Nanotechnology

This section is meant to give readers an insight into the emerging field of nanotechnologies and risk regulation. It informs and updates readers on the latest European and international developments in nanotechnologies and risk regulation across different sectors (e.g., chemicals, food, cosmetics, pharmaceuticals) and policy areas (e.g., environmental protection, occupational health and consumer product, food and drug safety). The section analyzes how existing regulatory systems deal with new kinds of risks and reviews recent regulatory developments with a focus on how best to combine scientific freedom and technological progress with a responsible development and commercialization of nanotechnologies.

How to Avoid International Trade Conflicts

*Nico Jaspers**

I. Introduction[1]

Nanosciences and nanotechnologies – the manipulation of matter at the molecular level – enable us to produce materials with new physical and chemical properties. At the nanoscale, gold changes colour and becomes highly catalytically active, aluminium becomes explosive, silicon turns from being an insulator to being a conductor, silver becomes a highly effective antimicrobial, and carbon becomes extremely strong and light. Nanotechnologies are "enabling" or "platform" technologies that will profoundly affect a range of industrial sectors, including energy production and storage, health care, consumer products, transportation, textiles, electronics, agriculture and others. Groundbreaking innovations include organically growing liquid crystals and quantum dots that facilitate the production of nano-enabled solar cells in the form of wall paper or paint;[2] silicon nanoparticles covered with a layer of gold that destroy cancerous tumours when activated by infrared light;[3] and silicon coated nanowires to produce a paper-like "sponge" to separate oil from water after an oil spill.[4] Nanotechnologies can also be employed to purify, desalinate and disinfect water more effectively,[5] to store energy more efficiently,[6] and to improve the quality of existing products such as tennis rackets, sunscreens, food storage containers, clothing and cleaning products.[7]

Across industrialised countries, hopes are high for nanotechnologies to start the "next industrial revolution."[8] The United States, Japan, South Korea and the larger European countries such as Germany, the United Kingdom and France have established themselves as leading developers of nanotechnologies. Emerging economies are also increasingly moving into applied and basic research in nanotechnologies, most notably China and Russia but also India, Mexico, Brazil and South Africa. Cumulative global public spending on nanotechnology research and development is estimated to have reached almost $50 billion by 2009, with another estimated $65 billion to be invested between 2010 and 2015.[9] Private sector investments have recently started to match public investments. If this trend continues, cumulative global public and private spending on

* Department of International Relations, London School of Economics.

1 Acknowledgements: My thanks go to Robert Falkner, Steffi Friedrichs, Michael Knowles and Cornelis Brekelmans for useful comments on an earlier version of this paper. The usual disclaimers apply.

2 Barry C. Thompson and Jean M.J. Fréchet, "Polymer-Fullerene Composite Solar Cells", 47 *Angewandte Chemie* (2007), pp. 58–77; and Stefan Lovgren, "Spray-On Solar-Power Cells are True Breakthrough", National Geographic News, 14 January 2005, available on the Internet at <http://news.nationalgeographic.com/news/2005/01/0114_050114_solarplastic.html> (last accessed on 9 April 2010).

3 D. Patrick O'Neal *et al.*, "Photo-Thermal Tumor Ablation in Mice Using Near Infrared-Absorbing Nanoparticles", 209 *Cancer Letters* (2003), pp. 171–6.

4 Jikang Yuan *et al.*, "Superwetting Nanowire Membranes for Selective Absorption", 3 *Nature Nanotechnology* (2008), pp. 332–6.

5 Jacques Theron *et al.*, "Nanotechnology and Water Treatment: Applications and Emerging Opportunities", 34 *Critical Reviews in Microbiology* (2008), pp. 43–69.

6 Wei-Ming Zhang *et al.*, "Tin-Nanoparticles Encapsulated in Elastic Hollow Carbon Spheres for High-Performance Anode Material in Lithium-Ion Batteries", 20 *Advanced Materials* (2008), pp. 1160–5.

7 The Project on Emerging Nanotechnologies, "An Inventory of Nanotechnology-Based Consumer Products Currently on the Market", available on the Internet at <http://www.nanotechproject.org/inventories/consumer/> (last accessed on 9 April 2010).

8 See, for example, Mihail Roco and William Bainbridge, *Societal Implications of Nanoscience and Nanotechnology* (NSET Workshop Report 2001); and Christine Peterson, "Molecular Nanotechnology: the Next Industrial Revolution", available on the Internet at <http://www.foresight.org/nano/ieeecomputer.html> (last accessed on 9 April 2010).

9 Cientifica, Nanotechnology Takes a Deep Breath … and Prepares to Save the World (Cientifica Report 2009).

nanotechnology research and development will reach over $200 billion by 2015.

As is the case with conventional chemical substances, the use of nanomaterials is not always free of risk. Some nanomaterials can enter the human body through mucous membranes or the skin and migrate via the bloodstream to vital organs, including the brain. This property can be used to design more effective and less toxic medicines, but it can also have adverse effects on human health due to unintentional uptake. Laboratory experiments have shown that certain nanomaterials may enter cells and interact with their molecular structure with cytotoxic or genotoxic effects,[10] and that the inhalation of certain insoluble ultrafine particles may cause pulmonary inflammation, tissue damage and lung tumours. In particular, two recent studies indicate that multiwalled carbon nano-tubes (MWCNTs) of a certain shape can cause mesothelioma in the linings of the lungs if they are inhaled,[11] and may thus have similar toxicological effects as asbestos. Nanosilver, which is used in textiles, washing machines, food supplements and surface coatings, has also been the focus of recent studies and NGO campaigns, for example over concerns that if released into wastewater it could adversely affect aquatic organisms, including those that are needed in sewage treatment plants.[12]

So far, there is no conclusive evidence that nanomaterials have caused any real health or environmental damage.[13] However, lingering uncertainty about (eco)toxicological effects, the adequacy of traditional protective equipment in preventing accidental inhalation or absorption through the skin, and possible changes in physico-chemical properties when nanomaterials interact with living systems,[14] has led to an intense debate among stakeholders over the past years about "nanotechnology risks". Amidst rapid technological change and an increasing rate of commercialisation of nano-enabled products, regulators are contemplating the regulatory implications of nanomaterial safety. Policy-makers face the difficult task of carefully reconciling scientific freedom and technological innovation with an adequate level of environmental, health and safety protection. This is particularly difficult for nanotechnologies, as in many cases, conventional risk management techniques, product categories, and weight- or volume-based categorisations of substances may be inadequate to address the novel risks posed by some nanomaterials.[15]

II. Recent regulatory developments

In the United States, regulators are currently relying on existing regulatory frameworks (such as those for environmental protection, workplace safety and consumer protection) to cover nanomaterials, and are planning to incrementally adjust these frameworks

10 Nancy Monteiro-Riviere *et al.*, "Multi-Walled Carbon Nanotube Interactions with Human Epidermal Keratinocytes", 155 *Toxicology Letters* (2005), pp. 377–384; Anna Shvedova *et al.*, "Exposure to Carbon Nanotube Material: Assessment of the Biological Effects of Nanotube Materials Using Human Keratinocyte Cells", 66 *Journal of Toxicology and Environmental Health* (2003), pp. 1909–1926.

11 Atsuya Takagi *et al.*, "Induction of Mesothelioma in p53+/– Mouse by Intraperitoneal Application of Multi-Wall Carbon Nanotube", 33 *Journal of Toxicological Sciences* (2008), pp. 105–16; Craig A. Poland *et al.*, "Carbon Nanotubes Introduced Into the Abdominal cavity of Mice Show Asbestos-Like Pathogenicity in a Pilot Study", 3 *Nature Nanotechnology* (2008), pp. 423–8.

12 See, for example, Senjen Rye, *Nanosilver – A Threat to Soil, Water and Human Health?* (Friends of the Earth Report 2007); International Center for Technology Assessment *et al.*, "Petition for Rulemaking Requesting EPA Regulate Nano-Silver Products as Pesticides" (2008), available on the Internet at <http://icta.org/nanoaction/doc/CTA_nano-silver%20petition__final_5_1_08.pdf> (last accessed on 9 April 2010). The exposure of biological systems and aquatic species to nanosilver, however, is much debated in scientific circles. See, for example, Kristen Kulinowski, "Environmental Impacts of Nanosilver, An ICON Backgrounder", 18 November 2008, available on the Internet at <http://cohesion.rice.edu/centersandinst/icon/resources.cfm?doc_id=12722> (last accessed on 9 April 2010).

13 One of the rare exceptions is a report by a Chinese toxicologist from 2009 on an industrial accident where seven workers were exposed to unspecified nanoparticles over five to thirteen months, which is said to have caused two of these workers to die and the remaining workers to be severely disabled (Y. Song *et al.*, "Exposure to Nanoparticles is Related to Pleural Effusion, Pulmonary Fibrosis and Granuloma", 34 *European Respiratory Journal* (2009), pp. 559–67). However, the toxicologist's claim that polyacrylate consisting of nanoparticles caused pulmonary inflammation and pulmonary fibrosis remains contested (see, for example, Andrew Maynard, "Nanoparticle Exposure and Occupational Lung Lisease – Six Expert Perspectives on a New Clinical Study", 18 August 2009, available on the Internet at <http://community.safenano.org/blogs/andrew_maynard/archive/2009/08/18/nanoparticle-exposure-and-occupational-lung-disease-six-expert-perspectives-on-a-new-clinical-study.aspx> (last accessed on 9 April 2010)).

14 ICON, Towards Predicting Nano-Biointeractions (ICON Workshop Report 2008).

15 See, for example, Royal Society and Royal Academy of Engineering, Nanoscience and Nanotechnologies: Opportunities and Uncertainties (RS&RAE Report 2004); SCENIHR, The Appropriateness of Existing Methodologies to Assess the Potential Risks Associated with Engineered and Adventitious Products of Nanotechnologies (SCENIHR Opinion 2006); CDC and NIOSH, Approaches to Safe Nanotechnology: Managing the Health and Safety Concerns Associated with Engineered Nanoparticles (DHSS Report 2009); SCCP, Safety of Nanomaterials in Cosmetic Products (SCCP Opinion 2008); RCEP, Novel Materials in the Environment: The Case of Nanotechnology (Royal Commission on Environmental Pollution Twenty-Seventh Report 2008); House of Lords, Nanotechnologies and Food (Science and Technology Committee 1st Report Session 2009–10).

on a case-by-case basis while developing or updating implementation guidelines. This "gradual approach" is exemplified by the Environmental Protection Agency's (EPA) decision in 2006 to regulate a washing machine using nanosilver as an antimicrobial under its regulatory framework for pesticides (FIFRA) and to require registration accordingly.[16] Moreover, EPA decided in 2008 that carbon nanotubes should be treated as new rather than existing chemicals under its regulatory framework for chemicals (TSCA), which move allows EPA to request a premanufacturing notice.[17] In late 2009, it announced more generally that the distinction between new and existing chemicals under TSCA needs to be reconsidered for nanomaterials, and that it might create a mandatory reporting system that requires producers to provide data on production, use and risks of nanomaterials.[18] The Food and Drug Administration (FDA) presented its views on the "regulatory challenges" of nanotechnologies a few years earlier, in 2007.[19] In its report, FDA notes limitations with regard to access to data and oversight capacity for certain products, such as cosmetics and dietary supplements, but explicitly rejects calls for the introduction of nano-specific labelling requirements, in line with its long-standing preference for case-by-case assessment of product risks and its objection to comprehensive, technology-based, labelling regimes.

In Europe, the European Union is responsible for most nanotechnology-related regulations and risk assessment. Similar to the US, the EU has also decided to rely primarily on existing regulations to cover nanomaterials,[20] but has since 2004 consistently stressed the need for "appropriate and timely regulation in the area of public health, consumer protection and the environment [...] to ensure confidence from consumers, workers and investors."[21] As part of this effort, the European Commission has reviewed EU-level legislation with regard to nanomaterial safety[22] and published a voluntary Code of Conduct for Responsible Nanosciences and Nanotechnologies Research in 2008, which calls for adherence to the precautionary principle and stresses the importance of "anticipating potential environmental, health and safety impacts" of nanotechnologies.[23] More recently, European food and cosmetics laws have been revised or recast to include nanotechnology-specific provisions that mandate labelling requirements for certain nanomaterials when used in food and cosmetic products.[24] EU regulators consistently stress the importance of the EU's new chemicals law REACH in covering nanomaterials.[25] Once fully implemented, REACH requires producers and importers to formally register nanomaterials produced and imported in quantities above one tonne, and to conduct safety assessments for nanomaterials produced or imported in quantities above ten tonnes.[26] If a nanomaterial is found to present a certain risk, REACH also authorises regulators to request additional safety information and to restrict the use of that nanomaterial independent of the tonnage triggers.[27]

16 EPA, "Pesticide Registration; Clarification for Ion-Generating Equipment", *Federal Register* 72(183), (2007).

17 EPA, "Toxic Substances Control Act Inventory Status of Carbon Nanotubes", *Federal Register* 73(212), (2008).

18 EPA, "Enhancing EPA's Chemical Management Program" (2009), available on the Internet at <http://www.epa.gov/oppt/existingchemicals/pubs/Existing.Chem.Fact.sheet.pdf> (last accessed on 9 April 2010).

19 FDA, *Nanotechnology Task Force Report 2007* (FDA Report 2007).

20 European Commission (2008), "Regulatory Aspects of Nanomaterials", *Commission Staff Working Document*, SEC(2008) 2036, available on the Internet at <http://www.euractiv.com/29/images/SEC%282008%29%202036_tcm29-173474.pdf>.

21 European Commission (2004), "Towards a European Strategy for Nanotechnology", *Communication from the Commission*, COM(2004) 338 final, available on the Internet at <http://ec.europa.eu/nanotechnology/pdf/nano_com_en.pdf>, p. 18.

22 European Commission (2008), "Regulatory Aspects of Nanomaterials", *Commission Staff Working Document*, SEC(2008) 2036, available on the Internet at <http://www.euractiv.com/29/images/SEC%282008%29%202036_tcm29-173474.pdf>.

23 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 on the Internet at <ftp://ftp.cordis.europa.eu/pub/fp7/docs/nanocode-recommendation.pdf>, p. 6.

24 Robert Falkner, Linda Breggin, Nico Jaspers, John Pendergrass and Read Porter, "Consumer Labelling of Nanomaterials in the EU and US: Convergence or Divergence?", *EERG Briefing Paper* 2009/03 (London: Chatham House, 2009).

25 European Commission. 2008, Regulatory Aspects of Nanomaterials. Communication from the Commission to the European Parliament, the Council and the European Economic and Social Committee, COM(2008) 366 final, available on the Internet at <http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=COM:2008:0366:FIN:EN:PDF>.

26 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).

27 European Commission (2008), "Regulatory Aspects of Nanomaterials", *Commission Staff Working Document*, SEC(2008) 2036, available on the Internet at <http://www.euractiv.com/29/images/SEC%282008%29%202036_tcm29-173474.pdf>.

The regulatory implications of nanomaterial safety are currently most extensively debated in the US and EU, but other industrialised countries have also investigated the potential risks of nanomaterials and are applying existing EHS regulations. Similar to the US and UK, Australia and Canada have asked producers of nanomaterials to voluntarily provide information on their safety. Canada is currently considering whether to make the provision of relevant information mandatory. Similarly, Korea and New Zealand have also reviewed their regulatory frameworks with respect to coverage of nanomaterials, and Japan has developed guidelines on the safe handling of nanomaterials. Few, if any, countries have adopted significant nanotechnology-specific rules and regulations beyond existing safety frameworks.[28] A range of emerging economies, including China, India, Russia, Brazil and South Africa, are keen to close the technology gap that exists between them and leading industrialised countries, and are beginning to produce nanomaterials and nano-enabled products at a notable scale. More often than not, however, regulatory capacities for nanomaterial safety in these countries are severely constrained, and regulatory activities are often limited to the selective assessment of potential environmental, health and safety risks.

The tendency to rely on existing regulatory frameworks in virtually all relevant countries implies that existing regulatory differences in protecting the natural environment and ensuring the health and safety of workers and consumers may translate into regulatory heterogeneity on nanomaterial safety. There exist some sector-specific dialogues between leading developers of nanotechnologies to harmonize regulation at the level of implementation.[29] However, once the number of relevant actors increases, nanotechnology commercialisation paths become more complex, and entrenched interests decrease flexibility at the level of implementation, existing dialogues may not suffice to promote convergence. More importantly, however, regulatory dialogue between leading developers of nanotechnologies and emerging economies is extremely limited. The fear is that nanotechnology-specific regulatory decisions that have recently been taken (e.g. "nano-labelling" for cosmetic products in the EU; registration requirements for applications of nanosilver in the US; voluntary or mandatory reporting requirements for nanomaterials in different countries) will end up increasing regulatory divergence. If such a trend does indeed become entrenched, then implications for international trade in nanotechnology applications – and thus also for commercial incentives to innovate – will be substantial.

III. Estimating the impact of nanotechnologies on international trade

Estimating the future impact of nanotechnologies on international trade is difficult for two reasons. First, reliable data on the commercialisation of nano-enabled products and on current trade in nano-enabled products do not exist.[30] Second, and more importantly, increasingly global supply chains mean that intermediate components cross international border multiple times before being integrated into the final product. Double counting is thus likely to inflate estimates of the value of traded nano-enabled products relative to the absolute value of nano-enabled products. Since different regulatory frameworks apply at different stages of a supply chain (e.g. chemical regulations cover the "raw" nanoparticle but product safety and disposal regulations cover the final product) the potential trade impact of regulatory heterogeneity increases exponentially with a growing complexity in supply chains and regulatory frameworks.

In light of the variety in commercial applications of nanotechnologies, the collection of data on trade in nano-enabled products and intermediates at each

28 The OECD Working Party on Manufactured Nanomaterials (WPMN) publishes an annual update of regulatory and risk assessment activities in participating countries, available on the Internet at <http://www.oecd.org/document/53/0,3343,en_2649_37015404_37760309_1_1_1_1,00.html>.

29 For example, the International Cooperation on Cosmetics Regulation (ICCR), available on the Internet at <http://www.fda.gov/InternationalPrograms/HarmonisationInitiatives/ucm114513.htm>; the Strategic Approach to International Chemicals Management (SAICM), available on the Internet at <http://www.saicm.org/index.php?ql=h&content=home>; and planned future activities in the area of nanomedicines, see <http://www.ema.europa.eu/pdfs/conferenceflyers/nanotech_workshop/Agenda.pdf>.

30 The Project on Emerging Nanotechnologies (PEN) at the Woodrow Wilson International Center for Scholars has counted over 1000 commercially available nano-enabled consumer products in 2009, but its inventory relies on the work of a small team conducting online research on credible "nano-claims" by producers on final products, see <http://www.nanotechproject.org/inventories/consumer/>. Following the request of the European Parliament, the European Commission is currently developing a more thorough inventory that is to be published in 2010, see <http://www.europarl.europa.eu/sides/getDoc.do?type=TA&language=EN&reference=P6-TA-2009-0328>.

stage of the value chain is challenging to say the least. An alternative way to obtain an estimate of the possible future impact of nanotechnologies on trade is to use existing data on trade in manufactured goods and relate that to projections of future nanotechnology commercialisation. Lux Research, a leading provider of intelligence on emerging technologies, estimates that by 2015, nanotechnologies will affect products worth $2.5 trillion worldwide,[31] or almost 16 % of all manufactured goods in 2015.[32] Global trade in manufactured goods amounted to $10.5 trillion in 2008, the last year for which data are available,[33] of which about 30 % consisted of intra-EU trade.[34] Since members of the EU's single market are subject to very similar if not identical regulatory frameworks in relevant areas, intra-EU trade needs to be subtracted from the above figure. This yields $7.4 trillion worth of relevant trade in manufactures in 2008. If we assume that the volume of global trade grows by its historical average of about 8 % per year between 1980 and 2008, the overall volume of global trade in manufactures (excluding intra-EU trade) will amount to $12.69 trillion in 2015. If we further assume that the share of traded "nano-manufactures" in overall traded manufactures is similar to the share of "nano-manufactures" in overall manufactures, nanotechnologies are likely to affect up to $2 trillion of international trade by 2015 (16 % of $12.69 trillion).

The margin of error in this estimate of course very much depends on the validity of the assumptions. For instance, the estimate increases if trade in nano-enabled products grows faster than trade in "regular" products, but decreases when the integration of global supply chains for nano-intermediates is weaker than the integration of global supply chains for "regular" intermediate products (i.e., when nano-intermediates cross borders significantly less often than regular intermediates). It is also important to note that the trade-related economic effect of regulatory heterogeneity is not uniform across different sectors and types of regulation. Due to their cross-sectoral relevance, divergence between different chemical regulations, for instance, may have a significantly larger effect on trade in nano-enabled products than divergence in the regulation of final consumer products. The above estimate of the impact of nanotechnologies on trade is thus only an approximation. What is important, however, is to understand the magnitude of the potential effect that regulatory heterogeneity may have on future trade in nano-enabled products. Whatever the precise trade impact of nanotechnologies, it is already clear that regulatory heterogeneity will impact trade worth tens of billions of US dollars, thus dwarfing the commercial stakes involved in long-standing transatlantic disputes such as over the use of growth hormones in beef production.[35]

IV. Towards regulatory convergence

The potential economic (and political) costs of regulatory heterogeneity present a strong case for promoting convergence. Adjusting regulatory policies at the national level, however, can be politically sensitive, especially when international coordination or harmonisation of environmental and consumer protection leads to an unwanted increase or lowering of national standards. Moreover, binding international rules, harmonisation agreements, or framework conventions – common tools to promote regulatory convergence in many policy areas – may not work in this particular case, as the scientific and commercial complexity of nanotechnologies and great uncertainties about risks imply that finding a meaningful agreement will be politically very difficult and time-

31 Lux Research, 2009, The Recession's Impact on Nanotechnology, available on the Internet at <http://www.luxresearchinc.com/blog/2010/02/the-recessions-impact-on-nanotechnology/>.

32 This figure is based on an estimate of global manufacturing output worth $15.8 trillion by 2015. See IHS Global Insight (2008), "Revised Forecast Advances Date of China Becoming the Preeminent Global Manufacturer", 12 August 2008, available on the Internet at <http://www.ihsglobalinsight.com/Perspective/PerspectiveDetail13718.htm>. This is very close to earlier predictions of nano-enabled products accounting for 15 % of global manufacturing output, reported in OECD and Allianz (2005), "Small Sizes that Matter: Opportunities and Risks of Nanotechnologies", Report in co-operation with the OECD International Futures Programme, available on the Internet at <http://www.oecd.org/dataoecd/32/1/44108334.pdf>; and Angela Hullmann (2006), "The Economic Development of Nanotechnology – An Indicator Based Analysis", European Commission, DG Research Report, available on the Internet at <ftp://ftp.cordis.europa.eu/pub/nanotechnology/docs/nanoarticle_hullmann_nov2006.pdf>.

33 WTO (2009), "International Trade Statistics 2009" available on the Internet at <http://www.wto.org/english/res_e/statis_e/its2009_e/its2009_e.pdf>, chapter 2, "Merchandise Trade by Product", p. 41.

34 See <http://www.wto.org/english/res_e/statis_e/its2009_e/its09_merch_trade_product_e.htm>.

35 Timothy E. Josling, "The Beef Hormone Dispute and Its Implications for Trade Policy", *Stanford University Forum on Contemporary Europe Working Paper* (2001), available on the Internet at <http://fce.stanford.edu/publications/beefhormone_dispute_and_its_implications_for_trade_policy_the/>.

consuming, if at all possible. One way to avoid a top-down approach to regulatory convergence would be to address some of the key underlying causes for regulatory heterogeneity: a very uneven distribution of regulatory capacities across countries, the lack of a reliable common scientific basis, and a lack of knowledge about the trade-related impact of specific regulatory policies.

Enhancing regulatory expertise and capacities in today's emerging and developing economies can be done in several ways. First, leading developers of nanotechnologies in North America, Europe and East Asia should actively share relevant expertise with emerging economies, for instance by establishing a permanent forum to promote international regulatory dialogue and coordination. Second, leading developers of nanotechnologies should create basic guidelines on, for example, regulatory practices, institutional requirements, past experiences, and effective regulatory tools. Third, they should extend participation in sector-specific dialogues to emerging economies and establish new forums if required. Fourth, an international advisory service could be created to provide technical expertise on conducting regulatory reviews, develop concrete regulatory options, assess specific capacity building requirements, provide technical and administrative training, and consult local firms on domestic and international trade-related regulatory requirements.

At the same time, the assessment of risk needs to be coordinated at the international level with greater involvement of emerging economies and other stakeholders, including industry and civil society. The OECD's Working Party on Manufactured Nanomaterials provides a useful forum to discuss developments in risk assessment and risk management in an exclusive circle of industrialised countries. In order to adequately address future challenges, however, this work must be stepped up dramatically and expanded to include other international institutions with a more inclusive membership base. UN agencies such as WHO or UNEP could provide a framework to coordinate and fund strategic research on (eco)toxicological properties of nanomaterials, the interaction of nanomaterials with biological systems over their life-cycle, exposure assessments including collecting data on the commercial availability of nano-enabled products, and gathering intelligence on future developments both in terms of commercialisation paths and scientific developments. Coordinating the production and sharing of relevant data at the international level is the best way to secure a thorough, credible and legitimate scientific basis for risk management.

Finally, leading developers of nanotechnologies should promote a systematic evaluation of the trade-related impact of regulatory policies. In an increasingly global economy, the effect of regulatory decisions is rarely confined to national or regional borders and may significantly affect a trading partner. Current provisions under international trade law, in particular on sanitary and phytosanitary (SPS) measures and on technical barriers to trade (TBT), are useful if there is international agreement on risk assessment procedures and relevant standards. The nature of nanotechnologies as a fast evolving scientific area with considerable uncertainties, however, makes it a "moving target" that will inevitably leave much room for disagreement. Common guidelines and codes of conduct on evaluating the trade-related impact of regulatory decisions are one way to increase the transparency and legitimacy of specific regulatory decisions. Countries should be encouraged to conduct such analyses and to thereby increase awareness on the external effects of regulatory heterogeneity.

V. Conclusion

Nanotechnologies will affect international trade more than most other scientific innovations, not least as nano-enabled components of a final product cross national border multiple times before reaching their final destination. The trade value of nano-enabled goods will therefore soon exceed the absolute value of nano-enabled goods, and regulatory heterogeneity may become a serious threat to the successful and responsible development of nanotechnologies. If the relevant environment, health and safety regulations in leading developers, importers and exporters of nanotechnologies were to systematically differ across sectors and stages of supply chains, this could soon disrupt trade worth $2 trillion in nano-enabled goods. Regulatory convergence can and should thus be actively promoted in the most important sectors and policy areas to avoid or minimize the potential economic and political costs of trade conflicts.

Considering the rapid technological and commercial development of nanotechnologies, the next few years present a unique window of opportunity to create the necessary frameworks for closer international cooperation and coordination to do so. Since creating complex international treaties or conventions is politically sensitive, technically difficult and potentially ineffective, leading developers of nanotechnologies need to reduce three types of uncertainties that profoundly affect the degree of international regulatory compatibility: (a) uncertainty about the effectiveness of existing regulatory regimes in securing a responsible development of nanotechnologies without limiting innovative and commercial potential; (b) uncertainty about the nature of the risk that some nanomaterials and applications of nanotechnologies present; and (c) uncertainty about the socio-economic and trade-related regional and international effects of regulatory policies. This article has argued that enhancing regulatory capacities in emerging economies; creating a reliable and legitimate scientific basis at the international level; and establishing guidelines to assess the impact of regulatory heterogeneity in a transparent and open manner can greatly help to reduce the threat of future trade conflicts over nanomaterial safety.