Institution: London School of Economics and Political Science

Unit of Assessment: 21: Politics and International Studies

Title of case study: Strengthening global regulatory capacity for nanomaterials risks

1. Summary of the impact (indicative maximum 100 words)

Dr Robert Falkner's research into international risk regulation for emerging technologies underpins the work of the Nanotechnology Policy and Regulation programme at LSE. On the basis of this work, Dr Falkner was tasked by the European Commission to lead the first ever comparative study of nanotechnologies regulation in the EU and US. This research has stimulated policy debates in the UK and Europe on how to strengthen regulatory capacity in the field of nanotechnologies. The research has highlighted, in particular, the importance of improved transparency about nanomaterials in consumer goods and supply chains. This research finding has influenced the conclusions of the first UK parliamentary enquiry into nanotechnologies regulation and has informed a recent shift in global policy debates towards comprehensive and mandatory nanomaterials registers.

2. Underpinning research (indicative maximum 500 words)

Research Insights and Outputs:

Falkner has examined the regulatory challenges posed by novel technologies in the field of environment, health and safety (EHS). His research has been recognised internationally through competitive research grant awards totalling over £500,000 since 2002, including from the ESRC, European Commission, MacArthur Foundation, Open Society Foundation and Rockefeller Foundation. In 2008, he established the Nanotechnology Policy and Regulation programme at LSE, which conducted two major research projects on nanotechnology regulation that focused on how to strengthen regulatory capacity in a transatlantic and international context. As part of this project, Dr Falkner oversaw the work of two early-career researchers in the Department of International Relations (Nico Jaspers, Carmen Gayoso) and collaborated with LSE experts in related fields, including Professor George Gaskell (Department of Social Psychology), Professor Bridget Hutter (Centre for Analysis of Risk and Regulation), and Professor Nik Rose (Department of Sociology/BIOS, until 2011).

Over the last decade, Dr Falkner's research has sought to answer the question of what regulatory institutions and instruments are needed to manage the often uncertain environmental and health risks of emerging technologies? The empirical focus of this work from 2002-2006 was in the area of biotechnology and genetically modified (GM) food but since 2006 has shifted as nanotechnologies moved centre stage.

Dr Falkner's early research on biosafety regulation for GM food revealed how persistent scientific uncertainty undermines both the development of robust regulatory oversight by national governments and international cooperation on risk regulation (publications 1, 3, 4). His analysis of the Cartagena Protocol on Biosafety, the world's first international regime to deal with safety risks of GM food, identified transparency, information disclosure through labelling, and prior informed consent rules as key regulatory mechanisms that strengthen regulatory oversight particularly in developing countries (publications 2, 5). These research findings were later applied to the regulation of nanomaterials. (Nanotechnologies make it possible to manipulate matter at the molecular level, typically at a scale of 100 nanometres or less (a nanometre being one-billionth of a metre). Nanomaterials (a) have particles or constituents of nanoscale dimensions or (b) are produced by nanotechnologies.) As with biosafety, a high degree of scientific uncertainty stymies attempts to strengthen regulatory capacity and develop international cooperation. In this regard, bio- and nanotechnologies were found to pose similar challenges for EHS regulation. A comparative study of EU and US nanotechnology regulation revealed that regulators lack comprehensive knowledge about the presence of nanomaterials in internationally traded goods,

despite estimates of over 1000 such products in circulation (publication 6). Dr Falkner's research demonstrates the urgent need to fill such knowledge gaps about the commercialisation of nanotechnologies and establish mandatory information disclosure requirements as a critical first step towards a strengthened regulatory capacity.

Key Researcher: Robert Falkner has been at LSE since 2002.

3. References to the research (indicative maximum of six references)

1. R. Falkner (ed) (2002) *The Cartagena Protocol* on Biosafety: Reconciling Trade in Biotechnology with Environment and Development? (London: RIIA/Earthscan) (with Christoph Bail and Helen Marquard). Available from LSE on request.

2. R. Falkner (2006) 'The Influence of the Cartagena Protocol on Biosafety: Comparing Mexico, China and South Africa', *Global Environmental Politics*, vol. 6, no. 4, 23-55 (with Aarti Gupta). LSE Research Online ID: 16433

3. R. Falkner (2007) 'The Political Economy of 'Normative Power' Europe: EU Environmental Leadership in International Biotechnology Regulation', *Journal of European Public Policy* vol. 14, no. 4, 507-526. DOI: 10.1080/13501760701314326

4. R. Falkner (2007) 'The Global Biotech Food Fight: Why the United States Got It So Wrong', *Brown Journal of World Affairs* 14(1), Fall/Winter: 99-110. LSE Research Online: 4082

5. R. Falkner (2009) 'The limits of *regulatory convergence: globalization and GMO politics in the South', International* Environmental Agreements vol. 9, no. 2, 113-133 (with Aarti Gupta). DOI: 10.1007/s10784-009-9094-x

6. R. Falkner (2012) 'Regulating Nanotechnologies: Risk, Uncertainty and the Global Governance Gap', *Global Environmental Politics* vol. 12, no. 1, 30-55 (with Nico Jaspers). http://www.mitpressjournals.org/doi/pdf/10.1162/GLEP_a_00096

Evidence of quality: publications in peer-reviewed international journals. Research income as reported in Section 2, paragraph 1.

4. Details of the impact (indicative maximum 750 words)

Dr Falkner's research has underpinned three distinct impacts on policy and regulatory debates, in the UK and in Europe. These impacts have resulted from systematic engagement of regulators, policy-makers and other stakeholders both in the research process itself and through a targeted strategy for disseminating research findings.

1) Shaping the Policy Debate on Nanomaterials Regulation

Outreach to the policy community was a central component of Dr Falkner's work for the LSE/Chatham House project on the comparative dimensions of EU and US nanotechnologies regulation. The project involved a survey of regulatory and policy experts and one-to-one meetings and interviews with 68 regulators, business leaders and civil society representatives on both sides of the Atlantic. The process of drafting and reviewing the project report included extensive involvement of key experts from regulatory institutions in London, Brussels and Washington, DC. These experts were asked to feed into the research process, and some participated in a review workshop or gave written comments on the draft report [Source C]. The close engagement of the policy community ensured a high level of awareness about the LSE/Chatham House project and trust in its findings.

The final report, *Securing the Promise of Nanotechnologies: Towards Transatlantic Regulatory Cooperation* [A], along with other publications resulting from the project, was widely circulated to

policymakers, regulators and other stakeholders through a series of outreach events both in the UK and abroad. The report was launched at a major international conference at Chatham House, London, in September 2009, which was attended by European and US policymakers, regulators and stakeholders from industry and civil society [B]. Four more outreach events were held in the autumn of 2009, in order to further disseminate the research findings to policy-makers and regulators in the capitals of key countries: Brussels, Berlin, Paris and Washington, DC. The research findings were also presented at a European Commission-sponsored conference in Brussels on 16 November 2009, which was attended by representatives of the European Commission and European Parliament [B].

The report's findings were reported widely by trade publications and in international media: The Financial Times' science editor Clive Cookson drew attention to the report's call for a mandatory register [D]; Nanomagazine referred to the project report as 'ground breaking' and reported on the call for the 'establishment of a mandatory reporting system for nano-enabled products' [E] and ENDS Europe similarly focused on the call for a nanomaterials register in its coverage of the report's findings [F].

2) Impact on UK House of Lords Science and Technology Committee Report on 'Nanotechnologies and Food'

As a result of the contribution to the policy debate of Securing the Promise of Nanotechnologies, Dr Falkner was called to give written and oral evidence [H] to the only parliamentary enquiry to date dealing with nanotechnology regulation: the 2009 House of Lords Science and Technology committee inquiry into nanotechnologies and food. Dr Falkner's evidence shaped the committee's focus on questions of transparency and information disclosure of nanomaterials in food and was used extensively in the committee report as evidence in support of their call for mandatory reporting. In its concluding report 'Nanotechnologies and Food' [I], published on 8 January 2010, the House of Lords committee relied extensively on Dr Falkner's testimony, noting his evidence in 13 separate sub-paragraphs, as well as making reference to the underlying research. The committee explicitly endorsed several of the research findings and policy recommendations, in particular the need for strengthened international coordination and information exchange by international organisations (6.29) and the creation of "a public register of foods containing nanomaterials" (7..24). The latter recommendation is beginning to have an impact on governmental thinking and practice as is evident from the UK government's response to the House of Lords report [J]. In it, HMG states that, with regard to paragraph 7.24 of the House of Lords report, the "Food Standards Agency accepts this recommendation and agrees that there are benefits in setting up a publicly accessible register of available food and food packaging products containing nanomaterials" (page 16).

3) Impact on European regulatory debate on mandatory nanomaterials reporting

European and international discussions on strengthened regulatory oversight of nanotechnologies are at an early stage. Nevertheless, active dissemination of Dr Falkner's research to policy audiences worldwide has contributed to stimulating policy debate particularly on the need to strengthen regulatory capacity and enhance transparency about nanomaterials. Dr Falkner's research has been cited by several civil society and science organisations particularly in the context of recent calls for the introduction of mandatory nanomaterials reporting. A feasibility study of mandatory nanomaterials reporting commissioned by Germany's Environment Ministry (BMU) refers to Dr Falkner's research as evidence of growing scientific support for the introduction of a nanomaterials register [K]. There is now growing recognition that existing voluntary reporting is inadequate, and momentum is growing in Europe for the introduction of formal reporting requirements, with France being the first EU country to establish a mandatory register in January 2013 [G].

Wider Implications: Manipulating matter at the molecular level to produce novel 'nanomaterials' has considerable potential commercial and societal benefits, including improvements in food safety

and storage, enhanced battery performance, water purification and environmental remediation, reduced weight and power consumption in electronics, more effective drug delivery systems, and stronger, lighter and more durable materials. Dr Falkner's contribution to developing robust risk regulation underpins the establishment of public trust in these novel technologies that is critical to realising of these benefits while simultaneously protecting the public against risk.

5. Sources to corroborate the impact (indicative maximum of 10 references)

All Sources are also available to view at https://apps.lse.ac.uk/impact/case-study/view/51

A. Robert Falkner 2009a. *Securing the Promise of Nanotechnologies: Towards Transatlantic Regulatory Cooperation*. Report. (London: Chatham House, September), 120 pages (with Linda Breggin, Nico Jaspers, John Pendergrass and Read Porter).
http://personal.lse.ac.uk/Falkner/_private/Nanotech%20report%20Sept%202009.pdf

B. International conference at Chatham House, London, 10-11 September 2009. (List of participants). European Commission conference, Brussels, 16 November 2008. **Source files:**
https://apps.lse.ac.uk/impact/download/file/434 https://apps.lse.ac.uk/impact/download/file/435
https://apps.lse.ac.uk/impact/download/file/436

C. Selection of stakeholders emails demonstrating impact of work on transatlantic nanotechnologies regulation. This source is confidential – available from LSE on request.

D. Clive Cookson, 'Nanotech register', *Financial Times*, 15.09.09.
http://www.ft.com/cms/s/0/24548514-a18f-11de-a88d-00144feabdc0.html#axzz2D3nQeS7D

E. 'Report calls for global mandatory register for nanomaterials', *Nanomagazine* 10.09.09.
http://www.nanomagazine.co.uk/index.php?option=com_content&view=article&id=252:reportcalls-for-global-mandatory-register-for-nanomaterials&catid=38:nano-news&Itemid=159

F. 'Call for EU-US register for nano-containing goods', *ENDS* 11.09.09.
http://www.endseurope.com/22126

G. 'France toughens laws on nanomaterials in consumer products', *Digital Journal*, 10.01.13
http://www.digitaljournal.com/article/340967Parliamentary enquiry in UK:

H. Written and oral evidence to House of Lords Science and Technology committee inquiry into nanotechnologies and food, 9 June 2009.
http://www.publications.parliament.uk/pa/ld200910/ldselect/ldsctech/22/22ii.pdf

I. House of Lords Science and Technology committee report on 'Nanotechnologies and Food', 2009 [references to Dr Falkner's evidence in sections 4.69-4.72 and 6.30-6.37].
http://www.publications.parliament.uk/pa/ld200910/ldselect/ldsctech/22/22i.pdf

J. Government Response to the Lord's Science & Technology Select Committee Report into Nanotechnologies and Food, 2010.
http://www.parliament.uk/documents/documents/upload/govresponsenandf.pdf

K. Feasibility study of mandatory nanomaterials reporting commissioned by Germany's Environment Ministry (BMU) (Germany) (see reference on page 12)
http://mobil.bmu.de/fileadmin/bmu-import/files/pdfs/allgemein/application/pdf/bericht_nanoproduktregister_en_bf.pdf