MEETING OF THE STATES PARTIES TO THE CONVENTION ON THE PROHIBITION OF THE DEVELOPMENT, PRODUCTION AND STOCKPILING OF BACTERIOLOGICAL (BIOLOGICAL) AND TOXIN WEAPONS AND ON THEIR DESTRUCTION

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Consideration of oversight, education, awareness raising, and adoption and/or development of codes of conduct with the aim of preventing misuse in the context of advances in bio-science and bio-technology research with the potential of use for purposes prohibited by the Convention

OVERSIGHT OF EMERGING TECHNOLOGIES: EXAMPLES OF UK APPROACHES TO RESPONSIBLE DEVELOPMENT OF SCIENCE

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Introduction

1. The outcome of the development of new and emerging technologies can be difficult to foresee, though there may be vast potential for both beneficial and detrimental applications. It is thus important to review regularly the advances in such technologies and to develop appropriate oversight strategies to ensure the responsible development of science and application of technologies, and to increase awareness of the implications for the Biological & Toxin Weapons Convention (BTWC). It is advantageous to involve a broad range of stakeholders, including researchers, professional associations, funding bodies, research institutions, industry and Government, in the early development of such strategies to ensure that the benefits balance the risks. The UK considers that the development of any oversight mechanism for emerging technologies must ensure that there is a careful balance between encouraging the benefits while minimising the risks.

2. This paper outlines examples of UK approaches to the oversight of emerging technologies, focussing on nanotechnologies and synthetic biology which were included in the

UK contribution on scientific and technological developments to the Sixth Review Conference.[1] These initiatives follow a holistic approach, considering a range of issues relevant to the development of the fields and covering both opportunities and risks. Such issues include: promotion and focussing of research activities; commercial opportunities; the need for appropriate regulation; health, safety and environmental implications (including biosecurity); education and training; stakeholder and public engagement; and global perspectives. The UK also participates in European and other international fora engaging stakeholders in the responsible development of these emerging technologies; however such initiatives will not be detailed in this paper, which will concentrate on UK initiatives.

Nanotechnologies

3. The development of nanotechnologies has vast potential for a wide range of beneficial applications in diverse fields, such as healthcare, cosmetics, food, environment, electronics, materials and energy. The area is growing rapidly and is attracting increasing investment from governments and businesses around the world. Some developments could have implications for the BTWC including the development of novel or enhanced biological agents, or improved drug delivery methods that could be adapted to enhance the delivery of BW agents through inhalation, the skin, the gastrointestinal tract or across the blood-brain barrier. However, it is too early to determine if materials with the potential to cause significant harm will emerge.[2]

Review Process

4. The UK Government's aim is for the UK to derive maximum benefits from these new technologies, while safeguarding health, safety and the environment and addressing public concerns and aspirations. In 2003, the Royal Society and the Royal Academy of Engineering were commissioned to carry out an independent study on current and future developments in nanotechnologies and their impacts. A working group was set up, including experts from science, engineering, social science, ethics and public interest groups, and consulted widely. The report, published in July 2004, made recommendations to ensure fulfilment of the potential of nanotechnologies, whilst minimising possible future uncertainties and risks. Some of these recommendations covered the responsible development of nanotechnologies, health, safety and environmental impacts, regulatory aspects and social and ethical issues.[3]

5. The Government's response was published in February 2005 setting out its agenda on nanotechnologies and demonstrating its commitment to the responsible development of new technologies.[4] A 2007 review by the Council for Science and Technology[5] reported that Government had made good progress on many commitments; work was still required,

[1] http://www.unog.ch/80256EDD006B8954/(httpAssets)/5B93AF9D015AD633C12571FE0049ADAF/$file/BWC-6RC-S&T-UK.pdf 'Scientific and technological developments relevant to the Biological Weapons Convention'. Submitted by the UK.
[2] New Scientist. No. 2666 26 July 2008, pp8-9: The end of the world is not nigh.
[3] 'Nanoscience and nanotechnologies: opportunities and uncertainties.' The Royal Society and the Royal Academy of Engineering. July 2004. RS Policy document 19/04. ISBN 0 85403 604 0. http://www.nanotec.org.uk/finalReport.htm
[4] Response to the Royal Society and Royal Academy of Engineering Report: 'Nanoscience and nanotechnologies: opportunities and uncertainties.' February 2005. http://www.berr.gov.uk/files/file14873.pdf
[5] The Council for Science and Technology is the UK Government's top-level independent advisory body on science and technology policy issues.

particularly on research into toxicology, health and environmental impacts. The review also recommended addressing potential gaps in the regulatory framework and enhancing public engagement.[6]

6. In February 2008, the UK Government made a statement about nanotechnologies which described what it is doing to achieve its objectives, working in collaboration with a wide range of others including academia, industry, civil society groups and international organisations.[7] The statement includes an account of how the UK Government is looking to ensure appropriate control of the potential risks of nanotechnologies. This includes issues of relevance to implications for the BTWC:

(i) regulatory reviews to assess the adequacy of existing legislation to deal with potential risks from nanoscale materials;

(ii) non-legislative controls, such as codes of conduct;

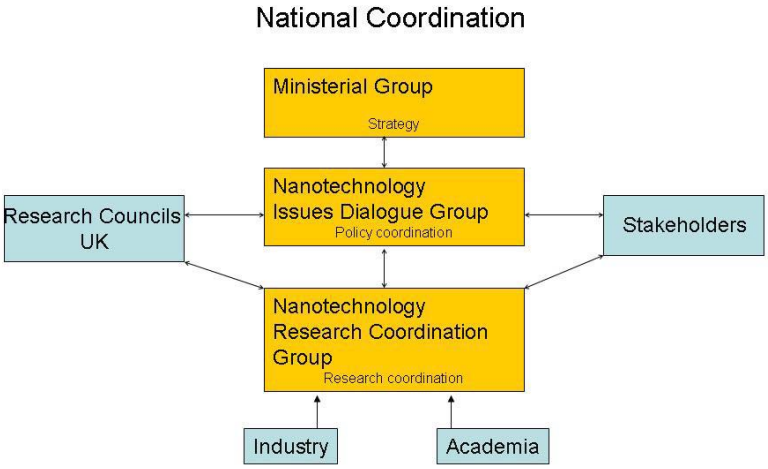
(iii) research into health, safety and environmental implications;

(iv) social and ethical dimensions;

(v) public and stakeholder engagement;

(vi) a voluntary reporting scheme, established by the Department for Environment, Food and Rural Affairs, for organisations to provide Government with relevant information on potential risks posed by new nanoscale materials.

7. The statement also outlines the structures for national coordination put in place to bring together the relevant players across Government departments and agencies, the Research Councils, industry, academia and other stakeholders:



The Ministerial Group, chaired by the Minister for Science and Innovation and comprising the Ministers for the Environment, Public Health, Competitiveness, and Health & Safety, gives

[6] 'Nanosciences and Nanotechnologies: A review of Government's Progress on its Policy Commitments' March 2007. http://www.cst.gov.uk/cst/business/files/nano_review.pdf

[7] Statement by the UK Government about Nanotechnologies. February 2008 http://www.dius.gov.uk/policy/documents/statement-nanotechnologies.pdf

strategic direction to the Government's activities on nanotechnologies. Academia and industry are engaged in discussion about future research needs via the Nanotechnology Research Coordination Group. Engagement with stakeholders and the public is achieved through the Nanotechnologies Stakeholder Forum. Research Councils UK has established a Nanotechnology Group, which coordinates activities across all UK Research Councils.

8. The Government commissioned an independent overview to identify any existing or potential gaps, inadequacies or inconsistencies in existing legislation relevant to potential risks from nanoscale materials.[8] This work concluded that the existing regulatory framework was broadly adequate, although there was potential for such materials to fall outside regulatory control in some circumstances, for example, in legislation that specifies maximum safe concentrations that are appropriate for macroscale material but may not be appropriate for nanoscale material. To determine if such potential gaps will be a reality requires a better understanding of the potential risks posed by nanomaterials. Research is underway to acquire this understanding, for example, through the Centre for Interdisciplinary Nano-Research at the Health & Safety Laboratory, an agency of the UK Health and Safety Executive (HSE).[9]

Industry Perspectives: voluntary code of conduct

9. In 2005, a group of companies from a variety of industry sectors formed the Nanotechnology Industries Association (NIA) to coordinate the views of the industrial groupings that were actively commercialising nanotechnologies. The NIA aims to promote the responsible use of nanotechnology and raise awareness of its many applications among key audiences including the media, Government, NGOs and other stakeholders.[10] Since 2006, the NIA has been working with the Royal Society and others to explore the societal and ethical impact of the technical, social and commercial uncertainties related to nanotechnologies. This includes facilitating the development of a **'Code of Conduct for Responsible Nanotechnology'** (The Responsible NanoCode).[11] The aim is to establish a consensus of good practice for those involved in the development and exploitation of nanotechnologies and to provide guidance on how to demonstrate responsible governance.

10. A working group has developed a principles-based code, combined with examples of good practice. A benchmarking framework, to allow organisations to be evaluated on how they are operating according to the code, will also be developed, and launch of the code is anticipated towards the end of 2008. Its objectives include raising awareness of the potential for risk, and addressing the often complex social and ethical issues in relation to governance, social impact and the impact of specific applications (e.g. military and security technologies). Several of the principles reflect these, covering health, safety and environmental risks; wider social, environmental, health and ethical implications and impacts; and transparency and disclosure. It does not explicitly address BTWC aspects, but covers areas relevant to its prohibitions. Although the code was developed within the UK, specifically for nanotechnologies, it was designed such that it could be adopted by organisations in any part of the world, and could potentially be adapted to apply to other emerging technologies.

[8] 'An Overview of the Framework of Current Regulation affecting the Development and Marketing of Nanomaterials.' December 2006. http://www.berr.gov.uk/files/file36167.pdf
[9] http://www.hsl.gov.uk/nanotech/hslhse-funded.htm
[10] http://www.nanotechia.co.uk/
[11] http://www.responsiblenanocode.org/

Awareness raising, education and training

11. One of the recommendations of the 2004 Royal Society and Royal Academy of Engineering report was that formal training of researchers working on advanced technologies, including nanotechnologies, should include consideration of relevant ethical and social implications. An example of such training is an international advanced course on 'Public Communication and Applied Ethics of Nanotechnology', supported by the Royal Academy of Engineering, NIA and NanoBio-RAISE.[12]

12. The UK Government has undertaken a number of public engagement activities on nanotechnologies.[13] Further dialogue is being undertaken by the Research Councils. The Government Office for Science is also running a 'Wider Implications for Science Programme' of stakeholder engagement to identify the safety, health, environmental, ethical, regulatory and social implications of new and emerging areas of science and technology, including nanotechnologies.[14]

Synthetic Biology

13. Advances in biotechnology, particularly in DNA sequencing and DNA synthesis, continue to increase the potential of developments in synthetic biology. Following previous publications on the synthetic construction of viruses, a recent report describes the construction of a complete synthetic bacterial genome.[15] The next step in creating a totally synthetic bacterium is to transfer the synthetic genome into another cell to see if it can use that cell's existing machinery to grow and reproduce. These endeavours still present formidable technical challenges, but are a step towards realising the potential of synthetic biology in areas such as healthcare, energy production, hazardous waste decontamination, and development of biological computers. It has been widely recognised that this rapidly growing field will raise ethical issues and also has the potential to create risks for society, either through unintentional harmful consequences for health or the environment, or deliberate misuse.

Government and parliamentary activities

14. Following media reports that raised concerns about the ease of obtaining synthetic DNA sequences that could potentially be used in the construction of dangerous pathogens,[16] the UK Government convened a cross-government meeting in August 2006 to consider the potential for misuse of DNA sequences and the implications for regulation. The meeting concluded that current legislation, on safety, security and export control, was adequate to cover current risks. However, it recognised the potential for technological advances to change the situation and the need to keep the issue under review. Key organisations, such as the Royal Society, were asked to

[12] http://nanobio-raise.org/Members/susanne/news_item.2008-07-16.5241308022
[13] http://www.bbsrc.ac.uk/society/dialogue/activities/nanodialogues_report.pdf http://www.involve.org.uk/negreport
[14] http://www.foresight.gov.uk/Horizon%20Scanning%20Centre/WIST.asp
[15] D.G. Gibson *et al*., *Science* **319**, 1215 (2008). Complete Chemical Synthesis, Assembly and Cloning of a *Mycoplasma genitalium* Genome.
[16] Peter Aldhous, *New Scientist* **2525**, p8 (2005). 'The bioweapon is in the post'. http://www.guardian.co.uk/world/2006/jun/14/terrorism.topstories3

alert Government if they became aware of any major developments that could lead to increases in risk.[17] No such alerts have been raised as yet.

15. HSE produced a short report on synthetic biology in 2007, which highlighted health and safety implications. It recommended that HSE needed to: be aware of the potential for a rapid increase in synthetic biology activities; consider the complex risks associated with use of this technology in the workplace; ensure there was suitable guidance in place; and be aware of the organisations involved in synthetic biology. The Scientific Advisory Committee for Genetic Modification (SACGM) provides technical and scientific advice to the HSE and other UK authorities on all aspects of the risks posed to human health and the environment regarding contained use activities with genetically modified organisms. It has identified synthetic biology as an area that should be kept under review. The SACGM Compendium of Guidance considers some implications for regulations, and concludes that synthetic approaches are covered by current GM regulations. Thus risks to human health and the environment must be assessed accordingly.

16. In January 2008, the UK Parliamentary Office of Science and Technology (POST) issued a note on synthetic biology outlining recent developments, possible applications and risks and examining policy options for the development and governance of research.[18] The policy considerations include biosecurity and biosafety concerns, and recognition that new or modified organisms could be developed for offensive use. The note recognises that synthetic biology should be developed with a global, open dialogue about its scientific, social, economic and ethical implications.[19]

National Academy Initiatives

17. In June 2007, the Royal Society issued a call for views on synthetic biology to inform its future policy work in that area and to encourage a wider debate on the social, ethical and legal issues. Responses were received from Government departments, policy organisations, NGOs, academics and individuals. Several key issues were highlighted in responses, including research capacity, higher education, appropriate regulation, stakeholder and public engagement, inclusion and global perspective, and innovation.

18. In late 2007, the Royal Society set up the Synthetic Biology Policy Coordination Group whose remit is to ensure that policy activities are coordinated from an early stage and to encourage the responsible and responsive development of synthetic biology. Members include those with a role in the funding and regulation of synthetic biology, or involved in research in this area, or with a stake or interest in the direction and development of the technology. Government departments and agencies, the Research Councils[20] and other funding bodies, NGOs and academia are all represented. The primary objectives are to: exchange information on synthetic biology related issues; identify gaps in current policy; and stimulate activities in identified gap areas. Issues identified for discussion in the development of a UK strategy for synthetic biology include definitions, funding, education, and public engagement. Regulatory

[17] http://www.berr.gov.uk/dius/science/science-in-govt/st_policy_issues/dna/page34906.html
[18] POST is the UK Parliament's in-house source of independent, balanced and accessible analysis of public policy issues related to science and technology.
[19] http://www.parliament.uk/documents/upload/postpn298.pdf
[20] Including BBSRC, EPSRC, ESRC and the Medical Research Council (MRC).

and oversight mechanisms have also been highlighted. The interdisciplinary make-up of the group should ensure that all aspects of these topics are covered, including the potential for misuse of the technology and its products.

19. The Royal Society has created a 'Synthetic Biology Resource' on its website. This resource summarises recent and ongoing activities, including research and policy, societal and ethical matters, undertaken by a range of organisations in the UK and internationally on synthetic biology. It also includes details on relevant journals, conferences and other events, courses and websites.[21]

20. The Royal Academy of Engineering has also recently established a working group to undertake a policy study on synthetic biology. Its terms of reference address issues such as: commercial, educational, societal and ethical impacts; development of interdisciplinary interfaces; and UK and international research capacities. A report is due to be published in late 2008.

Research Council Activities

21. Several UK research councils have been engaging on issues relating to synthetic biology. The Biotechnology and Biological Sciences Research Council (BBSRC) has undertaken work to ensure that its research policies and funding decisions take account of the ethical and social issues surrounding synthetic biology. In 2007 it held a workshop that brought together leading bioscientists, engineers and physical scientists, with social scientists and ethicists, to consider the emerging science and its wider implications. BBSRC works closely with the Engineering and Physical Sciences Research Council (EPSRC) and the Royal Society on how to advance public dialogue and engagement on the science of synthetic biology, and with the Economic and Social Research Council (ESRC) and the Arts and Humanities Research Council (AHRC) on wider societal issues.[22] These four research councils have recently announced funding for several new networks, involving eight universities, in synthetic biology to allow UK researchers to build links across institutions and discipline boundaries. By working together in this initiative, the four Research Councils ensure that the societal issues are considered from the start.[23]

22. The BBSRC commissioned an independent review of social and ethical challenges associated with research into, and the application of, synthetic biology; the report was published in June 2008.[24] Social and ethical issues raised include concerns about the development of synthetic organisms that could be either intentionally or accidentally released into the environment. It specifically referred to the risk of bioterrorism and the potential for misuse in contravention of the BTWC, but pointed out that the prospects of this were still uncertain. The fundamental need to raise awareness within the scientific community of the potential misuse of the technology is highlighted. Governance and oversight proposals depend on scientists being aware of and reporting potential misuses; this in turn requires researchers being aware of the possible applications and risks of synthetic biology.

[21] http://royalsociety.org/page.asp?id=7493
[22] http://www.bbsrc.ac.uk/media/news/2008/080125_synthetic_biology.html
[23] http://www.bbsrc.ac.uk/media/releases/2008/080529_synthetic_biology.html
[24] http://www.bbsrc.ac.uk/organisation/policies/reviews/scientific_areas/0806_synthetic_biology.pdf

23. The report's recommendations include the need for the scientific community to lead in debating the implications of research and engaging early with civil society groups, social scientists and ethicists, and the public. A review of current regulations and guidelines to ensure that an appropriate governance framework was in place before the applications of synthetic biology were realised was also seen as important.

Conclusions

24. This paper outlines some of the frameworks and activities that have evolved in the UK to address oversight and awareness issues arising from developments in emerging technologies. UK experience may be relevant for other States Parties in endeavours to develop their own approaches, or may provide contact points for further interactions.

25. A key issue is the **early** consideration of a wide range of policy, social and ethical issues in the development of strategies for the control, oversight and governance of emerging technologies and their applications. This enables an appropriate balance between the benefits and risks to be struck. An interdisciplinary approach, involving experts from across government, academia, industry, civil society, social science and ethics is essential to this process.

26. Reviewing the regulatory framework would be one way of ensuring appropriate oversight and control mechanisms for activities that are of more immediate relevance to the risk of misuse under the BTWC. However, other mechanisms, including education and awareness-raising are also important.

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