Evidence submitted to the House of Lords Science and Technology Select Committee on "Nanotechnologies and Food"

13 March 2009

Dr Robert Falkner, London School of Economics

1. The evidence provided below focuses on the regulatory framework for nanotechnologies in food. It is based on research currently being carried out as part of an international project on "*Regulating Nanotechnologies in the EU and US: Towards Effectiveness and Convergence*", which is funded by a grant from the European Commission and involves four institutions: the London School of Economics and Chatham House in the UK, and the Environmental Law Institute and the Project on Emerging Nanotechnologies in the US.[1] Research assistance by Nico Jaspers and Carmen Gayoso is gratefully acknowledged. Please note that the evidence below is given in a personal capacity and does not represent the views of the project consortium or the European Commission.

Q: Is the regulatory framework for nanotechnologies and nanomaterials fit for purpose? How well are imported food products containing nanotechnologies and nanomaterials regulated?

2. A clear-cut answer to this question is not possible. The regulatory framework *may* be fit for purpose, but given existing knowledge gaps about the presence of nanoscale materials in commercial use, their environmental and health risks, and methodologies for assessing such risks, changes to the regulatory framework are likely to be needed. In any case, greater efforts need to be undertaken to gain better knowledge about the potential risks involved in the use of nanotechnologies in food and other areas, as a first step towards a more robust regulatory environment.

3. Emerging nanotechnologies and nanomaterials are being regulated through existing laws and regulations at UK and EU level, in the fields of chemicals, food, cosmetics, pharmaceuticals, among others.[2] Given that nanotechnologies are best conceived as enabling technologies for a wide range of industrial applications, nanotechnology risks are likely to be dealt with by sector-specific and product-based, rather than comprehensive and process-based regulation. Current regulatory efforts in the UK, the European Union and other industrialised countries are focused on applying existing regulations to nanotechnologies and amending these in order to fill any potential gaps in the coverage of nanotechnology risks. Given existing knowledge gaps – about health and environmental risks, appropriate methodologies for risk assessment and the state of commercialisation of nanomaterials – it is not possible to establish with sufficient certainty whether the regulatory framework is fit for purpose.

[1] For further information, see the project website: http://www.lse.ac.uk/nanoregulation.

[2] For a review of existing EU regulation and how it applies to nanotechnologies, see Communication from the Commission to the European Parliament, the Council and the European Economic and Social Committee on Regulatory Aspects of Nanomaterials COM(2008) 366 final, available at: http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=COM:2008:0366:FIN:EN:PDF.

4. A central problem in nanotechnology regulation concerns the very definition of what constitutes the "nanoscale". Efforts are underway to establish common scientific and technical standards in this area, through the International Organization for Standarization (ISO) and the OECD (see below, paragraphs 15-17). However, the absence of reliable definitions has made it difficult so far to establish precisely what types of nanomaterials are in use in the food sector and whether these are adequately covered by existing regulations. The food industry has failed to provide comprehensive information about the size or properties of nanomaterials it currently uses as food ingredients, in food processing and in food packaging. Part of the problem is that, in the absence of clear defintions, the use of the term "nano" or "nanoscale" remains at the discretion of companies. Efforts are underway to address the uncertainty and incoherence surrounding company reporting, including by the European food and drinks industry association CIAA, which has set up a Nanotechnology Task Force. But governments will need to take the lead in removing uncertainty about definitions and establish unambiguous disclosure requirements about the presence of nanomaterials in food production and products.

5. In principle, imported food products should be covered by existing regulations in the same way as domestically produced food products. As with domestic producers, the main problem at the moment is the absence of reliable market data. Governments should therefore consider, as an immediate priority, the creation of a comprehensive reporting system for nanomaterials in the food industry, covering domestic and imported products. Given the limitations of voluntary reporting initiatives in this area (see below, paragraphs 7-13), disclosure and reporting of nanomaterials in food should be mandatory.

6. The need to update and revise existing food safety regulations in light of newly emerging nanotechnology applications has recently been confirmed by the European Food Safety Authority (EFSA). According to the agency's draft strategic plan for the next five years, nanotechnology is seen as one of the key "new challenges" that will require regulators to "upgrade existing and design new risk assessment practices to keep up with the pace of science and innovation".[3] More recently, EFSA emphasised that available data on risks relating to exposure to specific nanomaterials in food is "extremely limited". Given the limited knowledge of current usage levels and likely exposure products in the food area, the agency warned that lack of validated test methodologies could make risk assessment of specific nanoproducts "very difficult and subject to a high degree of uncertainty".[4]

Q: How effective is voluntary self-regulation either in the UK or EU or at an international level? What is the take up by companies working in the food sector?

7. The short answer is "not very effective". Industry has introduced a number of voluntary initiatives that address issues relating to nanotechnologies risk, and some governments have provided frameworks for reporting and codes of conduct for

[3] http://www.euractiv.com/en/sustainability/eu-food-safety-watchdog-outlines-future-challenges/article-176074.

[4] http://www.efsa.europa.eu/cs/BlobServer/Scientific_Opinion/sc_op_ej958_nano_en,0.pdf?ssbinary=true.

research that are of a voluntary nature. Many of these schemes have only recently been initiated, and little systematic evidence exists on industry self-regulation, but first assessments of governmental programmes for voluntary reporting suggest that such initiatives are not sufficiently effective.

8. Preliminary findings of a study currently being conducted at the LSE suggest that the majority of companies that have initiated voluntary initiatives on nanotechnology risk are to be found in the chemicals and pharmaceuticals sectors. These companies have a long tradition of engaging in corporate social responsibility initiatives and have been at the forefront of developing commercial applications of nanotechnology. Such CSR initiatives involve, for example, codes of conduct for nanotechnology applications (e.g. BASF, Evonik), participation in international research on environmental and health risks of nanotechnologies (e.g. American Chemistry Council Nanotechnology Panel; Occupational Safety & Health Consortium), nanotechnology-related statements in CSR reporting (e.g. Novartis, Hoffman-LaRoche) and public and stakeholder engagement activities. DuPont has recently developed a Nano Risk Framework in partnership with the US environmental organization Environmental Defense, which provides a guidance document for nanotechnology users for identifying and reducing potential risks as part of product stewardship programmes.

9. The food industry has been comparatively slow to develop voluntary initiatives for dealing with nanotechnology risk, but is faced with growing demands for greater transparency about its use of nanomaterials. So far, no industry-wide system of self-regulation has been created that could provide reliable information on the use of nanomaterials in food production and promote safety standards. Momentum is growing, however, for disclosure initiatives as a first step towards industry self-regulation. Investor activist groups in the US, for example, have filed resolutions for the 2009 annual meetings of Avon Products, Kellogg Company, Kraft Foods, and McDonald's Corporation and are requesting that companies publish a report detailing their use of nanomaterials in products and their overall nanomaterials policy.[5] In Europe, the food and drinks industry association CIAA is currently developing an industry-wide Code of Conduct for Nanotechnologies, which is expected to provide a first steps towards a self-regulatory framework.[6]

10. Governments have also sought to promote voluntary initiatives. The UK has been at the forefront of developing voluntary reporting schemes to improve the informational basis for risk assessment and management of nanotechnologies. DEFRA launched the UK Voluntary Reporting Scheme (VRS) for Engineered Nanoscale Materials, the world's first such governmental reporting scheme, in September 2006. Its two-year pilot phase of the project came to an end in September 2008, and DEFRA is currently considering how to develop a future reporting scheme. The record of the pilot phase has raised concerns about the effectiveness of voluntary reporting. Since its launch in 2006, DEFRA received only 12 submissions, which represent about a third of the companies currently manufacturing nanomaterials.[7]

[5] http://www.merid.org/NDN/more.php?id=1654.
[6] http://www.ciaa.be/e-newsletter/nsl2.asp?nsl_id=21&nsldet_id=134.
[7] http://www.defra.gov.uk/environment/chemicals/achs/081125/minutes081125.pdf; http://www.defra.gov.uk/environment/nanotech/pdf/vrs-seventh-progress-report.pdf.

11. The UK's experience with voluntary reporting is mirrored by the limited response to the US EPA's Nanoscale Materials Stewardship Program (NMSP), which was launched in January 2008 and is also meant to run for two years. NMSP invites voluntary reports on engineered nanoscale materials that are being manufactured, imported, processed or used in the US. A separate in-depth program invites producers to develop and submit data, including testing, over a longer time frame.[8] In its interim report of January 2009, EPA states that twenty-nine companies or associations had submitted information to EPA covering 123 nanoscale materials and a further seven companies have outstanding commitments to do so. Four companies have so far agreed to participate in the in-depth program.

12. Although EPA concludes that "the NMSP can be considered successful", it notes that "a number of the environmental health and safety data gaps the Agency hoped to fill through the NMSP still exist". Few of the reports received by NMSP contain information on health and environmental aspects of nanomaterials and, as EPA states in its review, "approximately 90% of the different nanoscale materials that are likely to be commercially available were not reported". Furthermore, commenting on the low take up of the more ambitious in-depth program of NMSP, EPA notes that "most companies are not inclined to voluntarily test their nanoscale materials". It is therefore not surprising that the agency is now considering how to use existing authorities under US chemicals legislation to fill those gaps, which signals a move to strengthen mandatory requirements in the coming years.

13. Other governments have already concluded that mandatory reporting is now needed to deal with the existing and emerging information gaps. France proposed in January 2009 to introduce a mandatory reporting requirement of manufactured and imported nanomaterials, including environmental and health data.[9] Canada announced in February 2009 that will introduce a mandatory reporting requirement for information relating to nanoscale materials.[10] In the absence of effective voluntary schemes, I would expect more governments to follow the lead of France and Canada in creating mandatory reporting requirements.

Q: Will current regulations be able adequately to control the next generation of nanotechnologies and nanomaterials?

14. We cannot establish with any degree of certainty that current regulations will be able adequately to control the next generation of nanotechnologies and nanomaterials. The nanosciences is a field of rapid innovation, and current indications suggest that the convergence of nanotechnology with biotechnology, information technology and the cognitive sciences will create new challenges and risks that will require more fundamental changes to existing regulatory frameworks. The project on "*Regulating Nanotechnologies in the EU and US: Towards Effectiveness and Convergence*", together with the Project on Emerging Nanotechnologies, commissioned two new reports on next generation nanotechnology and synthetic biology that shed further

[8] http://www.epa.gov/oppt/nano/stewardship.htm.
[9] http://www.safenano.org/SingleNews.aspx?NewsID=590.
[10] http://www.nature.com/news/2009/090204/full/457647a.html

light on the regulatory challenges that industrialised countries are likely to face in coming years.[11]

Q: Is there any inter-governmental co-operation on regulations and standards? What lessons can be learned from regulatory systems in other countries?

15. The main forum for international cooperation on nanotechnologies regulations and standards is the Organization for Economic Cooperation and Development (OECD). Two OECD working groups have been established with an explicit focus on nanotechnologies: the Working Party on Manufactured Nanomaterials (WPMN) was created in 2006 in the Environment Directorate and comprises 30 OECD member countries, the European Commission, five non-OECD countries and a small number of observers from international organizations, industry and civil society. It focuses almost exclusively on co-operation in safety assessments and on testing a representative set of nanomaterials.[12] The OECD's second group is the Working Party on Nanotechnology (WPN), which was set up in 2007 in the OECD's Directorate for Science, Technology, and Industry. Its remit is focused more broadly on emerging policy-relevant issues in science, technology and innovation, including nanotechnology research and development, outreach and public dialogue.[13]

16. The OECD working groups are widely seen to be the most important forum for international coordination in the field of nanotechnologies regulation. They are likely to produce greater convergence in the development of the basic building blocks for nanotechnology risk assessment. What is less clear, however, is whether the OECD can serve as the basis for developing a broader international framework for coordinated and convergent risk management practices. Some observers have expressed concerns about the OECD's suitability in this context, particularly with regard to its limited membership basis as an industrialised countries organization, its perceived lack of transparency and the limited nature of stakeholder involvement particularly by civil society groups.

17. The other main forum for developing internationally harmonised standards is the International Organization for Standardisation (ISO). Its technical committee on nanotechnologies (TC 229) promotes the standardisation of terminology, definitions, toxicity testing and environmental studies protocols, measurement techniques, calibration procedures, and reference materials. Much of this work will feed directly into regulatory developments at national and international level, as ISO standards are likely to be adopted in definitions of nanoscale materials and their properties.

18. Other international organizations have also begun to address policy issues arising from the rapid development and commercialisation of nanotechnologies, but none has so far provided a forum for inter-governmental cooperation on regulation and

[11] Michael Rodemeyer, "New Life, Old Bottles: Regulating First-Generation Products of Synthetic Biology", Project on Emerging Nanotechnologies, Woodrow Wilson International Center for Scholars, March 2009, forthcoming; and J. Clarence Davies, "Oversight of Next Generation Nanotechnology", Project on Emerging Nanotechnologies, Woodrow Wilson International Center for Scholars, 2009, forthcoming.
[12] http://www.oecd.org/department/0,3355,en_2649_37015404_1_1_1_1_1,00.html.
[13] www.oecd.org/sti/nano

standards. The WHO's Intergovernmental Forum on Chemical Safety (IFCS)[14] 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.[15] The United Nations Environmental Programme (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.[16]

[14] http://www.who.int/ifcs/documents/forums/forum6/meet_docs/en/
[15] http://www.who.int/ifcs/documents/forums/forum6/f6_execsumm_en.doc.
[16] http://www.unep.org/geo/yearbook/yb2007/PDF/7_Emerging_Challenges72dpi.pdf.