recall. The Regulation also allows provisional recall, withdrawal, or prohibitions on products that comply with the Regulation but present a ‘serious risk for human health’.

Adverse event reporting

The FDA has noted that one challenge of regulating products containing nanotechnologies and collecting information about such products is that it cannot require submission of adverse event reports for some product categories, including cosmetics. In the EU, the Cosmetics Directive similarly lacks explicit requirements for adverse event reporting. However, it does require responsible parties to maintain, as part of each product information file, existing data on the undesirable effects on human health caused by the product. The proposed Regulation, on the other hand, explicitly requires responsible parties and distributors to notify the Competent Authority when a serious undesirable effect occurs.

Inspection of records

Post-market surveillance is a key aspect of enforcement for cosmetics products. The product information file referred to above must include specified information, including the relevant cosmetic product safety assessment. The Directive authorizes inspectors to access regulated entities and view these files upon request. Inspection authority in the US is more limited; a former associate chief counsel for FDA noted that ‘[t]he existing law has some weaknesses ..., one of them being that the FDA does not have general authority to obtain manufacturers’ records and safety related data.’⁶⁰⁶ The relevant law has remained unchanged since this statement was made in 1978, and the FDCA does not authorize FDA to inspect all cosmetic manufacturer records. However, responsible parties may grant access voluntarily, as signatories to the PCPC’s Consumer Commitment Code have agreed to do. The FDCA also does not require responsible parties to maintain standardized records. As a result, safety substantiation data are not necessarily included in company records, particularly where the substantiation was carried out by a third party, such as the CIR.

Good manufacturing practices

To ensure safety of production, regulators in both the EU and US require manufacturers to comply with good manufacturing practices for certain product categories. In the US, cGMP regulations apply to drugs, but not to cosmetics. The FDA has issued non-binding guidance for good manufacturing practices for cosmetics products, however. In the EU, the Directive and proposed Regulation both require compliance with GMPs. The Directive does not define the term GMP, but the ISO has developed GMP guidelines for cosmetics.⁶⁰⁷ The proposed Regulation states that compliance with the GMP requirement is presumed when a manufacturer complies with ‘relevant harmonized standards’ published in the *Official Journal of the European Union*.

Labelling

In both the US and the EU, labelling is a primary tool for regulating cosmetics marketing. Each jurisdiction has developed unique rules for labelling, although important elements are common to both, such as ingredient lists, amount of contents, and the name and place of business of responsible entities.

In the US, the FDA’s FPLA authorities enable myriad regulations governing the contents of cosmetics labels, including the required warning that must be included on product labels if the product and its ingredients have not

606 Gilhooley (1978: 232).

607 ISO (2007).

been substantiated for safety. The FDA has indicated that it will not require the identification of nanoscale cosmetic ingredients on product labels, as it has determined that the risks and benefits of nanomaterials are uncertain and labelling would not provide substantial benefits to the public.

In Europe, the Cosmetics Directive and the proposed Regulation both include specific requirements for product label contents. The Cosmetics Directive does not require producers to identify nanomaterials on product labels. The proposed Regulation significantly alters this situation, requiring that 'All ingredients present in the form of nanomaterials shall be clearly indicated in the list of ingredients. The names of such ingredients shall be followed by the word "nano" in brackets.'⁶⁰⁸ This positive requirement of nanomaterial disclosure marks a significant change in labelling authority.

6.3.6 Information sharing

Regulators on both sides of the Atlantic have acknowledged challenges in ascertaining adequate information both to allow evaluation of both the safety of nanomaterials and the presence of products containing nanomaterials in the market, particularly for cosmetics. Acquisition of these data in the cosmetics context may be limited both by the content of relevant laws and regulations and by limits on agency ability to share confidential information.

Agencies acquire information through mandatory disclosure and voluntary submission. As noted above, the EU Cosmetics Directive requires pre-market authorization for UV filters, colorants and preservatives, and the proposed Regulation would require notification prior to the marketing of *any* product containing nanomaterials. Current notification and inspection authorities, as discussed previously, provide additional data sources, although they may lack specific data on nanomaterial ingredient safety.

FDA is not authorized to require similar disclosures for cosmetic products containing nanomaterials, although colour additives and drugs, including sunscreens, are subject to pre-market approval. The US instead established the VCRP to encourage voluntary submission of data about products in the marketplace. Information on cosmetic ingredients submitted pursuant to the VCRP is subject to disclosure under the FOIA. However, producers can request confidentiality for their disclosures; the FDA has promulgated regulations to govern how it will respond to such requests and enables retraction of submissions that will not be considered confidential.⁶⁰⁹

The FDA may also obtain information from the CIR. These data are not public by default, as the organization is a non-governmental entity. However, the CIR's studies are published in peer-reviewed literature and it has established procedures for its operations that provide for public availability of certain information.⁶¹⁰ Disclosable information under these procedures includes, *inter alia*, safety information and written data and information submitted to it. However, the CIR also declares some information non-disclosable, including, but not limited to, (i) records relating to any ingredient that the FDA has determined is exempt from public disclosure (i.e., is confidential or a trade secret); and (ii) adverse event reports or similar information, unless available to the public pursuant to FDA regulations.⁶¹¹ Portions of CIR expert panel meetings where non-disclosable information is discussed must be closed to the public, including to the FDA liaison.⁶¹²

As previously discussed, agencies may seek to share relevant information they acquire, and may be unable to do so owing to statutory requirements, such as the prohibition on disclosure of trade secrets in section 331(j) of the FDCA. Information disclosure in the US and EU is governed, respectively, by the FOIA and Regulation 1049/2001, as noted earlier. Each of these authorities provides for exceptions to disclosure, but allows the relevant agencies to share even confidential or trade secret information, provided that the confidentiality of such information is protected. The FDA and DG Enterprise and Industry have entered into memoranda of agreement that enable such information-sharing as pertains to cosmetics in particular.⁶¹³ The FDA has also established bilateral agreements with other DGs and Member States for general information-sharing. As a result, these agencies can share whatever information they acquire, while such information (if confidential) will remain unavailable to the public. However, the content of information is likely to remain limited with respect to inclusion of nanomaterials, pending adoption of the proposed Regulation.

608 European Commission (2008h: art. 19(1)).

609 21 C.F.R. § 720.8.

610 CIR (2009: § 51).

611 Ibid.

612 Ibid.

613 FDA (2007b).

7 Promoting Transatlantic Cooperation and Convergence in Nanomaterials Regulation

The previous three chapters provided a review of existing regulatory frameworks in the United States and the European Union in the fields of chemicals, food and cosmetics. They identified common approaches as well as differences in dealing with nanomaterials risk. In this final chapter, we take up the question of how the EU and United States can develop nanomaterials regulation in a way that promotes effectiveness and transatlantic convergence. One of the main objectives of this study is, as set out in the original call for proposals, to review ‘processes which foster the identification of best practices and the establishment of international requirements for and congruent approaches to safety’. This question is to be seen in the context of the broader objective set by the EU–US Summit of 2007, namely ‘to establish an international level playing field and promote regulatory convergence between the EU and the US’.⁶¹⁴ This chapter will, therefore, consider proposals for strengthening congruent approaches on both sides of the Atlantic. The focus here, as in the entire report, is on the regulation of environmental and health risks of nanomaterials, rather than the promotion of nanotechnologies, in response to the original call for proposals.

The debate on regulatory convergence is a complex one that is fraught with misunderstandings and misperceptions. Some conceptual clarification, therefore, is needed. As outlined in chapter 1, we understand regulatory convergence to be a process rather than a specific outcome. It involves the gradual adjustment of regulatory frameworks, institutions and practices, but can occur through a variety of processes and mechanisms. These range from informal policy diffusion to international coordination and cooperation, whether formal or informal, and to treaty-based international harmonization efforts. When speaking of the promotion of greater regulatory convergence in the field of nanotechnologies, we therefore have in mind the full range of convergence processes that can be observed in other international policy areas, from environmental to financial regulation, and from trade policy to investment rules.

At the same time, we recognize the limits to regulatory convergence, in terms of both its feasibility and desirability. In the area of environment, health and safety (EHS) regulation, full harmonization of national rules and practices is rarely, if ever, achieved. As discussed in chapter 1, there are some distinctive benefits, but also costs, that result from regulatory convergence, and policy-makers ultimately need to decide how to balance these. The subsequent discussion reflects this reality and seeks to enlighten the political and regulatory debate by identifying opportunities for, but also barriers to, a movement *towards greater transatlantic consistency and convergence*.

In what follows, we present the findings of our research and the recommendations that have come out of our consultation with relevant stakeholders. These ideas reflect the preceding analysis of existing regulatory frameworks – in chemicals, food and cosmetics – as well as the wide-ranging and often diverse views of the regulators, stakeholders and experts whom we interviewed as part of this project.⁶¹⁵ They seek to reflect the state of thinking in the transatlantic debate on nanomaterials regulation while pointing towards potential future developments. As is to be expected from any debate on regulatory effectiveness and convergence, the different actors and observers involved do not agree on all of these ideas and recommendations. We reflect this in the following section by indicating approximate levels of support among relevant stakeholders throughout, to give a better sense of the state of the current debate.

While some of the ideas discussed below enjoy broad support among experts on both sides of the Atlantic – and are indeed being pursued by regulators and policy-makers – others are of a more controversial nature, or are shared only by a small group of stakeholders. Such disagreements reflect differences in views between Europeans and Americans, or between regulators and interest groups, or between different types of interest groups (e.g. industry versus consumer groups). The fact that there is no consensus on some of the policy ideas does not invalidate them, however. We feel it is important to reflect such ideas and include them in this report, because they provide critical perspectives on the status quo and may indeed point the way in the direction of improvements to existing regulatory approaches.

In presenting the policy ideas and recommendations that result from our research, we have had to make a selection. We focus on three clusters of issues that we identified as the most important areas, particularly in the

614 Both quotations are from the European Commission's Call for Proposals. See chapter 1 for further details of the remit of this study.

615 For further information on the research methodology and details of the consultation with nanotechnology experts, see chapter 1.

context of transatlantic efforts to create more effective and convergent regulation of nanomaterials. The first concerns the creation of the scientific building blocks that are necessary for risk assessment. The second addresses existing knowledge gaps, with regard to the commercialization of nanomaterials and potential EHS risks. The third relates to questions of societal and ethical perspectives and how they are addressed in risk management. Although this last area is currently of only secondary importance to transatlantic regulatory convergence debates, we believe it should be given greater attention by regulators and policy-makers.

7.1 Scientific building blocks for risk assessment

Our research has shown that scientific uncertainty is a key challenge in developing an effective regulatory response to potential risks of nanomaterials. Nearly all experts whom we consulted – from scientists to regulators and stakeholders in industry and civil society – agreed on the need to establish a firm scientific basis for risk assessment and management. Creating this scientific basis is an urgent task that is best done in an internationally coordinated manner. In our view and in the view of many experts, such international coordination creates opportunities for greater regulatory convergence, not only between the United States and the EU, but also internationally among other economies with an existing or emerging stake in nanotechnology.

Recent academic analyses and regulatory reviews by governmental institutions have revealed a number of areas in which scientific uncertainty is undermining the effectiveness of existing regulatory frameworks. In their widely noted 2004 report, the UK's Royal Society and Royal Academy of Engineering pointed to existing gaps in our knowledge and understanding of nanomaterials and their associated risks.⁶¹⁶ More recent studies have underlined fundamental uncertainties with regard to the classification of nanomaterials, the precise definition of nanotechnology and nanomaterials, identification of hazards, exposure levels, and environmental and health effects, in particular over the life-cycle of different nanomaterials.⁶¹⁷

In their reviews of regulatory frameworks for nanomaterials, both EU and US agencies have acknowledged that, while nanomaterials are broadly covered by existing frameworks, scientific uncertainties remain to be resolved in order to strengthen the implementation of regulatory oversight mechanisms. The European Commission stated unequivocally in June 2008 that there is 'a need for a rapid improvement of the scientific knowledge basis to support the regulatory work'.⁶¹⁸ In similar vein, the EPA in its 2007 Nanotechnology White Paper declared that, while the 'overall risk assessment approach used by EPA for conventional chemicals is thought to be generally applicable to nanomaterials', ambiguities and uncertainties exist with regard to chemical representation and nomenclature conventions, the environmental fate of nanomaterials, environmental detection and analysis of nanomaterials, human exposure models and toxicity testing.⁶¹⁹ Similarly, in the Nanotechnology Task Force Report, the FDA concluded that '[t]here may be a fundamental difference in the kind of uncertainty associated with nanoscale materials compared to conventional chemicals, both with respect to knowledge about them and the way that testing is performed'. As a result, it recommended supporting efforts to enhance understanding of 'biological interactions of nanoscale materials', 'novel properties of nanomaterials that might contribute to toxicity', and 'measurement and detection methods', among others.⁶²⁰

Recent scientific reviews also have underlined how persistent scientific uncertainties limit existing risk assessment approaches. In the area of cosmetics, for example, the EU's Scientific Committee on Consumer Products (SCCP) pointed to significant knowledge gaps and uncertainties with regard to available data and testing methods.⁶²¹ In its scientific opinion on nanoscale silver for use in food supplements, the European Food Safety Authority (EFSA) likewise declared that toxicological data were insufficient to allow hazard characterization of the substance.⁶²² In its Nanotechnology White Paper, the EPA points to ambiguities with regard to chemical characterization of nanomaterials and knowledge gaps about the behaviour of nanomaterials in the environment, among others.⁶²³

616 The Royal Society and the Royal Academy of Engineering (2004).

617 ICON (2008).

618 European Commission (2008a: 8).

619 EPA (2007a: 30, 32, 33, 40, 51, 53).

620 FDA (2007a: 13–16).

621 SCCP (2007: 5–6).

622 EFSA (2008).

623 EPA (2007a). The lack of a scientific basis for risk assessment will not necessarily stop other actors from trying to manage their exposure to risks.

The insurance sector has been very clear that it views nanotechnology as a looming issue. Lloyd's Emerging Risks Team, for example, issued a report on nanotechnology that noted that 'due to the potential impact to the insurance industry if something were to go wrong, nanotechnology features very highly in Lloyd's top emerging risks' (Lloyd's 2007: 6). Similarly, Zurich Insurance's Canadian office ranked nanotechnology in the top tier of emerging global risks (along with climate change and deteriorating infrastructure). See Canadian Underwriter, *Nanotechnology, climate change, infrastructure among top risks*, 22 November 2007, available at <http://www.canadianunderwriter.ca/issues/ISArticle.asp?id=76768&issue=11222007> (accessed 8 July 2009).

Creating a reliable science base is thus an essential first step towards an effective risk assessment process for nanomaterials. Many of the experts that we consulted have identified scientific gaps as the main area of concern for the effective implementation of existing regulatory frameworks. In order for regulation to work, regulators need data and scientific tools to develop a clear understanding of the nature of the materials that may cause harm, how to identify these materials, define the different types of risks involved, and establish appropriate testing methods and appropriate and effective methods of measuring nanomaterials in the environment, among others. In a rapidly changing field such as that of the nanosciences, where even the boundaries of what is considered to be a nanoscale material or structure are as yet ill-defined, it is of vital importance to establish those basic scientific tools as the basis for risk assessment and subsequent risk management.

Many of these scientific building blocks are as yet missing or have not been internationally standardized. Regulators and experts in the United States, Europe, and elsewhere are currently seeking to fill existing gaps and are working together in various international forums to create mutually agreed scientific standards, as discussed further below. These efforts are focused on the following key areas, among others:

- *definitions*: terminology, nomenclature, categorization;
- *characterization*: physical/chemical characterization of nanomaterials (e.g. length, shape, composition, aggregation, catalytic properties, surface chemistry);
- *metrology*: measurement techniques and instruments;
- *testing*: safety testing and hazard evaluation methodologies.

Developing common practices in these areas is a critical step towards more effective regulation; they are key building blocks of risk assessment. Such common practices play a key role in clarifying how existing regulations apply. They allow regulators to identify where more detailed implementation guidelines may be desirable that specifically focus on nanomaterials, and to provide guidance to producers on special requirements for identification, reporting and testing of nanomaterials in commercial use. Moreover, they enable regulators more fully to exchange information about human health and environmental impacts of nanomaterials.

It is encouraging to note that for the last few years, international efforts have been under way to advance scientific understanding of the health and environmental effects of selected nanomaterials and to create internationally agreed standards in the area of scientific building blocks. **Our research suggests that ongoing work on creating scientific building blocks for risk assessment needs to be stepped up and expanded if it is to produce results in a timely fashion.** As some interviewees have pointed out, the rapid pace of commercialization of nanomaterials demands a **greater sense of urgency** in this area.

Ongoing bilateral links between relevant regulatory authorities in the EU and the United States (e.g. the FDA and DG Enterprise and Industry and DG SANCO; the EPA and DG Environment and DG Enterprise and Industry) play an important role in this respect. They provide regular opportunities for information exchange and informal learning, and the regulators we interviewed generally praised such bilateral processes as important elements of transatlantic coordination. Inter-agency links between the United States and EU have tended to be informal in nature and lack transparency. This is of course part of their strength, as it creates a space for regulators to learn from one another's experiences away from the political spotlight. Informal links of this kind are thus an integral element of a transatlantic regulatory convergence agenda, but cannot replace more formal, transparent and inclusive processes that are open to a broader range of stakeholders.

Furthermore, as discussed in chapter 3, a number of standard-setting bodies have focused on the question of scientific and technical terminology in the field of nanotechnologies.⁶²⁴ They include international bodies such as the International Organization for Standardization (ISO) and ASTM International, among others. Most experts whom we consulted agree on the importance of the work carried out by such organizations, particularly the ISO within an international context. In the words of one stakeholder, the 'main strength of ISO is that it provides the most established and recognised mechanism for the development of international science-based standards'. Some have pointed out that the ISO process is cumbersome and slow-paced, but few dispute the ISO's important contribution in this area. Having started its nanotechnology-related work in 2005, the ISO's Technical Committee 229 published the first set of standards in January 2009. It addresses terminology questions regarding nanoparticles, nanofibres and nanoplates, and is the first in a series of forthcoming terminology and definitions documents.⁶²⁵ Because the ISO enjoys a high degree of legitimacy among regulators and stakeholders, and its standards are recognized in international trade law, the outcome of this work is set to make a valuable contribution to the development of congruent and convergent regulatory approaches in the EU and United States. It is limited in its scope, however,

624 Gale (2008).

625 ISO/TS 27687:2008. ASTM International has also developed a range of standards including on terminology. See Committee E56 on Nanotechnology, available at <http://www.astm.org/COMMIT/SUBCOMMIT/E56.htm> (accessed 8 July 2009).

being focused exclusively on standardization in technical and scientific fields, and interviewees representing civil society groups have complained about the lack of transparency and participation in the ISO standardization process.

The OECD, in contrast, plays a much wider role in promoting congruent approaches and, to some extent, international convergence in the field of nanomaterials regulation. It is undoubtedly the predominant international forum for coordination efforts by regulators and industry experts from the United States, the EU and a select group of other countries. Our research has shown that its work on nanomaterials enjoys a high degree of legitimacy, especially among regulators and industry representatives. In the words of one regulator, the ‘OECD is a great forum to bring together the right parties to talk about coordination’. Another commented that cooperation among government officials at the OECD has been ‘outstanding’.

Most regulators and stakeholders in the EU and United States expect the OECD to help advance the international coordination and convergence agenda. They see it as being particularly useful in creating the scientific building blocks for risk assessment. This work alone is seen by some as having a *de facto* convergence effect, mainly by informing and shaping the implementation of regulatory frameworks in different countries. Some also consider it to be the preferred forum for addressing other issues that relate to risk assessment and risk management, but few expect it to produce early results in this area. A significant number of our interviewees in fact expressed doubts about the OECD’s ability to promote convergence on risk assessment and particularly risk management, and none saw it as the forum for creating a comprehensive international regulatory framework for nanomaterials.

Most interviewees agree that the OECD is the right forum for international coordination efforts among industrialized countries, given its track record in intergovernmental coordination of economic and technology-related policies. A large number of them praise the work carried out so far and the pace at which it has proceeded. Others, however, are disappointed with the pace, scope and depth of certain OECD projects and point to certain limitations of the OECD’s institutional nature. While stakeholders that are accredited observers at the OECD have access to the proceedings of the working groups, others feel their views are not adequately represented in the OECD process. Broad participation by such stakeholders is complicated not least by the fact that outsiders find it difficult to understand the state of play in the OECD’s ongoing work, as much of it remains inaccessible to them. The OECD’s complex process of reaching decisions on the declassification of reports that its nanotechnology working parties have produced has caused significant delays in the publication of such documents. The experience with the working parties thus echoes more general concerns regarding the lack of transparency in the OECD’s intergovernmental processes.

Such differences in assessment of the institution’s work reflect in part differences in expectations: interviewees who have given a more positive assessment of ongoing work at the OECD tend to be content with the international body’s role in promoting burden-sharing through information exchange and joint testing programmes and limited efforts to harmonize test methods and guidelines; in contrast, others who are more sceptical of its achievements to date view its efforts in the light of a broader agenda of creating convergent regulatory approaches. Moreover, participants in the OECD processes are generally positive about the progress being made, whereas some stakeholders who are not among the limited direct participants are more sceptical; this points to problems with transparency and inclusiveness.

We conclude that, on balance, the OECD enjoys broad legitimacy in promoting coordination on the building blocks for risk assessment, and is thus a central institution in the context of transatlantic regulatory convergence. At the same time, more political energy and resources need to be invested in the OECD process in order to speed up its work. While it is desirable for the nanotechnology working parties’ inclusiveness and transparency to be enhanced in order to facilitate broader participation and openness, it will be a serious challenge to accomplish this within the existing structures and processes of the OECD.

7.2 Knowledge gaps

A common theme running through our analysis of regulatory frameworks and their implementation is the impact of uncertainty about nanomaterials, especially their commercial applications and potential risks. As discussed in section 7.1, significant uncertainty exists in the field of scientific definitions, characterization, metrology, and testing methodologies – what we have called ‘scientific building blocks’. In this section, we discuss additional areas of uncertainty: knowledge gaps with regard to the presence of nanomaterials in commercial products and the EHS risks associated with the production and use of nanomaterials. We treat such knowledge gaps separately from building blocks because, even after scientific building blocks have been created and internationally agreed, regulators still face uncertainty about the presence of nanomaterials in commercially traded products and the potential risks that they pose for human health and the environment. For nanomaterials regulation to be effective, regulators need to possess a sufficiently robust knowledge base in these areas, and additional efforts are required to close those knowledge gaps.

A number of authoritative scientific reviews carried out in recent years have revealed significant gaps in our understanding of how nanomaterials interact with the environment and affect the human body. As the Royal Society and Royal Academy of Engineering reported in their 2004 study, many important questions remain unanswered with

regard to the specific properties of nanomaterials, their toxicity and environmental behaviour, and levels of exposure throughout the life-cycle of nanomaterials. A more recent review by the United Kingdom's Royal Commission on Environmental Protection emphasized the continued knowledge gaps in the area of EHS risks of nanomaterials. Its 2008 assessment concluded that 'there is a plausible basis for concern that some manufactured nanomaterials could present a hazard to human health and environment', and that '[h]owever good the research effort, significant uncertainties and areas of ignorance will remain'.⁶²⁶ Thus, although there is no evidence of actual harm from current applications of nanomaterials, uncertainty about the behaviour of nanomaterials in the environment or in living organisms makes it difficult to know whether there are adverse effects and, if there are, the nature of such effects.

A further complication arises from the rapid and often unpredictable development and commercialization of nanotechnologies in a global context. Technological innovation is proceeding at a pace that governments are finding difficult to keep up with, and, while much of the current regulatory focus is on manufactured nanomaterials, few, if any, efforts are being directed at dealing with the regulation of emerging risks resulting from future generation nanotechnologies.⁶²⁷ But even gaining a sound knowledge base about the commercial use of first-generation nanotechnologies poses a challenge to regulators today. Uncertainty exists on the extent to which nanomaterials are being manufactured and used by companies as well as traded internationally, making it difficult for regulators to establish unequivocally that all current applications of the new technology are adequately covered by regulations.

These two dimensions of uncertainty, regarding EHS risks and the state of commercialization of nanomaterials, are closely linked and complicate the search for effective regulatory answers. Knowing as soon as possible what types of nanoscale products are on the market, what types of nanomaterials are used and how they move through possible product life-cycles provides some grounding for establishing research needs in the field of EHS risks. Uncertainty in both these areas afflicts the US and EU regulatory systems in equal measure. We believe that transatlantic cooperation on reducing uncertainty on the commercial use of nanomaterials and on EHS risks would help both sides in addressing certain regulatory challenges.⁶²⁸

7.2.1 EHS risk research

In our research, we found broad agreement among regulators and stakeholders on the need to promote research on the environmental and health effects of nanomaterials.⁶²⁹ Given the pervasive nature of scientific uncertainty about nanomaterials and their potential EHS risks, it is not surprising that most of our interviewees generally advocate an extension of current research efforts into EHS risks of nanomaterials in an effort to reduce current gaps in scientific understanding. **We conclude that, as a matter of priority, governments on both sides of the Atlantic need significantly to increase funding for research into EHS risks of nanomaterials.**

Many interviewees commended ongoing efforts in this area, such as the EU's 7th Framework Programme and various US research efforts, some of which can be tracked through the National Nanotechnology Initiative (NNI).⁶³⁰ However, some interviewees commented that these existing initiatives did not succeed in setting out a comprehensive research strategy on EHS risks or provide sufficient funds to support the agenda that they have created. They also pointed to a lack of an implementation strategy for EHS research, and lack of international coordination of such research. Not all agree that research efforts can or should be directed at the international level, but we encountered considerable support among interviewees for better coordination of existing national or regional research strategies in a transatlantic context.

For some of our interviewees, increases in national research funding need to be complemented by greater coordination of research strategies and even pooling of resources at the international level. Such coordination would help avoid duplication of research and deepen the division of labour in the various scientific communities that already maintain close transatlantic links. Such coordination efforts would allow regulators to benefit from a more strategic use of scarce funding resources, greater exchange of information and mutual learning effects.

Other interviewees saw the research convergence agenda in more critical light. Some questioned the very need for substantial increases in research funding and transatlantic coordination. One regulator questioned the push for greater research funding, pointing out that '99% of nanomaterials are not dangerous'. Even if this is true, the challenge with nanotechnology, given the high novelty, is knowing, or not knowing, which 1% is toxic. A calculation done at Rice University indicated that by simply modifying a number of variables of the 20 major types of single-walled nanotubes –

626 RCEP (2008: 55).

627 See Davies (2009) and Rodemeyer (2009).

628 For an example of such an initiative, see Aitken et al. (2009).

629 See also RCEP (2008: chapter 3).

630 See NNI website, available at <http://www.nano.gov/> (accessed 8 July 2009). For an overview of all EU nanotechnology funding programmes, see *EU nanotechnology R&D in the field of health and environmental impact of nanoparticles*, available at <ftp://ftp.cordis.europa.eu/pub/nano-technology/docs/final-version.pdf> (accessed 8 July 2009). As discussed in chapter 3, the United States has seen both legislative and administrative attempts to set forth a unified research agenda. For example, the NNI has published an updated research agenda, but it requires participating agencies to fund and carry out research independently.

variables involving manufacturing process, range of tube lengths, methods of purification and possible surface coatings – over 50,000 possible variants of this one nanomaterial were possible.⁶³¹ Which ones pose risks? Given the large and growing uncertainty around emerging risks, significant effort and funding needs to be focused on testing techniques (e.g. tiered screening and high throughput testing) that allow for a rapid and cost-effective screening of substances.

Yet other interviewees warned that there would be insufficient political interest in international coordination of research funding. Governments prefer to fund national research programmes and are wary of committing resources to international initiatives, and national institutions would find it hard to agree on international research priorities and strategies. Indeed, some of our interviewees questioned whether even existing national research programmes were sufficiently integrated and strategically focused, thus advocating a higher priority to achieve coordination and strategic orientation within national contexts.

We recognize that international research coordination has its limits and can be difficult to achieve, but **conclude that the benefits of improved transatlantic coordination of EHS research outweigh the costs**. Such coordination in research can take many different forms, and it is beyond the scope of this study to identify specific solutions. But it is clear to us that, **against the background of strained public finances and urgent research needs, greater transatlantic cooperation would give a greater sense of strategic direction to existing research efforts and strengthen the support basis for sustained research funding streams into the future**.

We note that the first efforts towards better coordination of research in the field of nanotechnologies are under way. Existing private-sector initiatives, such as the International Alliance for Nano EHS Harmonization,⁶³² provide a first step in this direction but need to be scaled up, with greater involvement by and funding from governmental bodies. At the intergovernmental level, the OECD's Working Party on Manufactured Nanomaterials is currently engaged in a project on research strategies (project 2; see chapter 3). Because its work has yet to be declassified and made publicly accessible, it is difficult to assess the progress it has made in this area. A greater sense of urgency and more transparent international processes are therefore needed to achieve better coordination of research efforts. One area in which the OECD has made progress, however, is the recently launched OECD Database on Research into Safety of Manufactured Nanomaterials, a global resource that provides summary information on research projects that investigate EHS risks of nanomaterials.⁶³³ Building on a database initially developed by the Project on Emerging Nanotechnologies (PEN) at the Woodrow Wilson International Center for Scholars, the new OECD Database is set to become the focal point for international information exchange on past, ongoing and planned research projects in this area. The database is likely to enhance the informational environment for EHS-related nanotechnology research but should be seen as only a first step. In our view, the members of the **OECD working parties should now step up efforts to agree on strategic priorities, expand nanomaterials testing and deepen the division of labour in this area, and promote information-sharing for research activities that are of relevance to nanomaterials regulation**.

We believe that the international coordination of research funding on EHS risks provides an opportunity for transatlantic convergence. Developing a sound scientific base for understanding the toxicology and ecotoxicology of nanomaterials is a widely accepted objective, and collaboration and coordination of efforts would allow regulators to close some of the knowledge gaps that have been identified in the past. As the world's largest funders of research in this area, the United States and the EU are well placed to set strategic priorities for research at an international level. As one of our survey respondents stated:

If the US, EU, and others can agree on, for example, what data are needed for risk evaluation, how to generate those data, how to use those data in assessments, and how to direct research to fill gaps in basic knowledge, and can cooperate in meeting these needs, then the foundation is laid for consistent decision-making based on sound science.

Regulators would also benefit from better access to information available to their counterparts abroad, particularly in the area of potential EHS risks. The sharing of commercially sensitive data poses a number of problems, however, given rules on confidential business information. Companies that are obliged to provide testing data will seek to shield this information from competitors, and this has been cited as one reason why industry participation has been limited in voluntary reporting initiatives. As discussed in chapters 4, 5 and 6, the current regulatory situation with regard to information disclosure is uneven and does not necessarily point in the direction of closer transatlantic coordination.

631 Vicki Colvin, 'Nanomaterials in the Environment: An application and comment on implications' Presentation, Nanotechnology and the Environment, Brussels, 30 March 2006; Available at: <http://www.nanoforum.org/dateien/temp/Vicki%20Colvin.pdf?06062006102323>.

632 See International Alliance for NanoEHS Harmonization homepage, available at <http://www.nanoehsalliance.org/sections/Home> (accessed 8 July 2009).

633 See Database on Research into Safety of Manufactured Nanomaterials: General Information, available at http://www.oecd.org/document/26/0,3343,en_2649_37015404_42464730_1_1_1_1,00.html#Database_on_Research_General_Information (accessed 8 July 2009).

Governments therefore need to create the right environment in which relevant data can be exchanged while business interests are protected. We have found considerable support among stakeholders for a reform of the current rules on information-sharing among regulators. **We encourage regulators and policy-makers to explore all options available to them, whether through domestic reform or international agreement, for promoting better information-sharing of EHS risk-related data on nanomaterials that ensures commercially sensitive data remain protected.** This would enable regulators to deal more effectively with the current problem of an uneven information basis for risk assessment, help avoid duplication of safety testing, and promote learning between different regulatory institutions.

7.2.2 Reporting of nanomaterials in commercial use

As mentioned above, uncertainty exists not only about EHS risks of nanomaterials but also with regard to the commercial use of nanomaterials, and specifically what type of nanomaterial is contained in which intermediate or consumer products. Our research has shown that many companies themselves are uncertain about the use of nanomaterials within their own industry. In part this reflects the competitive nature of the industrial innovation process; companies usually seek to protect their technological advances and prevent competitors from gaining knowledge about their use of new materials and processes. But it also reflects a general state of uncertainty in industry circles and beyond about the level of adoption of nanomaterials in internationally integrated sectors such as chemicals, food and cosmetics. The globalization of production and trade has made it more difficult to establish a sound knowledge base on the commercial use of nanomaterials.

Existing attempts to establish comprehensive market registers are laudable but need to be taken further. As mentioned above, the Project on Emerging Nanotechnologies, a partner institution in this project, was the first to establish a database of commercially available products containing nanomaterials. It includes information about at least 1,000 products that were made with or contain nanomaterials, but PEN has clearly stated the limitations of its product register: it contains data that are not independently verified and may not be comprehensive in its coverage of products on the market.

Regulators on both sides of the Atlantic have also acknowledged that they currently do not have comprehensive knowledge about the presence of nanomaterials in commercially traded goods. Current regulations in the United States and EU contain reporting mechanisms for chemicals and pesticides that result in the reporting of nanomaterials under certain conditions (see chapter 4), but these are not designed to generate comprehensive data on the commercial use of nanomaterials in different sectors and products, throughout potential life-cycles.

Likewise, recently introduced voluntary substances reporting programmes, which aim to generate data about both the commercial use of nanomaterials and potential EHS risks, are unlikely to fill commercial use knowledge gaps. The United Kingdom's environment ministry launched the UK Voluntary Reporting Scheme (VRS) for Engineered Nanoscale Materials in September 2006, and a review of the two-year pilot phase, which came to an end in September 2008, revealed concerns about the effectiveness of such voluntary reporting. Since its launch in 2006, only 12 submissions were received by UK authorities, which represents about a third of the companies currently manufacturing nanomaterials in the United Kingdom.⁶³⁴

The EPA's Nanoscale Materials Stewardship Program (NMSP) in the United States, a two-year project launched in January 2008, has similarly had only limited success in generating data on engineered nanoscale materials that are being manufactured, imported, processed or used in the United States. The NMSP seeks a wide range of data from manufacturers and importers, including identifying information about the substance and general production, importation and use of information.⁶³⁵ Although the EPA concludes that 'the NMSP can be considered successful', it states in its review that 'approximately 90% of the different nanoscale materials that are likely to be commercially available were not reported'.⁶³⁶

Several of our interviewees commented on the limitations of voluntary reporting requirements pertaining to commercial use.⁶³⁷ Given the persistence of knowledge gaps about the commercialization of nanomaterials, **we believe that governments on both sides of the Atlantic should strengthen existing mandatory reporting requirements and, where necessary, create new ones, with a view to gaining a comprehensive overview of the commercial use of nanomaterials.** We note that the idea of mandatory reporting is gaining ground in the debate on how to develop better knowledge on both commercialization of nanomaterials and their potential EHS risks, despite the challenge of protecting intellectual property rights and commercially sensitive information in such reporting schemes. In its review of existing schemes, the United Kingdom's RCEP has recently come down in favour

634 DEFRA (2008: 9); see also DEFRA's *The UK Voluntary Reporting Scheme for Engineered Nanoscale materials: Seventh Quarterly Report*, available at <http://www.defra.gov.uk/environment/nanotech/pdf/vrs-seventh-progress-report.pdf> (accessed 8 July 2009).

635 See *Concept Paper for the Nanoscale Materials Stewardship Program under TSCA*, available at <http://www.regulations.gov/fdmspublic/component/main?main=DocumentDetail&d=EPA-HQ-OPPT-2004-0122-0058> (accessed 8 July 2009).

636 EPA (2009a: 27).

637 See also Maynard and Rejeski (2009).

of a mandatory system, and the governments of France and Canada have recently indicated their intention to move in this direction.⁶³⁸

Given the high degree of economic interdependence between the United States and EU, any effort to enhance market transparency through improved reporting schemes would benefit from a coordinated effort by both sides. Were such a market register to be developed, a number of design questions would have to be addressed, including whether the register is product- or application-based, and whether the register would be available only to regulators or to the public at large. Such an initiative could build on existing initiatives sponsored by non-governmental organizations, such as PEN, to establish market surveys of existing or emerging nanotechnological applications.⁶³⁹ Whatever design were to be chosen, we believe that this is an area in which transatlantic, and ultimately international, cooperation could provide a fruitful approach towards laying the foundations for more congruent regulatory responses to the challenges of nanomaterials.

7.3 Consumer labelling and ethical concerns in risk management

The above discussion has focused on issues that are central to the risk assessment process. We now turn to issues in *risk management*,⁶⁴⁰ and particularly those issues that relate to calls for labelling of nanomaterials in products and ethical concerns, as outlined in the original remit for this study. Risk management builds on risk assessment and is primarily concerned with reaching decisions on how to minimize or avoid exposure to identified risks. It involves the weighing of the costs and benefits of different types of regulatory action or inaction, and it is here that societal values and perceptions enter the risk regulation process.

The first point to note is that much of the current focus on international dimensions of nanotechnology oversight revolves around risk assessment rather than risk management. While the first regulatory management decisions have already been taken by United States and EU authorities (see chapters 4–6), efforts to promote international coordination and cooperation are currently focused on establishing the scientific building blocks needed for risk assessment. This is not surprising or unusual, given the relative novelty of nanomaterials risks and the considerable uncertainty that surrounds the scientific debate on such risks. As several interviewees pointed out, it may therefore be somewhat premature to discuss transatlantic convergence in risk management.

Several interviewees also expressed scepticism about the very idea of promoting transatlantic convergence in the field of risk management, which is more politically sensitive and responds more closely to domestic social and political demands, particularly when contrasted with science-driven risk assessment. One interviewee commented that in risk management, ‘countries usually go their own way’, and another argued that the United States and EU would first need to establish their own risk management approaches for nanomaterials before they can even begin to discuss greater coordination. Others, however, have pointed out the desirability of better international coordination and cooperation in risk management, however difficult to achieve.

On the basis of our findings and consultations with experts, it is clear that EU–US convergence in this area is more difficult to achieve, and efforts to coordinate approaches are less likely to show early results. As one interviewee put it, risk management ‘is going to require a great degree of cultural sensitivity and awareness, and may be an area where various approaches are worth trying, so there are more hurdles to convergence’.

We conclude that international coordination efforts on risk management are likely to be less productive, may be premature, and would face greater obstacles compared to those dealing with building blocks for risk assessment. At the same time, the internationalization of the nanosciences and nanotechnologies will inevitably bring any differences in risk management approaches into sharper focus in transatlantic relations. As more and more nanomaterials are adopted commercially and enter global supply chains, differences in national or regional risk management approaches may end up complicating the free flow of goods across national boundaries (see the discussion on regulatory convergence in chapter 1). For this reason, **coordination in the area of risk management will need to be given greater prominence on the international agenda in the coming years.**

7.3.1 Consumer labelling

Within this area, we were asked specifically to ‘examine means of addressing the safety and ethical concerns expressed by citizens, and understand the implications of calls in the United States and the EU for the labelling of

638 RCEP (2008: 69–70); see also *Mandatory Nanomaterial Declaration proposed by French Government* on Safenano website, available at <http://www.safenano.org/SingleNews.aspx?NewsID=590> (accessed 8 July 2009); ‘World’s First Mandatory National Nanotech Requirement Pending’, available at: <http://www.nanotechproject.org/news/archive/7061/>.

639 PEN, Consumer Products Inventory, at: <http://www.nanotechproject.org/inventories/consumer/>.

640 Risk communication, often singled out as the third stage in the risk regulation process (after risk assessment and management), is beyond the scope of this study.

nanomaterial products from the point of view of safety, legislation, and international trade'. We now turn to these questions in more detail, outlining the main findings of our research. The focus of this will be on consumer labelling provisions for nanomaterials, as this has been the most widely discussed tool of risk management in this area, in a debate that has otherwise been relatively muted.

The identification of regulated materials through labelling is a widely used instrument of risk management. This is done for two principal reasons: to inform consumers about the presence of hazardous substances in products and provide guidelines on safe use; and to enable consumers to make an informed choice.

As discussed in some detail in chapters 5 and 6, both the United States and the EU use mandatory consumer labelling schemes for materials that have been classified as dangerous or whose use is restricted. For example, in the United States, cosmetics must be labelled if they have not been tested for safety by the manufacturer under the FFDCAs misbranding authority; in the EU, the Novel Foods Regulation requires producers to label food or food ingredients that are no longer equivalent to existing food or food ingredients.

So far, neither the United States nor the EU has introduced legally binding consumer labelling requirements that specifically target nanomaterials, even though some companies have recently introduced the first voluntary labelling in positive (identifying nanomaterials) and negative (declaring to be free of nanomaterials) forms. However, the European Parliament has recently included a provision for mandatory consumer labelling in the latest version of the proposed EU Cosmetics Regulation, and many observers expect it to enter into force as part of the new Regulation. Regulators on both sides of the Atlantic maintain that nanotechnology-specific labelling is not required, but remain open to the possibility of further developing guidance documents for the implementation of existing labelling requirements that may also cover nanomaterials. The further evolution of regulatory praxis may lead to a gradual expansion of such labelling based on existing regulatory provisions. The European Commission, for example, has noted the 'possibility that a need would be identified for specific labelling requirements', but expects existing provisions in European law to be the main basis for nanomaterials labelling.⁶⁴¹

Our interviewees expressed strongly divergent views on the need to go beyond this state of affairs by creating more comprehensive labelling requirements, and on whether more convergent approaches in the United States and EU could and should be developed in this area. Some warned that labelling would be a costly way to inform the public about the presence of materials that will most likely be of little consequence to human health or the environment. Meaningful labelling is, as one interviewee put it, 'hard to get right'. Both US and EU industry interviewees, in particular, questioned the usefulness and legitimacy of a general labelling requirement for all products that contain nanomaterials. Some compared this to the labelling of GM food in the EU, which informs the consumer of the use of a certain technology, but not of specific risks involved in the consumption of GM food. Others noted the danger of information overload and worried that labels might confuse consumers more than inform them.

On the other hand, some interviewees suggested that the labelling of nanomaterials in food and cosmetics products will be of particular importance, not least as a means of building consumer trust through enhanced transparency. Some see this becoming increasingly important as more and more nanomaterials enter the market. While most producer companies remain sceptical about a general labelling requirement, some retail firms (e.g. supermarkets) are likely to view nano-labelling more favourably as a way of assuring consumers that no risks, whether actual or potential, are hidden from them. Several civil society and consumer groups have thus called for better labelling provisions as part of a broader attempt to ensure consumers' 'right to know' and 'informed choice'.⁶⁴²

The 'informed choice' argument for nanomaterials labelling is seen by proponents as a means of ensuring that consumers are free to express views not only on the safety of nanomaterials but also on ethical dimensions of the use of nanotechnologies, particularly in food and cosmetics. In this perspective, labelling becomes a tool for embedding nanomaterials regulation in a wider social and ethical context without sacrificing the scientific foundations of the core risk assessment process. Opponents, however, have pointed out that any comprehensive labelling of nanomaterials would be misleading, particularly if it failed to notify consumers of specific health or environmental risks or of specific benefits of the nanomaterials. The question that is at the heart of such disagreements is whether ethical concerns that are unrelated to specific concerns about environmental and health risks are legitimate reasons for introducing a labelling regime.

In the light of the contentious nature of labelling, in terms of its general necessity and specific form of implementation, **we have concluded that there is no overwhelming case for arguing that the United States and EU should prioritize international efforts to create new, mandatory, labelling requirements or harmonize existing ones at this time.** Both

641 The European Commission states: 'There are no provisions in Community legislation dealing specifically with nanomaterials. However, without excluding the possibility that a need would be identified for specific labelling requirements, nanomaterials have to comply with the existing provisions of Community law addressing the labelling of products, warnings to consumers and users based on the properties of products, instructions for use, or any other information requirements.' (European Commission 2008a: 10). In a recent, non-binding, resolution, however, the European Parliament voted by 362 votes to 4, with 5 abstentions, to support the introduction of a general labelling requirement for nanomaterials in consumer products (European Parliament 2009c).

642 See *Nanomaterials in Cosmetics: BEUC cautiously welcomes new regulation*, available at <http://www.eubusiness.com/Consumer/beuc-press.09-03-25> (accessed 8 July 2009).

sides should still consider the implications of different labelling requirements, whether already established or newly created, for the proper functioning of international trade in a transatlantic context.

Some coordination efforts in this context are already under way at the international level. Both the United States and EU are in the process of implementing the Globally Harmonized System of Classification and Labelling of Chemicals (GHS), which will standardize the information on hazards and toxicity from internationally traded chemicals and is expected to provide a basis for harmonization of rules and regulations on chemicals.⁶⁴³ In the food area, the Codex Alimentarius Commission has promoted international harmonization of rules on food safety labelling. While Codex has made progress in a number of areas, an international agreement on standards for the labelling of biotech food products has so far proved elusive.⁶⁴⁴ International agreement on cosmetics labelling has similarly failed to materialize, underlining the complexity of reaching international agreement in the field of labelling.

In our view, **US and EU authorities should explore the implications of potentially diverging consumer labelling requirements for nanomaterials, particularly in the context of international trade obligations.** If the United States and EU were to explore the possibility of developing common approaches or standards for nanomaterials labelling, such an undertaking should involve a multi-stakeholder forum to engage relevant groups from industry and civil society in order to give full weight to the different commercial and ethical concerns. Current transatlantic dialogues, such as those within the Transatlantic Consumers Dialogue (TACD) and the Transatlantic Business Dialogue (TABD), could provide useful forums for taking this debate forward. Such an effort would be less urgent than the creation of common building blocks for risk assessment, but is nevertheless important in its own right.

7.4 Conclusion: the way forward for international coordination and regulatory convergence

Our review of existing regulatory frameworks for nanomaterials in the fields of chemicals, food and cosmetics outlines how regulators are currently using and in some cases could use their authorities to address potential EHS risks posed by nanoscale materials. However, it also points to uncertainties and ambiguities in the scope and effectiveness of the regulatory frameworks; opportunities for the further development of the scientific building blocks for risk assessment; persisting knowledge gaps with regard to the commercialization of nanomaterials and EHS risks; and uncertainties regarding the use of existing or future consumer labelling for nanomaterials.

Efforts are under way in the United States and EU to reduce some of these uncertainties and close potential knowledge gaps. Regulators are also actively pursuing transatlantic coordination and cooperation to promote convergent approaches, but are constrained, of course, by the peculiarities of their existing legal and regulatory frameworks. Fully harmonized nanomaterials regulation is, therefore, not on the agenda, nor does it seem to be desirable. Virtually all our interviewees welcomed greater international efforts to achieve transatlantic coordination and cooperation, but few expected that a process of convergence would result in deep harmonization.

The notion of regulatory convergence is much discussed and often misunderstood. One of the central tasks for this project was to address the effectiveness of existing regulatory approaches with a view to identifying the potential for transatlantic regulatory convergence. In chapter 1, we defined convergence as a process rather than an outcome, encompassing different mechanisms and involving different levels of the 'growing alike' of regulatory structures and processes. We recognized a wide spectrum of strategies and levels of convergence, and identified three primary mechanisms. These may often overlap in reality and cannot always be neatly separated, but provide ideal-type scenarios to guide our discussion. As outlined in chapter 1, we distinguish between:

- *policy diffusion*: an informal process of communication and policy learning between regulators;
- *international coordination and cooperation*: a formal or informal process of developing congruent approaches without a large-scale adjustment of domestic laws and regulation; and
- *treaty-based harmonization*: formal negotiation of an international agreement on common rules and standards for domestic regulation.

As is evident from our analysis, international efforts to promote greater convergence between US and EU regulatory approaches for nanomaterials have been focused on the first two mechanisms. Authorities dealing with chemicals, food and cosmetics regulation have engaged in regular but informal transatlantic links, in order to promote exchange of information and experiences with the implementation of existing nanomaterials

643 See United Nations Economic Commission for Europe, available at http://www.unece.org/trans/danger/publi/ghs/ghs_welcome_e.html (accessed 8 July 2009).

644 Sand (2006).

regulations. Moreover, regulators, scientists, industry representatives and other stakeholders from civil society have established formal coordination processes through the OECD's two working parties on manufactured nanomaterials and nanotechnology policy. Finally, parallel processes of international standardization, such as those conducted under the auspices of the ISO, are aimed at creating technical and scientific standards that are central to effective risk assessment processes.

No efforts have been undertaken as yet to create a formal, treaty-based, international framework for nanomaterials regulation – the third mechanism of regulatory convergence. Indeed, our interviews with regulators and stakeholders revealed little if any interest in pursuing the more ambitious objective of creating an international treaty on nanomaterials regulation.⁶⁴⁵ **We conclude that, in the current situation, there is no immediate need for negotiating an international regulatory regime on nanomaterials.** In our view, the political energies that would need to be invested in such a project are better spent on strengthening existing forums for international coordination and adjusting domestic regulatory frameworks where needed. Given the globalized nature of nanotechnological developments and commercialization, however, one cannot rule out the possibility that such a need for an international framework treaty might arise in the future, particularly as new players from the developing world are emerging in the global nanotechnology business.

Among our interviewees, nearly all regulators and many stakeholders expressed satisfaction with the current forms of international coordination and collaboration. But we also heard more critical voices regarding the state of the transatlantic and international coordination agenda. Some pointed to the need for greater urgency in the work being carried out under the auspices of organizations such as the OECD and ISO. Others highlighted the limitations of these organizations, and particularly the OECD, in terms of transparency, inclusiveness regarding stakeholders and participation by developing countries. We note the high level of support that the OECD enjoys among regulators and urge the organization and its member states to invest greater resources and energy in its ongoing nanomaterials-related work programmes. Moreover, the OECD's contribution and legitimacy could be strengthened by addressing concerns regarding its transparency and openness to participation by a broader range of stakeholders.

At the same time, the EU and the United States, as much as the rest of the international community, should perceive of the global governance challenges arising from nanomaterials in broader terms. **The OECD serves an important function as a forum for coordination among leading industrialized countries, but its work should be complemented by the development of international governance capacity in other areas, and there should be greater inclusion of developing countries.** Other international organizations, such as the United Nations Environment Programme (UNEP) and the World Health Organization (WHO), play important roles in their respective areas of global environmental protection and health promotion, but are only just beginning to identify the EHS risks of nanomaterials as emerging areas of concern.⁶⁴⁶ The current imbalance in the development of international governance capacity should thus be redressed, not least to ensure that developing countries are better represented in global regulatory cooperation.

As global leaders in developing regulatory oversight for nanomaterials, the EU and United States should extend their leadership to other areas and institutions of international governance. This would ensure that the twin goals of securing the future of nanotechnologies while safeguarding against potential environmental and health risks of nanomaterials are firmly established at the international level.

645 For an example of what such an international treaty could encompass, see Abbott et al. (2006).

646 The WHO's Intergovernmental Forum on Chemical Safety (IFCS) has issued the 'Dakar Statement on Manufactured Nanomaterials', which notes the 'lack of an inclusive global policy framework' and recommends increased efforts to fill gaps in scientific understanding, promote information sharing, international cooperation on the development of national codes of conduct, among others (Final Report available at http://www.who.int/ifcs/documents/forums/forum6/f6_execsumm_en.doc, accessed on 8 July 2009). UNEP has called for 'swift action' by policy-makers to properly evaluate the new science of nanotechnology. UNEP's 2007 *Geo Yearbook* identifies nanotechnology and the environment as a key emerging challenge for international policy-making but stops short of outlining an alternative vision for international nanotechnologies regulation (*Yearbook* section 'Emerging Challenges: Nanotechnology and the Environment', available at http://www.unep.org/geo/yearbook/yb2007/PDF/7_Emerging_Challenges72dpi.pdf, accessed on 8 July 2009).

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