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.

Nano-Safety or Nano-Security? Reassessing Europe's Nanotechnology Regulation in the Context of International Security Law

Hitoshi Nasu and Thomas Faunce***

I. Introduction

The rapid development of nanotechnology over the last decade has resulted in a widespread introduction of engineered nanomaterials (ENMs) into the consumer products of developed countries. Because of the potential toxicity of ENMs, however, concerns for health and environmental safety have led to controversial public debates in many countries as to whether and how the safety of products containing ENMs should be specifically ensured. In Europe, the European Commission signalled the significance of such efforts when it confirmed in 2004 that the obligations to ensure a high level of human health protection and to preserve, protect and improve the quality of the environment under the Treaty Establishing the European Community,[1] would be applicable to nanotechnology research and development.[2]

In these regulatory debates, however, the role nanotechnology plays in addressing various contemporary security challenges is given little, if any, at-

* Dr. Hitoshi Nasu is a senior lecturer in law at the Australian National University (ANU) College of Law; contact: <NasuH@law.anu.edu.au>.

** Dr. Thomas Faunce is a Professor at the ANU College of Law and ANU College of Medicine, Biology and Environment; contact: <thomas.faunce@anu.edu.au>.

1 OJ C-325 (24 December 2002), Articles 152, 153 and 174. As of 6 May 2012, these provisions have been incorporated into the Treaty on the Functioning of the European Union, OJ C-83/47 (30 March 2010), Articles 168, 169 and 191.

2 European Commission, "Towards a European Strategy for Nanotechnology: Communication from the Commission", 2004, p. 5, available on the internet at <http://ec.europa.eu/nanotechnology/pdf/nano_com_en.pdf> (last accessed on 16 July 2012).

demonstrated the fine line between nuclear safety and security, where no harmful intention was present.[11] As the volume of ENMs and related products rapidly increases across the world, a wide and uncontrolled release of harmful nano-substances may well be seen as posing an existential threat to the conditions that allow modern societies to function.

Under general international law, states are required 'to ensure that activities within their jurisdiction and control respect the environment of other states or of areas beyond national control'.[12] This general legal obligation is considered to originate from the *Trail Smelter* arbitration, where it was observed that 'no state has the right to use or permit the use of its territory in such a manner as to cause injury by fumes in or to the territory of another'.[13] Similar obligations have also been codified in specific contexts such as for the marine environment,[14] Antarctica,[15] and the transboundary movements of hazardous wastes.[16] There are also specific legal obligations not to develop, produce, acquire, stockpile or transfer toxins and toxic chemicals of types and quantities that have no justification for peaceful purposes under the Biological Weapons Convention and Chemical Weapons Convention.[17]

Those international legal obligations do not so much dictate the way in which states should regulate the use of toxic substances, with the exception of their use as weapons. But rather, states are required to prevent or control exposure to toxic substances, which can be seen as providing legal protection against potential environmental security threats to a sovereign state or to particular geographical areas. One way to implement these legal obligations is, in general, to develop standards of diligence by reference, for example, to the use of 'best available technology' and 'best practicable means' to mitigate exposure.[18]

III. Evaluation of the Current Regulatory Approaches in Europe

Despite the unique difficulty of ascertaining the toxicity of ENMs, regulatory authorities have manifested varying degrees of urgency and attention to detail in developing policies and taking formal regulatory action on the safety of the manufacture and use of nanotechnology. The European Union (EU) is considered to be at the forefront of nanotechnology regulation, introducing regulatory requirements that expressly apply to the safe use of nanotechnologies and nanomaterials in cosmetics,[19] novel foods,[20] and biocidal products.[21] The Registration, Evaluation, Authorization and Restriction of Chemicals (REACH) regulation controls the manufacture and import of chemicals by reference to their safety information, which theoretically applies to nanomaterials.[22] Although aborted, the proposal to ban the use of nanosilver and multi-walled carbon nanotubes in electrical and electronic equipment was designed to address health and environmental safety concerns

11 Naoto Kan, "Former Japanese PM Naoto Kan on the Fukushima Disaster: A Changing View of Nuclear Power", *Foreign Affairs*, 8 March 2012, available on the internet at <http://www.foreignaffairs.com/features/letters-from/former-japanese-pm-naoto-kan-on-the-fukushima-disaster> (last accessed on 12 July 2012).

12 "Legality of the Threat or Use of Nuclear Weapons", Advisory Opinion, 8 July 1996, *ICJ Reports* (1996), pp. 226 *et sqq*., at p. 242, para. 29.

13 35 *American Journal of International Law* (1941), at 716.

14 United Nations Convention on the Law of the Sea, 10 December 1982, in force 16 November 1994, 1833 *United Nations Treaty Series*, pp. 397 *et sqq*, Articles 192–5; Convention on the Prevention of Marine Pollution by Dumping of Wastes and Other Matter, 29 December 1972, in force 30 August 1975, 1046 *United Nations Treaty Series*, pp. 120 *et sqq*., and its Protocol, 8 November 1996, in force 24 March 2006, 36 *International Legal Materials*, pp. 1 *et sqq*.

15 Protocol on Environmental Protection to the Antarctic Treaty, 4 October 1991, in force 14 January 1998, 30 *International Legal Materials*, pp. 1461 *et sqq*.

16 Basel Convention on the Control of Transboundary Movements of Hazardous Wastes and Their Disposal, 22 March 1989, in force 24 May 1992, 1673 *United Nations Treaty Series* (1992), pp. 57 *et sqq*.

17 Biological Weapons Convention, *supra* note 6; Convention on the Prohibition of the Development, Production, Stockpiling and Use of Chemical Weapons and on Their Destruction, 13 January 1993, in force 29 April 1997, 1974 *United Nations Treaty Series* (1997), pp. 45 *et sqq*.

18 Patricia Birnie and Alan Boyle. *International Law and the Environment*, 3rd ed. (Oxford: Oxford University Press 2009), at p. 113.

19 Diana M Bowman, Geert van Calster, and Steffi Friedrichs, "Nanomaterials and Regulation of Cosmetics", 5 *Nature Nanotechnology* (2010), p. 92.

20 P7_TC2-COD(2008)0028, adopted at second reading on 6 July 2011. The amended regulation is not in force due to refusal by the European Union Council.

21 Regulation of the European Parliament and of the Council concerning the Making Available on the Market and Use of Biocidal Products, PE-CONS 3/12 (effective from 1 September 2013), Art. 4(4).

22 Iris Eisenberger, Michael Nentwich, Ulrich Fiedeler, et al., "Nano Regulation in the European Union", 17 *Nano Trust-Dossiers* (2010), pp. 1 *et sqq*., at p. 3. The Commission launched a comprehensive REACH Implementation Project on Nanomaterials in 2009, which has been providing reports on technical aspects of the implementation of REACH. Also, in cooperation with the CARACAL Group on Nanomaterials (CASG Nano, composed of member states and stakeholder experts) the Commission has discussed how the provisions of REACH apply to nanomaterials and what issues need to be addressed. See, European Commisison, "Nnaomaterials", available on the internet at <http://ec.europa.eu/environment/chemicals/nanotech/index.htm#ripon> (last accessed on 16 July 2012).

tention. Pertinent security challenges in this context include the role of nanotechnology in addressing climate security, water security, and energy security, as well as its potential to facilitate the implementation by states of their international legal obligations that address those security challenges. This perspective article proposes that these contemporary security challenges should be more clearly incorporated into regulatory decision-making about nanotechnology, while protecting the public from potential health and environmental security threats that may result from exposure to a widespread and uncontrolled release of ENMs. It demonstrates the significance of enhancing this security perspective to nanotechnology regulation by: (1) highlighting international legal obligations relevant to nanotechnology; and (2) examining the current regulatory approaches adopted in Europe in light of various security considerations relevant to the implementation of those international legal obligations.

II. International Security Law Requirements for Nanotechnology Regulation

Traditionally international law relating to security centred upon the prevention and resolution of armed conflicts – cardinal to this is the Charter of the United Nations, which prohibits the use of force by a sovereign state against another without authorisation by the UN Security Council or under exceptional circumstances of self-defence. However, particularly since the end of the Cold War and the introduction of the concept of human security into international policy discourse in the 1990s, security concerns have expanded beyond the traditional domain to cover such issues as economic security, environmental security, health security, water security, food security, energy security and climate security. Nanotechnology, as a revolutionary enabling technology, is expected to play a significant role in facilitating international efforts in addressing these non-traditional security threats.[3]

There is a general legal obligation to facilitate innovation and technology transfer, as found in the 1994 World Trade Organisation (WTO) Agreement on the Trade-Related Aspects of Intellectual Property Rights (TRIPS),[4] and in the European context, the 2000 Cotonou Agreement between the EU, African, Caribbean and Pacific (ACP) countries.[5] The same legal obligation also exists with regard to specific security issues such as bio-security,[6] climate security,[7] and energy security.[8] Although these obligations leave great leeway in determining what kind of incentives and policies facilitate technology transfer, no policy or regulation should discourage or disable developing countries from manufacturing nano-enabled products that address their own security concerns. In addition, to the extent that ENMs are categorised as industrial chemicals, states party to the 1998 Rotterdam Convention on the Prior Informed Consent Procedure for Certain Hazardous Chemicals and Pesticides in International Trade are required to 'cooperate in promoting technical assistance for the development of the infrastructure and the capacity necessary to manage chemicals to enable implementation of this Convention'.[9]

On the other hand, there is a potential risk that health and environmental safety concerns in relation to certain toxic ENMs may well be 'securitised' through the development of a shared understanding among the public. Traditionally, the distinction between safety and security in general has been explained by reference to the element of intention, as illustrated by the policy discourse of the International Atomic Energy Agency (IAEA) on nuclear safety and security.[10] However, the nuclear disaster in Fukushima following the 11/3 earthquake, with potentially more devastating and widespread exposure and contamination of radiation, has arguably

3 Thomas Faunce, *Nanotechnology for a Sustainable World* (Cheltenham: Edward Elger, 2012).

4 Annex 1C of the Marrakesh Agreement Establishing the World Trade Organization, 15 April 1994, in force 1 January 1995, 1867 *United Nations Treaty Series* (1995), pp. 3 *et sqq*, Articles 7, 8.2, 66.2.

5 OJ L 317/3.

6 Convention on the Prohibition of the Development, Production and Stockpiling of Bacteriological (Biological) and Toxin Weapons and on their Destruction, 10 April 1972, in force 26 March 1975, 1015 *United Nations Treaty Series* (1976), pp. 163 *et sqq*. (hereinafter Biological Weapons Convention), Article X.

7 United Nations Framework Convention on Climate Change, 9 May 1992, in force 21 March 1994, 1771 *United Nations Treaty Series* (1994), pp. 107 *et sqq*., Article 4(3).

8 Energy Charter Treaty, 17 December 1994, in force 16 April 1998, 2080 *United Nations Treaty Series* (1999), pp. 100 *et sqq*.

9 Rotterdam Convention on the Prior Informed Consent Procedure for Certain Hazardous Chemicals and Pesticides in International Trade, 10 September 1998, in force 24 February 2004, 2244 *United Nations Treaty Series* (2004), pp. 337 *et sqq*., Article 16.

10 International Nuclear Safety Group, "The Interface between Safety and Security at Nuclear Power Plants", International Atomic Energy Agency (IAEA), INSAG-24, 2010, paras. 7–8, available on the internet at <http://www-pub.iaea.org/MTCD/publications/PDF/Pub1472_web.pdf> (last accessed on 12 July 2012).

without having regard to its manifest security implications.[23]

Thus, the existing regulatory approaches in Europe have focused on the regulation of the 'use' of nanomaterials for the purpose of ensuring the safety of consumer products. However, there are a number of important reasons why the existing regulatory approaches focused on the safety of ENMs should take into account equally significant risks of causing or exacerbating various security threats.

First of all, although it is this toxicity of certain ENMs that drives the regulatory move on safety grounds, it does not necessarily lead to a risk unless it is exposed to a human body or the environment. The modern 'risk society' is already exposed to various risks such as pollution involving a high level of human agency in producing and mitigating such risks particularly by the intentional use of toxic substances.[24] There is inevitably the possibility of accidental release of toxic ENMs or a hostile application of ENMs with malicious intent,[25] no matter how robust the safety measures in place are. Therefore, scientific inconclusiveness of health and environmental hazards of ENMs is, in a sense, immaterial to security considerations, which places greater weight on the extent to which risks – which may or may not materialise – can be contained or controlled. Regulatory policy-making, based on security considerations, requires a greater clarification of, and attention to, the scope of exposure when ENMs are released in various scenarios and the extent to which the exposure to ENMs can be contained or controlled. In this respect, it is interesting to contrast European regulatory approaches to Japan's regulatory focus, which has been given to exposure prevention and control rather than the reporting and registration of nanomaterials for use.[26] In this context, the challenge of specific measurement and analysis of ENMs released through environmental media such as air and water must be acknowledged. Currently there is very limited information available on the potential of bioaccumulation of ENMs, the potential persistence of nanoparticles in the environment, and the presence or removal of nanoparticles during various waste treatment processes, particularly in relation to weathered nanoparticles that have undergone agglomeration and transformation.[27] Seaton et al suggest that response to those challenges require collaboration between designers, industrial hygienists and toxicologists to develop methods of assessing possible exposure scenarios.[28]

Second, the regulatory approach focused on measures to control or contain exposure to toxic substances to mitigate the health and environmental hazards is more consistent with the obligation of due diligence that states are required to exercise under various international legal instruments. Implementation of the aforementioned international legal obligations can be seen as legal endorsement by the international community of measures to mitigate the risks of causing transboundary environmental security threats. In this respect, waste management has been a weak link in the regulation of consumer products containing ENMs to mitigate their environmental impacts. Most consumer products which have been disposed of are buried in landfills or are subject to incineration without much regulatory restriction. However, toxic nanoparticles may be released into the environment from residue paint, cosmetics and pharmaceuticals, or in the case of metallic nanoparticles, in the form of toxic ions.[29] Even if ENMs are firmly embedded

23 Hitoshi Nasu and Tom Faunce, "The Proposed Ban on Certain Nanomaterials for Electrical and Electronic Equipment in Europe and Its Global Security Implications: A Search for an Alternative Regulatory Approach", 2(3) *European Journal of Law and Technology* (2011), available on the internet at <http://ejlt.org//article/view/79> (last accessed on 12 July 2012).

24 Anthony Giddens, "Risk and Responsbility", 62 *Modern Law Review* (1999), pp. 1 *et sqq*.

25 An example is nano-energetics to enhance the lethality of explosives. See, Alba Ramaswamy, Pamela Kaste, Andrzej Miziolek, et al, 'Nanoenergetics Weaponization and Characterization Technologies', in Andrzej Miziolek, Shashi Karna, J Matthew Mauro, et al, (eds), *Defense Applications of Nanomaterials* (Washington DC: American Chemical Society,, 2005), pp. 180 *et sqq*.

26 *Nano Zairyou Kankyou Eikyou Kiso Chousa Kentoukai* [Commission of Inquiry into the Impact of Nanomaterials on the Environment], "*Kougyouyou Nano Zairyo ni kansuru Kankyou Eikyou Boushi Gaidorain* [Guideline for the Prevention of Environmental Hazard in relation to Industrial Nanomaterials]", 2009, available on the internet at <http://www.env.go.jp/press/file_view.php?serial=13177&hou_id=10899> (last accessed on 16 July 2012); Ministry of Health, Labour and Welfare, "On Preventive Measures for the Purpose of Preventing Workplace Exposure during the Manufacturing and Treatment of Nanomaterials", 2008, available on the internet at <http://wwwhourei.mhlw.go.jp/hourei/doc/tsuuchi/200207-a00.pdf> (last accessed on 16 July 2012);

27 Satinder K Brar, Mausam Verna, R.D. Tryagi and R.Y. Surampalli, "Engineered Nanoparticles in Wastewater and Wastewater Sludge – Evidence and Impacts", 30 *Waste Management* (2010), pp. 504 *et sqq*.; Fadri Gottschalk and Bernd Nowack, "The Release of Engineered Nanomaterials to the Environment", 13 *Journal of Environmental Monitoring* (2011), pp. 1145 *et sqq*., at pp. 1145–1146.

28 Anthony Seaton, Lang Tran, Robert Aitken and Kenneth Donaldson, "Nanoparticles, Human Health Hazard and Regulation", 7 *Journal of Royal Society Interface* (2010), pp. S119 *et sqq*., at pp. S126-S127.

29 Grazyna Bystrzejewska-Piotrawska, Jerzy Golimowski and Pawel L. Urban, "Nanoparticles: Their Potential Toxicity, Waste and Environmental Management", 29 *Waste Management* (2009), pp. 2587 *et sqq*., at p. 2592.

in larger structures and are difficult to separate from the structural components, application of strong kinetic energy or dismantling through open-air incineration may well result in a widespread release of toxic nanoparticles into the environment across national borders.

A significant development in this context concerns the regulation of 'e-waste', which has recently become one of the priority issues in waste management in many developed countries, due to the potential adverse health and environmental consequences of mishandling and unsafe treatment. The European Union adopted the Directive on Waste Electrical and Electronic Equipment (WEEE Directive) in 2003 based on the principle of extended producer responsibility.[30] Concerned with the health and environmental impact of ENMs contained in 'e-waste', two amendments were proposed to the draft legislative resolution during the European Union Parliamentary debate on the WEEE Directive recast, which were both adopted in the final text.[31] On 19 January 2012, the European Parliament adopted a compromise text in its second reading of the legislative resolution, which called upon the European Commission to assess whether selective treatment should be applied to nanomaterials, like asbestos waste and components that contain asbestos.[32] It remains to be seen how the European Commission might assess the feasibility of selective treatment of nanomaterials within the existing framework of the WEEE Directive and to what extent security considerations will be incorporated in the design of regulatory measures to prevent or control exposure to ENMs.

Third, it has to be acknowledged that the application of ENMs has the potential to address various international security issues in areas such as energy, resource and food security, which may well assist states in implementing technology transfer obligations mentioned above. The growth in population and industrialised economy means ever increasing demands for resources, posing a greater strain on scarce resources such as fossil fuel, rare earth metals, and even clean water. Some commentators have even predicted large-scale conflicts over deposits of precious resources.[33] Scientists and industries have a strong interest in taking advantage of the unique properties of ENMs for potential applications in solar cells,[34] water filtration,[35] and as an alternative to rare earth metals.[36] A premature and unnecessarily strict restriction of the use of ENMs in European countries may well result in an unnecessary barrier or delay in technological advancement that assists international efforts in addressing various security threats that are particularly pressing in developing countries.

IV. Conclusion: Towards Security-Oriented Nanotechnology Regulation

It is clear that existing international legal obligations require states to prevent or control exposure to toxic substances both in general and specific contexts. States are also, in one context or another, under a legal obligation to facilitate innovation, technology transfer and technical assistance particularly to developing states, which is of utmost significance in their efforts to address various security threats that confront them at present. These obligations are not adequately taken into consideration in the current regulatory approaches adopted in Europe that focus on the safety of ENMs alone.

In light of these international legal obligations, regulatory authorities should not be solely concerned with the safety of ENMs, but rather are required to shift their regulatory focus to the measures and methods to mitigate exposure to toxic ENMs. Those regulatory measures may encompass, for example, requiring, as part of an environmental risk assessment, identification of measures or methods to mitigate exposure in various scenarios, including the application of kinetic energy or flame; requiring the development of detection, removal and containment

30 Directive 2002/96/EC.

31 European Parliament, Debate on Waste Electrical and Electronic Equipment, 3 February 2011, CRE 03/02/2011–5.

32 P7_TC2-COD(2008)0241, para. 18.

33 Thomas F Homer-Dixon, *Environment, Scarcity, and Violence* (1999), at pp. 133–168; Peter H Gleick, "Environment and Security: The Clear Connections", 47(3) *The Bulletin of Atomic Science* (1991), pp. 17 *et sqq.*, at pp. 19–20; Richard H Ullman, "Redefining Security", 8 *International Security* (1983), pp. 129 *et sqq.*, at pp. 139–146.

34 Thomas Faunce, "Future Perspectives on Solar Fuels", in Tom Wydrzynski, Warwick Hillier, Laurie Peter, Ferdi Schuth and Tim S. Zhao (eds), *Molecular Solar Fuels: RSC Energy and Environment Series* (London: Royal Society of Chemistry, 2012), pp. 506 *et sqq.*

35 Nora Savage, Mamadou Diallo, Jeremiah Duncan, et al. (eds), *Nanotechnology Applications for Clean Water* (New York: William Andrew, 2009); Thembela Hillie and Mbhuti Holphe, "Nanotechnology and the Challenge of Clean Water", 2 *Nature Nanotechnology* (2007), p. 663.

36 Katherine Bourzac, "New Magnets Could Solve Our Rare-Earth Problems", *MIT Technology Review*, 20 January 2011, available on the internet at <http://www.technologyreview.com/energy/27112/page1> (last accessed on 16 July 2012).

measures and devices by manufacturers, importers and scientists; and promoting contingency planning with relevant national authorities at different levels for evacuation and containment.

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