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Governance of Emerging Technologies

Scan of International Institutions

Carin Christou & Marc Saner

Institute for Science, Society and Policy (Ottawa)

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issp.uottawa.ca

About the Authors

Carin Christou recently joined the ISSP having completed a Master's of Public Administration degree from Queen's University. While at Queen's, Carin worked as a research assistant in the Defense Management Studies department, conducting research for the Chair of Defense Management. Prior to attending Queen's, she worked as a research assistant in a gene therapy and molecular virology laboratory at the Ottawa Hospital Research Institute. In addition to having an MPA, Carin also has an M.Sc. in Biochemistry from the University of Ottawa. She completed this degree under the supervision of one of the leading experts in the field of oncolytic virus therapy and cancer research.

Marc Saner is the Director of the Institute for Science, Society and Policy (ISSP). He has approximately twenty years of experience carrying out assessments and conducting analytical work in the natural sciences and humanities. Previously, he was Executive Director of the Regulatory Governance Initiative at Carleton University, Executive Vice President and Director of Assessments at the Council of Canadian Academies, a Director at the Institute on Governance, and Managing Director of the Ethics and Policy Issues Centre at Carleton University. He also spent several years carrying out regulatory risk assessment for the Government of Canada. He has a broad field of experience that also covers biotechnology, synthetic biology, nanotechnology, ethics, and risk management.

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Abstract

Emerging technologies have a major impact on the economic, social and environmental welfare of a nation. At the same time, governing these technologies presents a major practical challenge. Within this context, we undertook the charge *to scan the approaches that other nations use to address the challenges and opportunities of emerging technologies*.

The utility of such a scan is two-fold: it enhances existing approaches by describing the international context within which improvements can be made, and sheds light on potential gaps in the governance or regulatory capacity of Health Canada, or the federal government at large

We interviewed an international group of experts and used their personal judgment as key guidance for research and selection of a menu of twenty-eight models. The diversity is such that we opted for short descriptions of the models as opposed to in-depth analysis of any of the cases. We formatted the options onto postcards (single- or double-sheet summaries) that can easily be removed from and used independently of the report.

It is our hope that some of these models will become the basis for discussion and further research into how to optimize the governance of merging technologies in Canada.

Acknowledgments

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Governance of Emerging Technologies: Scan of International Models

Introduction

It is widely accepted that emerging technologies have a major impact on the economic, social and environmental welfare of a nation. As a result, governments are attempting to assess what the immediate technology future brings in order to harness benefits and control risks. In the health sector, this assessment is a task shared by different federal departments and agencies (for example Health Canada, the Public Health Agency of Canada and the Canadian Food Inspection Agency) as well as provincial and local authorities. Furthermore, watchdog groups, patient organizations, the health care industry and even the public at large play a role in the assessment, debate and governance of emerging technology. The system, thus, is complex. To illustrate the complexity with just one example: Health Canada alone has dozens of external bodies with mandates to advise on issues related to emerging technologies ranging from the very narrow to the very broad.

At the same time, it is also universally accepted that governing emerging technologies is very difficult. Continuous, *proactive* work in this domain does not always secure the attention of those who work in the fast-paced, immediate and contextual reality of public policy. Furthermore, predicting the future is very hard and, if anything, we know that futurists, academics, policy analysts and pundits are not really good at it. Finally, technologies are arriving ever faster - both in the form of promising innovation platforms and as novel consumer products - that may require regulatory capacity and purview.

This is the context within which we understood our charge *to scan the approaches that other nations use to address the challenges and opportunities of emerging technologies*. The utility of such a scan is two-fold: it enhances existing approaches by providing an international backdrop against which improvements can be made, and sheds light on potential gaps in the governance or regulatory capacity of Health Canada or the federal government at large. As we will show, processes and structures are highly variable.

The creation of a **menu of interesting approaches** requires that some choices be made. We focused on a few nations that are most likely to provide useful models for Canada and Health Canada in particular (the US, EU and selected European Countries, Australia, Japan and selected international bodies). As this paper was commissioned by Health Canada, we focused more on the regulatory challenges than on innovation strategies. Finally, we accepted that the selection of interesting models requires a huge amount of judgment.

There are many independent bodies that advise governments on emerging technologies. Among the most prominent of these are the US National Academies of Science (NAS) and the UK Royal Society. Canada now has a counterpart with the Council of Canadian Academies (CCA). Both have contributed significantly to the body of knowledge around emerging technologies. Since the US Office of Technology Assessment (OTA) was defunded in 1995, the NAS, along with the Government Accountability Office (GAO) and the Congressional Research Service (CRS), has provided the US government with advice on emerging technologies. Likewise, the UK Royal Society has published influential research reports on topics such as geoengineering, nanotechnology, and synthetic biology. We chose, however, to focus our attention on bodies that are less known, hopefully novel to readers, and able to spark discussions of the governance processes currently in place in Canada. In a nutshell, you will find here information about the UK Foresight Program but not the OECD.

We interviewed an international group of experts and used their personal judgment as the key guidance in the creation of a menu of models. The diversity of the processes we studied is such that we opted for short descriptions of a rich variety of some thirty models as opposed to in-depth analysis of a more limited number of cases. We present these options in a **postcard format** – the summary of each model has been condensed to fit onto one or two double-sided sheets that can be used (mostly) independently of others. Our hope is that users of this report will select a handful of these postcards, the most inspiring models, as the basis for further research and discussion.

Methods

Interviews

We began our survey of governance processes by contacting international experts on governance and regulation of emerging technologies. Of the sixteen experts we contacted, we interviewed thirteen. Interviewees were from diverse backgrounds: governance of health technologies, biotechnology, nanotechnology and synthetic biology; bioethics; risk management; public engagement; and foresighting. The participants are researchers from NGOs, think tanks (The Hasting's Center, The Woodrow Wilson Center), universities, and government departments; located in the US, Europe (including the UK and European Union), Australia, and Canada.

Literature

The applicability of academic literature is generally limited to the development of theoretical frameworks. Therefore, we restricted the number of academic papers reviewed and focused instead on grey literature (i.e. policy papers, progress reports, program reviews, and regulatory frameworks), information from departmental websites, and recommendations of interviewees regarding the most important or interesting literature. The bulk of the information contained in this report is the result of recommendations made during the interviews, followed by an Internet search.

Postcard Models

The interviews have helped frame the review and have highlighted some of the most important processes and structures on the governance of emerging technologies that are in place in various jurisdictions.

Some noteworthy examples (this is not a complete list):

- The Australian government's National Enabling Technologies Strategy;
- The European Commission's MASIS project: Monitoring Policy and Research Activities on Science in Society in Europe;
- Research bodies and committees that advise the FDA and EPA;
- Presidential committees such as the Presidential Commission for the Study of Bioethical Issues (PCSBI);
- The National Science Advisory Board for Biosecurity (NSABB) and its work on dual use of emerging technologies;
- The United Kingdom's Foresight Programme; and
- The Finnish "Government Foresight 2030 Report" to be published by the Prime Minister's Office.

The outcome is 28 "postcard"-type summaries (one-to-two pages) of the most interesting examples on governance or regulation of emerging technologies from around the world.

Experts Interviewed Regarding "Governance of Emerging Technologies"

Contact	Affiliation
Craig Cormick	Manager, Public Awareness and Community Engagement National Enabling Technologies Strategy, Department of Industry, Innovation, Science, Research and Tertiary Education, **Government of Australia**
David Rejeski	Director, Woodrow Wilson International Center for Scholars Project on Emerging Technologies, **USA**
Diana Bowman	Assistant Professor, Health Management and Policy and the Risk Science Center, School of Public Health, University of Michigan, **USA** Member of the Expert Forum, National Enabling Technologies Strategy (NETS), **Australia**
Gary Marchant	Regents' Professor of Law Faculty Director and Faculty Fellow, Center for Law, Science & Innovation, Sandra Day O'Connor College of Law Arizona State University, **USA**
George Sakellaris	Senior Researcher, National Hellenic Research Foundation, Institute of Biotechnology, **Greece, EU**
Greg Kaebnick	Research Scholar & Director of the Editorial Department, The Hastings Center, **USA**
Greg Paoli	Principal Risk Scientist, Risk Sciences International, **Canada**
Kenneth A. Oye	Associate Professor of Political Science and Engineering Systems, MIT, **USA**
Michael Gusmano	Research Scholar, Hastings Center, **USA**
Michèle Garfinkel	Former Policy Analyst, J. Craig Venter Institute, **USA** EMBO, Heildelberg, **Germany**
Ortwin Renn	Professor of Environmental Sociology and Technology Assessment, University of Stuttgart, **Germany, EU**
Pat Mooney	Executive Director, ETC Group, **Canada**
Philippe Galiay	Principal Administrator, Governance and Ethics, **European Commission, EU**

Postcard Models

This report presents twenty-eight models of governance of emerging technologies that experts judged to be interesting. We drew from expert opinion to summarize processes from the USA, Europe, Australia, and Japan, as well as multi-national initiatives internationally and within the European Union. The summaries are presented as one-to-two page postcards that present an initial description of the governance structure or process. The postcards are written in simple language and are structured so that they can be studied independently of the rest of the report. Our intention is to provide the reader with a good background of the process so that they may then research in greater depth those examples they find interesting.

The postcards are clustered regionally (USA, Europe & EU, Australia & Japan, and International). Within each region, postcards are further classified according to the type of process or structure; e.g., government, presidential, regulation, non-governmental organization, research etc. These sub-classifications are not always the same as the processes and structures vary with region and context. We have made a deliberate choice to include only current and ongoing examples in this report. However, we made an exception for the now-defunded US Office of Technology Assessment (OTA), and the EU's Citizen Participation in Science and Technology (CIPAST) project. The OTA remains one of the best examples of a process for the governance of emerging technologies, and was recommended for inclusion by several interviewees.

What we present here is not a comprehensive list of all the potential processes and structures that can be useful to Canada, nor are the postcards intended to provide in-depth analysis of the efficacy of the models. The processes and structures summarized here reflect what we judge to be the most interesting examples and what the experts we interviewed have recommended as worthy of discussion. Our goal is to deliver an illustrated menu from which further research and analysis will be possible.

USA

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US Office of Technology Assessment (OTA)

ABSTRACT: Created by US Congress in 1972 and discontinued in 1995, The Office of Technology Assessment (OTA) was cited by several interviewees as one of the best structures to be put in place for technology assessment. It is included here as an example of an advisory body that had significant impact on the regulatory and governance landscape in the US.

SPONSORING INSTITUTION: US Congress.

The Office of Technology Assessment carried out technology assessments on request of Congressional Committees. It acted as a support agency tasked to provide Congress with objective and authoritative analysis of complex science and technology issues. The aim was for these analyses to aid in policymaking, particularly the policy consequences of applying new technologies.

Studies of the OTA focused on primarily on providing information on the *impacts* of technologies, as well as the potential benefits and risks. During 23 years of operation, the OTA produced over 750 studies. Currently, the model of the OTA is being implemented in several European countries, including the Netherlands and Sweden.

Critics of the OTA cite the following reasons for de-funding: difficulty completing reports in time; lack of utility to congressional decision-making, alleged “liberal” bias; and partisan politics.

Proponents of the OTA defend the utility of the studies to decision making, the unbiased and non-partisan nature of the advice to Congress, and the need for Congress to maintain its own support agency dedicated to assessing technology.

There are now alternative sources of information in the National Academies of Science (NAS), the Congressional Research Service (CRS) and the Government Accountability Office (GAO) that all advise Congress when necessary. Although some of the research capacity of the OTA is now being fulfilled by the NAS, CRS and GAO, OTA was unique in that it combined the ability to access the highest levels of expertise, to assess information in a politically unbiased manner, the ability to frame issues in a manner that was useful to legislators and staffers, and the ability to address emerging issues.

Note: one interviewee pointed out that OTA reports often took so long to complete that the technologies it was reviewing were no longer “emerging” and the reports were no longer considered “foresight”.

The OTA's uniqueness is derived from its authoritativeness and credibility, derived from commissions and oversight from high-levels of government, the lack of policy recommendations (the OTA provided options, never recommendations), and through technical and analytical accuracy, and balanced consideration of stakeholder interests.

The OTA was overseen by a Technical Advisory Board composed of six Senators and six Representatives, divided equally between the two parties. Although de-funded, the OTA has not been officially disbanded and there have been recent (failed) petitions for its reinstatement.

FURTHER READING

"Technology Assessment in Congress: History and Legislative Options", CRS Report for Congress, 2005.

Downloaded from: http://www.fas.org/sgp/crs/misc/RS21586.pdf

Written Testimony of Francesca T. Grifo, Ph.D., Senior Scientist with the Union of Concerned Scientists Scientific Integrity Program Before the Appropriations Subcommittee on Legislative Branch, U.S. House of Representatives. 2010.

Downloaded from: http://www.ucsusa.org/assets/documents/scientific_integrity/Grifo_OTA_Written_Testimony_24_Feb_2010.pdf

Epstein, G.L. (2009). "Restart the Congressional Office of Technology Assessment". Science Progress.

Downloaded from: http://scienceprogress.org/2009/03/restart-ota/

Three US Presidential Offices and Advisory Structures in the Areas of Science, Technology, and Policy (OSTP, PCAST, NSTC)

ABSTRACT: The White House has created several advisory bodies and structures that are intended to provide the President with information on various topics on science and technology – the Office of Science and Technology Policy (OSTP), the President's Council of Advisors on Science and Technology (PCSAT), and the National Science and Technology Council (NSTC).

SPONSORING INSTITUTION: United States Administration, Executive Office of the President.

These Offices, Committees, and Advisory Councils engage in science advisory activities in a variety of different ways, including public engagement, expert panels, research, and process reviews.

Office of Science and Technology Policy (OSTP)

The Office was established in 1976 with the mandate to advise the President on the effects of science and technology on domestic and international affairs.

The OSTP is authorized to lead interagency efforts to develop and implement sound science and technology policies and budgets, and to work with the private sector, state and local governments, stakeholder communities, and other nations.

President's Council of Advisors on Science and Technology (PCAST)

Administered by the OSTP and established in 2009, PCAST is an advisory group of leading scientists and engineers who directly advise the President and the Executive Office of the President, and make policy recommendations in areas where understanding of science, technology and innovation is key to strengthening the economy and forming policy.

National Science and Technology Council (NSTC)

Established in 1993, the NSTC is an executive-level Council and is the principal means by which the executive branch of government to coordinate S&T policy across the diverse entities that make up the Federal R&D enterprise. It was created to help establish clear national goals for federal science and technology investments.

Chaired by the President, members include the Vice President and the Director of the OSTP, as well as Cabinet Secretaries and Agency Heads with significant science and technology responsibility.

The Council prepares research and development strategies coordinated across federal agencies to form investment packages for accomplishing multiple national goals.

Work is organized under five primary committees: Environment, Natural Resources and Sustainability; Homeland and National Security; Science, Technology, Engineering and Math (STEM) Education; Science and Technology, these committees oversee subcommittees and working groups.

FURTHER READING

OSTP

http://www.whitehouse.gov/administration/eop/ostp/about

PCAST

http://www.whitehouse.gov/administration/eop/ostp/pcast/about

NSTC

http://www.whitehouse.gov/administration/eop/ostp/nstc/about

US Presidential Committee for the Regulation of Emerging Technologies, ETIPC

ABSTRACT: Created in 2010, the Emerging Technologies Interagency Policy Coordination Committee was established to address the challenges of emerging technologies, particularly to give attention to new technologies whose policy implications are still unknown.

SPONSORING INSTITUTION: United States Administration: joint effort by the Office for Science and Technology Policy (OSTP), the Office of Management and Budget's Office of Information and Regulatory Affairs (OIRA), and the Office of the US Trade Representative (USTR).

Emerging technologies are by definition novel and their impacts on public policy are difficult to assess. The White House Emerging Technologies Interagency Policy Coordination Committee (ETIPC) was created under the Office for Science and Technology Policy an effort to develop mechanisms of emerging technology oversight, and to provide a framework for balancing benefits and risks. The Committee consists of Assistant Secretary-level representatives from approximately twenty federal agencies.

In its first meeting, the Committee emphasized:

- The need for a coordinated, high-level interagency group to focus on policy issues related to emerging technologies;
- A commitment to scientific integrity;
- The promotion of innovation and open government;
- Assurance that benefits of regulation justify the costs; and
- The importance of facilitating international trade.

The Committee's approach favours risk-benefit-based oversight that "ensures safety without stifling innovation, stigmatizing emerging technologies, or creating trade barriers".

It appears highly supportive of nanotechnology, and seems to reject generalizations of the risks of emerging technologies, emphasizing instead the importance of managing expectations realistically and neither under- nor overselling potential risks or benefits.

FURTHER READING

Emerging Technologies Interagency Policy Coordination Committee

http://www.whitehouse.gov/blog/2010/05/15/emerging-technologies-ipc-has-inaugural-meeting

http://www.lawbc.com/regulatory-developments/entry/white-house-etipc-releases-policy-principles-concerning-regulation-and-over/

http://www.nanotechia.org/global-news/us-regulatory-actions-on-nanoscale-materials-etipc-principles-for-regulation-and-oversight-of-applications-of-nanotechnology

The Presidential Commission for the Study of Bioethical Issues (PCSBI) and Summary of the Report "The Ethics of Synthetic Biology and Emerging Technology"

Includes annotations indicating progress on recommendations as reported by the Woodrow Wilson International Center for Scholars' "Synthetic Biology Scorecard"

ABSTRACT: In light of the Craig J. Venter Institute's announcement of the first synthetic cell, the US President commissioned a review of the policy implications of the announcement. The Commission was established in 2009 to advise the President on bioethical issues that may emerge as a consequence of advances in biomedicine and related areas of science and technology.

SPONSORING INSTITUTION: The White House, Presidential Commission.

Through expert opinions, public meetings and public commentary, the Commission emphasizes the need for ongoing public engagement, improved science education, a publicly accessible "fact-checking mechanism" for advances in biotechnology, and ongoing efforts to promote clear communication of science.

The Commission was tasked with identifying and promoting policies and practices which ensure that scientific research, healthcare delivery, and technological innovation are conducted in an ethically responsible manner.

The Commission has published reports on topics such as ethics of synthetic biology ("New Directions: The Ethics of Synthetic Biology and Emerging Technology", recommendations summarized below), international research panels, "ethically impossible" STD research in Guatemala, and human research subjects.

One of our interviewees indicated that the influence of the PCSBI on policymaking has traditionally been limited, due to the general, non-specific nature of its reports. However, the Obama Administration has commissioned more targeted research than previous Administrations, potentially resulting in reports that have a greater impact on science and technology policy. The results of the report on synthetic biology are also applicable to the wider context of emerging technologies. We summarize the recommendations of the report for that reason below.

Summary: "New Directions: The Ethics of Synthetic Biology and Emerging Technologies"

At the request of the President and in light of the announcement of the Craig J. Venter Institute's "synthetic cell" in 2010, the Commission was tasked with studying the implications of advancements in synthetic biology.

The Commission endorses neither a moratorium nor "unfettered freedom" in synthetic biology research. Rather, it calls for "prudent vigilance", which includes the principles of: middle ground; carefully monitor, identify, and mitigate potential and realized harms over time; requiring clarity, coordination and accountability across government

The report outlined Five Ethical Principles for Assessing Emerging Technologies: (1) public beneficence, (2) responsible stewardship, (3) intellectual freedom and responsibility, (4) democratic deliberation, and (5) justice and fairness.

Recommendations ***(Woodrow Wilson International Center for Scholars' "Synthetic Biology Scorecard" assessment in boldface)***:

1. Public Funding Review and Disclosure: Central body (e.g., Executive Office of the President, EOP) to undertake coordinated evaluation of current public funding for synthetic biology activities, risk assessment and risk education, Ethical, Legal, and Social Issues; to be completed within 18 months and the results publicized ***(no federal activity, results expected June 2012)***

2. Support for Promising Research: National Institutes of Health (NIH), Department of Energy and others to continue to evaluate research proposals to ensure that the most promising research is conducted on behalf of the public ***(federal activity, no results expected)***

3. Innovation Through Sharing: Executive Office of the President (EOP) should determine whether current research licensing and sharing practices are sufficient to ensure synbio research results can promote innovation, and whether and how additional policies or best practices are needed. Input from NIH, Department of Energy, NASA, US Patent and Trademark Office, industry, academia, public civil society groups. To be completed in 18 months and results publicized ***(federal activity, results expected June 2012)***

4. Coordinated Approach to Synthetic Biology: There is no need for additional bodies specifically for synthetic biology, but there should be clear, defined and coordinated approach, with a mechanism or body identified to:
   a. Leverage existing resources by providing ongoing and coordinated review of developments in synbio
   b. Ensure that regulatory requirements are consistent and non-contradictory
   c. Periodically and on a timely basis inform the public of its findings

   (no federal activity, no results expected)

5. Risk Assessment Review and Field Release Gap Analysis: Ongoing assessments needed as field progresses, especially given uncertainty, and regulatory processes evaluated and updated as needed. EOP should convene interagency process to discuss risk assessment, reasons for differences, harmonization strategies, and identify gaps ***(federal activity, results expected June 2012)***

6. Monitoring, Containment and Control: Review potential for harm in the case of environmental release, and develop reliable containment and control mechanisms ***(no federal activity, no results expected)***

7. Risk Assessment Prior to Field Release ***(no federal activity, no results expected)***

8. International Coordination and Dialogue: International coordination is essential for safety and security. Coordination between EOP, Departments of State, Health and Human Services, and Homeland Security to collaborate with international governments, the WHO and other relevant parties. Promote ongoing dialogue ***(no federal activity, no results expected)***

9. Ethics Education: Ethics education similar to training required in medical and clinical research should be developed and required for all researchers and students. EOP in consultation with the National Academies of Science, National Academy of Engineering, scientific community, and the public to convene panel to consider training requirements and options. Review to be completed in 18 months and results reported ***(federal activity, results expected June 2012)***

10. Ongoing Evaluation of Objections: Periodically revisit discussions of moral objections to synbio, reassess concerns regarding implications of synthetic biology for humans, other species, and the environment. Iterative, deliberative process for consideration of moral objections ***(no federal activity, no results expected)***

11. Fostering Responsibility and Accountability: Government to support culture of individual and corporate responsibility and self-regulation by research community. Includes institutional monitoring, watchfulness, and application of National Institutes of Health Guidelines for Recombinant DNA Research. EOP to evaluate and re-evaluate effectiveness of current oversight mechanisms, mechanisms that foster accountability but do not limit intellectual freedom. Engage academic and private institutions, the public, NIH, and federal funders of synbio, review to be completed in 18 months and results reported ***(federal activity, results expected June 2012)***

12. Periodic Assessment of Security and Safety Risks: Continue to assess specific security and safety risks both within institutions and outside. EOP, Department of Health Services, FBI and others to undertake periodic assessments and updates, with initial review to be completed within 18 months and results made public ***(federal activity, results expected June 2012)***

13. Oversight Controls: Concerns identified in previous recommendations could necessitate making compliance with oversight or reporting measures mandatory for all researchers (institutional and non-institutional), and revising export controls without restraining free exchange of information and materials between international scientific community ***(federal activity, no results expected)***

14. Scientific, Religious and Civic Engagement: Maintain ongoing exchange of views, share perspectives with the public and policymakers, with scientists and policymakers taking into account all perspectives relevant to synbio ***(federal activity, no results expected)***

15. Information Accuracy: Use clear and accurate language; a mechanism should be created to fact-check claims relevant to synthetic biology ***(no report)***

16. Public Education: Educational activities to be expanded and directed at diverse populations of students, civil society organizations, and other groups, and to be encouraged and supported by various sources. EOP with input from scientific community, the public, and relevant private organizations to identify and disseminate strategies promoting scientific and ethical literacy ***(federal activity, no results expected)***

17. Risks in Research: Risks in research should not be borne unfairly by certain individuals, groups or populations. EOP should lead interagency evaluation or current requirements to develop mechanisms that ensure risks are not unfairly distributed in consultation with relevant scientific, academic and research communities. Review to be completed in 18 months and the results made public ***(federal activity, results expected June 2012)***

18. Risks and Benefits in Commercial Production and Distribution: Manufacturers and developers of synthetic biology should ensure risks and benefits to communities and environment are assessed and managed so that risks and benefits are evenly distributed. EOP to evaluate current statutory mandates or regulatory requirements for distributions of risks and benefits, develop guidance materials and voluntary recommendations to assist manufacturers ***(no federal activity, no results expected)***

FURTHER READING

PCSBI
http://bioethics.gov/cms/about

Presidential Commission for the Study of Bioethical Issues (2010). Downloaded from:
http://bioethics.gov/cms/synthetic-biology-report

Woodrow Wilson International Center for Scholars Scorecard
http://www.synbioproject.org/scorecard/

US Food and Drug Administration (FDA) Processes for the Regulation of New Health and Therapeutic Technologies

ABSTRACT: FDA Centers (Center for Biologics Evaluation and Research, the Center for Drug Evaluation and Research (CDRH), and the Center for Devices and Radiological Health) are not equipped to regulate combination products, the number of which is expected to increase with the advancement of technologies. In order to cope with these emerging technologies, the Office for Combination Products was created in 2002. The Innovation Pathway and CDRH are mechanisms within the Office to streamline the pre-market process for new technologies.

SPONSORING INSTITUTION: US Food and Drug Administration.

The FDA's approach to emerging technology review and regulation includes establishing mechanisms for reviewing existing programs in order to make changes or improvements, stakeholder engagement, and consultation, all aimed at strengthening the regulatory capacity of the agency.

Office for Combination Products

Combination products are therapeutic and diagnostic products combining drugs, medical devices, and/or biological devices. As technologies advance, the number of combination products is expected to increase, crossing separations between the FDA's centers.

Established in 2002, the Office's mandate is to ensure combination products are promptly assigned to FDA Centers such that premarket review and post-market regulation of products can occur, especially those that do not fit into one particular regulatory category.

Innovation Pathway and Center for Devices and Radiological Health (CDRH)

The Innovation Pathway was developed to provide a streamlined path to the market for new technologies and to facilitate swifter, more predictable decisions when products are being assessed.

Through this process, regulators develop new tools and processes in order to (1) promptly classify products and determine regulatory direction; (2) determine standards and requirements for first in-human clinical trials; and (3) provide a space for FDA staff, industry, patients, scientists, and developers to collaborate.

An early version of the Innovation pathway was developed through the Center for Devices and Radiological Health (CDRH) Entrepreneurs in Residence Program:

- Pilot program sponsored by the White House Office for Science and Technology Policy (OSTP) with the aim of establishing collaborative relationships between innovation experts and federal agencies in order to achieve economic growth, job creation, and leadership & innovation.

Under the Innovation Pathway program, the Center for Devices and Radiological Health (CDRH) commits time and resources earlier in the product development process, so that any scientific issues and regulatory hurdles can be identified early, and delays avoided.

To increase FDA's preparedness for emerging technologies, the CDRH identifies emerging trends in science and technology through *enhanced horizon scanning*; incorporates information from a broad range of sources including public health needs and stakeholder and manufacturer input; and considers technologies regulated by other agencies (horizontal coordination).

Enhanced horizon scanning

As part of the priorities for 2012, CDRH has adopted three strategies for enhacing the capacity for anticipating emerging technological trends: (1) foster the development of innovative medical devices (begin implementing the Innovation Pathway); (2) further develop a personalized medicine program (continue to develop policies and procedures to ensure products are innovative or provide innovative uses); and (3) strengthen regulatory science (ensure mechanisms of collaborative worth between the FDA and other partners, and expand computer and simulation efforts to support regulatory science).

FURTHER READING

Office for Combination Products

http://www.fda.gov/CombinationProducts/AboutCombinationProducts/default.htm

Innovation Pathway

http://www.fda.gov/AboutFDA/CentersOffices/OfficeofMedicalProductsandTobacco/CDRH/CDRHInnovation/InnovationPathway/default.htm
http://www.fda.gov/AboutFDA/CentersOffices/OfficeofMedicalProductsandTobacco/CDRH/CDRHVisionandMission/ucm288735.htm#Priority4

Developing Capacity Through the Use of Internal and External Science Advisory Groups: US Environmental Protection Agency (EPA)

ABSTRACT: The EPA utilizes the expertise of a number of advisory groups with different mandates, ranging from coordination and communication to providing expertise on clean air. The advisory bodies use a variety of tools including expert opinions, stakeholder engagement, and interagency coordination to provide advice to the EPA as necessary.

SPONSORING INSTITUTION: US Environmental Protection Agency.

A number of internal and external advisory committees provide expert opinions to the EPA. While none have the express mandate to review emerging technologies, they do provide the EPA with the capacity to review and govern those technologies.

Internal advisory bodies

Environmental Technology Council (ETC)

The role of the Council is to enhance communication and coordination of all EPA technology-related activities.

The ETC provides a network of people inside and outside the EPA who exchange information and problem solve in order to:

1. Improve results of core regulatory, enforcement, and voluntary programs;
2. Facilitate innovative technology solutions aligned with EPA's strategic plans and focused on environmental outcomes;
3. Identify opportunities for environmental problem solving through technology; and
4. Identify innovative technologies.

The ETC is made up of Action Teams (members of the council, personnel from EPA, states, tribes and other agencies) that exist temporarily to meet defined objectives.

The objectives of the Council are aligned with the five EPA goals: Clean Air and Global Climate Change; Clean and Safe Water; Land Preservation and Restoration; Healthy Communities and Ecosystems; and Compliance and Environmental Stewardship.

Office of the Science Advisor (OSA)

The OSA provides a leadership role, acts as an honest broker for cross-agency science and technology policy, and facilitates integration of science and technology into policies and decisions made by the EPA. It also manages multiple programs and projects including studies on scientific integrity, human research ethics, and risk assessment.

Roles and responsibilities of the OSA include the following:

1. Advise the EPA Administrator on science and technology issues;
2. Hold a corporate view and coordinating cross-agency science and technology policy issues;
3. Resolve conflicts on science and science policy;
4. Provide vision in science and technology and emerging issues; and
5. Serve as the face and spokesperson for the EPA as a whole.

Office of Science Policy (OSP)

The Office is located within the EPA's Office of Research and Development (ORD). Its role is to integrate and communicate scientific information from laboratories and centers, as well as provide expert advice on the use of scientific information, to ensure the EPA's decisions and environmental policies are informed by sound science.

The OSP leads efforts in science *integration, coordination, and communication* across the ORD, and between the ORD and the EPA's programs, regions, and external parties.

Science and Technology Policy Council (STPC)

The Council is a mechanism for addressing the EPA's science policy issues beyond regional and program boundaries, integrating policies that guide decision-makers in their use of scientific and technical information.

It works on the implementation and success of initiatives selected and recommended by external advisory bodies (e.g., the National Research Council and the Science Advisory Board), Congress, industry, environmental groups, and EPA staff.

External Advisory bodies

National Advisory Council for Environmental Policy and Technology (NACEPT)

Established by the EPA in 1988, NACEPT consists of a panel of outside experts from academia, industry, private sector, state, local and tribal governments. It provides independent advice to the EPA Advisor on a range of environmental policy, technology, and management issues.

The NACEPT Council is comprised of a Chair and a Vice Chair, a NACEPT Designated Federal Officer and committee members. Membership is in two-year terms and is based upon recommendations from stakeholders.

NACEPT has provided recommendations on various issues including environmental technology, environmental stewardship, environmental information, energy, sustainable water infrastructure, venture capital, environmental futures etc. It is designed to work through *ad hoc* subcommittees involving large numbers of stakeholder representatives, and publishes reports and recommendations for the EPA.

Science Advisory Board

Established in 1978,the Science Advisory Board was given a broad mandate to advise EPA on technical matters.

Its principal mission is to:

1. Review quality and relevance of the scientific and technical information being used or proposed as the basis for EPA regulations;
2. Review research programs and the technical basis of applied programs;
3. Review generic approaches to regulatory science;
4. Advise the EPA on broad scientific matters in science, technology, social, and economic issues; and
5. Advise the EPA on emergency and short-notice programs.

The majority of the preliminary work of the Board is done by subcommittees or panels created to focus on specific topics. Recommendations are then forwarded to the Science Advisory Board to review recommendations. Reports are sent on to the EPA only if deemed appropriate by the Board.

FURTHER READING

Science Advisory Bodies
http://www.epa.gov/epahome/sciadvisory.htm

Office of the Science Advisor
http://www.epa.gov/OSA/index.htm

Office of Science Policy
http://www.epa.gov/osp/

Science and Technology Policy Council
http://www.epa.gov/OSA/spc/index.htm

National Advisory Council for Environmental Policy and Technology
http://www.epa.gov/ocem/nacept/index.html

Science Advisory Board
http://yosemite.epa.gov/sab/sabpeople.nsf/WebCommittees/BOARD

Structure and Activities of Offices of the National Institutes of Health: the Recombinant DNA Advisory Committee (RAC)

ABSTRACT: The Recombinant DNA Advisory Committee was created in 1974 amid public concerns about the safety of manipulating genetic material through recombinant DNA techniques. The RAC is designed to be a forum for open deliberation on a range of ethical, legal, and social issues (ELSI) raised by recombinant DNA (rDNA) technology.

SPONSORING INSTITUTION: US National Institutes of Health, Office of Biotechnology Activities.

The RAC is a Federal advisory committee that serves the NIH Office of Biotechnology Activities (OBA), the scientific community and the public. It is comprised of wide range of experts from medical and scientific fields, ethicists, patient and lay communities.

Currently, its major current responsibility is to review human gene transfer research on behalf of the NIH.

Membership of the Committee is comprised of 21 voting members (in addition to non-voting representatives from Federal agencies), the majority of whom must be knowledgeable in relevant fields. Subcommittees and working groups are established on an *ad hoc* basis to respond to emerging research questions.

As part of its responsibilities, RAC provides advice on various advances in rDNA technology and associated ELSI studies, and organizes safety symposia and public conferences.

The RAC also developed the NIH Guidelines for Research Involving Recombinant DNA Molecules (1976), which outlines appropriate biosafety practices and containment measures, and continues to provide advice on changes necessary to the Guidelines.

Discussion of any protocols that raise novel or important scientific, safety or ethical considerations occurs at quarterly public meetings. Reports of the Committee are published online to maintain accessibility and transparency.

FURTHER READING

Recombinant DNA Advisory Committee (RAC)
http://oba.od.nih.gov/rdna_rac/rac_about.html

Structure and Activities of Offices of the National Institutes of Health: the National Science Advisory Board for Biosecurity (NSABB)

ABSTRACT: Scientific information or technologies can be misused to create a threat to humans, posing a threat to national security. As part of the National Institutes of Health, the National Science Advisory Board for Biosecurity is a federal advisory committee that operates in the context of the *National Strategy for Countering Biological Threats.* It is chartered at two-year intervals, subject to renewal by the Department of Health and Human Services.

SPONSORING INSTITUTION: US National Institutes of Health, and the Department of Health and Human Services.

NSABB is governed by up to 25 voting members who are subject matter experts and are not full-time Federal Government employees, as well as 15 *ex officio* members from 15 federal agencies and departments (non-voting), providing advice on a range of topics.

The overarching purpose of NSABB is to provide advice, guidance, and leadership on biosecurity oversight of dual use research. While NSABB advises on policies governing oversight of research, it does not regulate the conduct of experiments. It may review and provide guidance on experiments that represent a notable or novel category of dual use research, or on sensitive information that may be considered dual use research of concern.

NSABB also makes recommendations and provides guidance on issues such as fostering a culture of responsibility among those with access to biological agents and/or toxins (including the development and promotion of codes of conduct for relevant groups); outreach, education, and training in dual use research issues for those in the field; policies governing publication, public communication, and dissemination of dual use research issues (such as the recent H5N1 avian influenza virus issue); fostering international engagement on dual use research issues; and advising on policies regarding conduct, communication, and oversight of dual use research and results.

The Government responds to recommendations made by NSABB by tasking Federal agencies to analyze findings and recommendations and identify options for considering recommendations.

FURTHER READING

National Science Advisory Board for Biosecurity
http://oba.od.nih.gov/biosecurity/about_nsabb.html

The Synthetic Biology Engineering Research Center (SynBERC): Practices Research Thrust

ABSTRACT: The US National Science Foundation sponsored the creation of SynBERC in 2006, allocating it a budget of $16 million over five years. It was initiated by the California Institute for Quantitative Biosciences, which includes UC Berkeley, UC Santa Cruz, and UC San Francisco. Partners include Harvard, MIT, and Prairie View A&M University, in addition to UCB, UCSC, and UCSF.

SPONSORING INSTITUTION: US National Science Foundation.

As a National Science Foundation Engineering Research Center, SynBERC is part of a group of interdisciplinary centers located in US universities that work in close partnership with industry.

These centers aim to develop foundational understanding of emerging technologies and technologies for building biological components; train engineers specializing in synthetic biology; and educate the public about benefits and potential risks of synthetic biology.

Focused on education (with programs targeted to high school, undergraduate, and graduate level students), SynBERC also conducts training and outreach activities, particularly to women and underrepresented minorities.

Practices Research Thrust

SynBERC conducts its activities in four areas: Parts, Devices, Chassis, and Practices.

The Practices area intersects across all researchers and partners at SynBERC to ensure that activities in synthetic biology result in a benefit for society and the environment, with emphasis on the impacts of economic, political and cultural factors on the development of synthetic biology.

Different activities include training researchers, framing research questions, and engaging with public policymakers and regulators. These activities are carried out within four overarching themes:

1. Core essentials, including safety and security;
2. Strategic policy initiatives, studying questions of ownership, sharing and innovation, and “beyond containment”, i.e., considerations for the development of microorganisms for use outside controlled environments;
3. Gap minding, i.e., identifying gaps that would have significant negative impacts if left unaddressed; and

4. Community, fostering and supporting a diverse community of scholars and practitioners in synthetic biology.

FURTHER READING

SynBERC

http://www.synberc.org/about

http://berkeley.edu/news/media/releases/2006/08/03_SynBerc.shtml

Practices Research Thrust

http://www.synberc.org/practices

SynBERC Education programs

http://www.qb3.org/education/synberc

The Public Engagement and Governance Initiative "Synthetic Biology Project" Undertaken by the Woodrow Wilson International Center for Scholars (WWICS).

ABSTRACT: Non-governmental organizations are involved in research and outreach activities on the governance of emerging technologies, positioning themselves at the interface between government regulatory processes and emerging technology research. Within this context, The Woodrow Wilson International Center for Scholars (WWICS) is bridging the gap between the field of synthetic biology and the public, creating a platform for public discourse through informing decision-making.

SPONSORING INSTITUTION: Non-governmental organization, Woodrow Wilson International Center for Scholars.

Neutrality of the WWICS allows it to go into a space where government is not especially welcome and act as an honest broker, engaging with a community that would be difficult to regulate should it choose to go underground.

The Synthetic Biology Project is an initiative of the Foresight and Governance Program of the WWICS and focuses on implications of advancements in synthetic biology. The Project is a collaboration between researchers, government, industry, non-governmental organizations, policymakers, and others.

The Project aims to identify gaps in knowledge of potential risks, explore public perceptions, and examine governance options that ensure public safety while facilitating innovation.

It covers topics such as defining synthetic biology; governance, policy, and regulatory issues; public perceptions; ethical considerations; and producing research reports, poll results, and newsletters on its website.

A component of the Synthetic Biology Project is a collaboration with the DIYbio community (made up of extra-institutional researchers including amateur biologists or citizen scientists) that resulted in holding DIYbiosafety Workshops.

DIYbiosafety Workshop

In collaboration with representatives of the DIYbio community, WWICS held two meetings, one in London (with participants from Ireland, Germany, Great Britain, France, and Denmark), and one in San Francisco (with participants from Houston, LA, NYC, Boston, San Francisco, and Mountain View) to draft versions of a "DIYbio Code" that serves as a framework for establishing safe, productive, global research communities.

> European DIYbio Code of Ethics: transparency (sharing of ideas, knowledge, data and results); safety; open access (promote citizen science and decentralization);

education; modesty (know you don't know everything); community (listen to concerns and questions, respond honestly); peaceful purposes; respect (for humans and all living systems); responsibility; and accountability.

US DIYbio Code of Ethics: open access; transparency; education; safety; environment; peaceful purposes; tinkering (tinkering with biology leads to insight, insight leads to innovation).

Linking the DIYbio community to expert advice and government security organizations (FBI's Weapons of Mass Destruction Directorate) has made significant advances in biosecurity preparedness and provided points of contact for the DIYbio community and other scientific communities. The result is anticipated to be more responsible and more informed research, development of goodwill, promotion of transparency and trust, and maintaining engagement with the community.

Upstream/downstream workshops

The purpose to these workshops is to cover synthetic biology issues that are still outside the scope of regulation. They link researchers to policy experts to discuss the *large-scale implications* of discoveries and experiments (e.g., potential threats to ecosystems upon environmental release), and *early engagement* of the two communities. These activities inform researchers of the kinds of information they should make available to regulators in order to avoid downstream issues.

FURTHER READING

Synthetic Biology Project

http://www.synbioproject.org/about/

FBI's Weapons of Mass Destruction Directorate

http://www.synbioproject.org/process/assets/files/6409/_draft/you_presentation.pdf

National Science Foundation-Funded Centers for Nanotechnology in Society (CNS): Arizona State University (ASU) and University of California, Santa Barbara (UCSB)

ABSTRACT: As part of the National Nanotechnology Initiative's focus on "responsible development", the National Science Foundation (NSF) supports research that investigates societal aspects of nanotechnology as a "promising but uncertain technology", funding two multi-million dollar Centers for Nanotechnology in Society at Arizona State University (ASU) and the University of California, Santa Barbara (UCSB). Initial funding was announced in 2005, and the centers began operations in 2006. In 2010, NSF renewed funding of over $12.5 million ($6.5M for CNS-ASU and $6.07M for CNS-UCSB) over the next five years.

SPONSORING INSTITUTION: US National Science Foundation.

Both research centers address questions around the social implications of nanotechnology and have similar mandates, but their emphasis and structures are somewhat different.

ASU Approach: Use "real-time technology assessment" (RTTA) as a tool to develop a strategic vision for anticipatory governance and to answer the question "how well can anticipatory governance guide societal research and assure responsible development of nanotechnologies?"

Research involves collaborations with other universities, and is conducted in thematic clusters: research and innovations systems assessment; public opinion and values; anticipation and deliberation; reflexivity and integration; equity, equality and responsibility; and "nano and the city".

The ASU program also provides training to students at undergraduate to post-graduate levels on social dimensions of nanoscale science, coordinates outreach activities for the general public, and provides information for policymakers through briefings to the US Congressional Nanotechnology Caucus and the Woodrow Wilson International Center for Scholars (see previous card).

UCSB Approach: Greater focus on the implications of nanotechnology, with a mandate to conduct interdisciplinary research on the challenges of successful nanotechnology development. Like ASU, research at UCSB addresses the issues that help achieve, and those that prevent, socially equitable and environmentally sustainable nanotechnologies.

UCSB has created an evolving international infrastructure (“network hub”) through which it conducts collaborative research; provide interdisciplinary educational opportunities through graduate fellowships and research assistantships; and establish a dialogue between academic researchers, regulators, educators, scientists and policymakers.

FURTHER READING

Arizona State University, Center for Nanotechnology in Society

http://cns.asu.edu/

UC Santa Barbara, Center for Nanotechnology in Society

http://www.cns.ucsb.edu/

National Science Foundation

http://www.nsf.gov/news/news_summ.jsp?cntn_id=117862

EUROPE

ISSP

The European Parliamentary Technology Assessment (EPTA) Network and Assessment Process

ABSTRACT: Parliaments must be informed on the impacts of emerging technologies for effective governance of these technologies. The European Parliamentary Technology Assessment (EPTA) Network was established in 1990 to carry out assessments of emerging technologies on behalf of parliaments. Given the increasing complexity of science and technology issues, many governments are relying on advisory bodies created to inform the decision- and policymaking process of the executive.

SPONSORING INSTITUTION: Several European Parliaments.

The EPTA Network aims to advance the establishment of technology assessment as an integral component of policy consulting in European parliamentary decision-making, and to strengthen links between technology assessment units in Europe.

Technology assessment is *institutionalized* through the establishment of permanent parliamentary committees for technology assessment, the creation of separate technology assessment units as part of parliamentary administrations, and the creation or encouragement of independent institutions with mandates to serve as permanent consulting institutions of parliament.

Network partners (14 members and four associate members – one of which is the US Government Accountability Office) strive to provide impartial and high quality information on issues concerning bioethics and biotechnology, public health, environment and energy, information and communication technology, and research and development policy.

The Network's activities are guided by a Council which decides on organizational matters (e.g., cooperation within the network, status of members and associates). The President of the EPTA network is responsible for coordinating network activities, hosting the annual EPTA Conference, Council meeting and Directors' meeting. The presidency changes every year.

In order to be considered a full member, a candidate country must fulfill certain criteria: it must operate in Europe; be devoted to technology assessment or related activities; serve the parliament; have its own budget and secretariat; have competence regarding issues with a science and technology component; and submit a written membership application. Associate status is given to units that have technology assessment

programs and resources but lack other eligibility criteria. Associates are not represented in Council.

FURTHER READING

European Parliamentary Technology Assessment Network

http://eptanetwork.org/about.php

Office of Technology Assessment at the German Bundestag (TAB)

ABSTRACT: The Office of Technology Assessment at the German Bundestag (TAB) is an independent institution created in 1990 to advise the German Bundestag (Lower House) and its committees on issues relating to research and technology. It is a member of the European Parliamentary Technology Assessment (EPTA) Network and is cited by one interviewee as an excellent example of science and technology-related capacity-building within parliaments.

SPONSORING INSTITUTION: German Parliament, German Bundestag, Committee on Education, Research and Technology Assessment.

The Office of Technology Assessment at the Bundestag (TAB) is a parliamentary advisory body that has been operated since 1990 by the Institute for Technology Assessment and Systems Analysis (ITAS) at the Karlsruhe Institute of Technology.

It was established as a permanent institution in 1993, after a three-year pilot phase.

The purpose of TAB is to analyze potential the of new science and technology developments and explore to opportunities for application of these technologies.

The TAB's mandate also allows it to examine framework conditions for implementing science and technology developments; analyze potential impacts, opportunities and possibilities for avoiding/mitigating associated risks; and provide policymakers with alternative options in policymaking process.

Research topics are initiated by the Committees of the Bundestag and proposals on workability, objectives, substance and methodology are accepted when one third of committee members do not oppose it.

In 2008, TAB's contract was extended for another five years. Its current mandate ends in 2013.

FURTHER READING

Office of Technology Assessment at the German Bundestag (TAB)
http://www.tab-beim-bundestag.de/en/index.html

The Austrian Institute of Technology Assessment (ITA)

ABSTRACT: Founded in 1994, the Institute of Technology Assessment (ITA) was created to inform the decision- and policymaking process of the executive. It is an interdisciplinary research institute of the Austrian Academy of Sciences and is involved in research on technological change and societal conditions that shape options and impacts.

SPONSORING INSTITUTION: Austrian Academy of Sciences.

An element of the technology assessment methodology of the ITA is interdisciplinary participatory procedures, i.e., the inclusion of various bodies of knowledge, values and interests, sometimes in collaboration with external partners.

The aim of the ITA is to generate knowledge for decision-making and to identify intended and unintended consequences of development.

These activities are targeted at supporting politics and administration of policies, as well as informing the general public.

The ITA undertakes a variety of projects in the themes of information society (E-governance, information and communication technologies in government, privacy, and networked environments); governance of controversial technologies (production, public perception, utilization of knowledge, reconciling fact-value conflicts); technology and sustainability; and technology assessment basics (potential of emerging technologies, and new applications of technologies).

Results of research projects are translated into options for decision-making and are aimed at decision-makers in positions of effecting change.

The activities of the ITA occur on national and supranational levels. For example, the ITA is a partner in the Parliaments and Civil Society in Technology Assessment (PACITA) project (governance of controversial technologies), which is a four-year European Union-funded study that aims to increase capacity and enhance institutional foundations for knowledge-based policymaking on issues of science, technology, and innovation.

The ITA is also a member of the European Parliamentary Technology Assessment (EPTA) Network, and is renowned for the international annual TA conferences it has organized for years.

FURTHER READING

Institute of Technology Assessment

http://www.oeaw.ac.at/ita/e1-1.htm

The Swedish Stockholm Environment Institute (SEI)

ABSTRACT: Like Austria, the Netherlands, and Germany, the Swedish government created an independent research institute in 1989 with the mandate to support decision-making and advise government on various issues associated with science. The Stockholm Environment Institute (SEI) is a non-profit, independent research and policy institute that specializes in environmental issues and sustainable development at local, national, regional, and global policy levels.

SPONSORING INSTITUTION: Government of Sweden.

Research within the SEI is highly collaborative and includes stakeholder involvement at its core, as well as emphasizing the importance of local knowledge and values. Research is conducted in accordance with four themes: climate change, energy systems, vulnerability, and governance. SEI projects aim to help build capacity and strengthen institutions on a variety of research topics such as reducing climate risk, managing environment systems, transforming governance for sustainable livelihoods, and rethinking development.

The SEI is non-partisan and non-profit, and carries out its advisory activities as an honest broker. The Institute is committed to “rigorous and objective scientific analysis to support improved policymaking” and works to promote transition into a more sustainable world.

The overarching institutional goals are the provision of policy-oriented knowledge and bridging gaps between researchers and policymakers. Projects of the SEI help to build the decision-making capacity and institutional strength in client companies, in order to equip companies with long-term knowledge on issues of development and the environment.

The Governing Board of the Institute is made up of a Chair and 14 members appointed by the Swedish government. It has several locations and associated entities in Europe, the US, Asia, and Africa.

In 2011, the *Global Go To Think Tank Index* ranked SEI in eighth place among environmental think tanks.

FURTHER READING

Stockholm Environment Institute (SEI)
http://www.sei-international.org/about-sei

Dutch Independent Research Organizations With Mandates to Advise the Government (The Rathenau Institute and TNO)

ABSTRACT: The Dutch government utilizes research results and advice provided by independent research institutions, such as the Rathenau Institute (created in 1986) and the Netherlands Organization for Applied Scientific Research (TNO, established in 1932).

SPONSORING INSTITUTION: Government of the Netherlands.

The Rathenau Institute

The Institute was created upon the recommendation to the Dutch government that there be ongoing and systematic monitoring of societal significance of all technological advances. It is an **i**ndependent organization founded and funded by the Ministry of Education, Culture and Science, and governed by the Royal Netherlands Academy of Arts and Sciences (KNAW).

It is a member of the EPTA Network, and does research on behalf of the European Parliament as part of the Science & Technology Options Assessment program.

The Institute studies the organization and development of science systems, publishes on the social impact of new technologies, and organizes debates on issues in science and technology. Its two key tasks are to stimulate public debate and the formation of political judgments (*Technology Assessment,* see below), to and describe the Dutch science system (*Science System Assessment*, see below).

Technology Assessment: activities within this task include identifying the social and societal effects of new developments in science and technology, analyzing the developments, and bringing them to the attention of government, parliament, and the public.

Science System Assessment: "…attempts to increase knowledge about the science system itself, doing so by means of innovative and applied research", with a focus on increasing the understanding of how the science system operates; integrating information currently available; and gathering any missing data. In this capacity, it acts as a national centre of expertise, conducting its own research and collaborating heavily with other organizations.

The Netherlands Organization for Applied Scientific Research (TNO)

The TNO was established by law with the mandate to support companies and governments with the development of innovative, practical knowledge.

The TNO is a statutory institution and has a number of functions:

- Grants licenses for patents and specialist software;
- Tests and certifies products and services;
- Issues independent evaluation of quality; and
- Sets up new companies to market innovations.

In addition to these functions, the TNO also conducts activities in research and commercialization.

It provides contract research and specialist consulting services on seven themes that are strongly centered on innovation, including industrial innovation, energy, and defense, safety and security. Furthermore, experts in strategy and policy studies advise on decision-making, and cater to governments, international institutions, and industry.

The TNO, along with universities, has established *thirty knowledge centres*, (which include private companies), to "develop knowledge" in selected fields and function as innovation centers.

Commercialization: Knowledge developed by the TNO is typically commercialized by its customers. However, in the event that the market is in its infancy, TNO will establish a company under the umbrella of TNO Companies, a holding company for approximately 90 privately owned TNO divisions.

Companies are mostly technology-oriented and translate TNO knowledge into products and services and introduce them into the market. TNO Companies seeks outside financing, with the ultimate goal of selling start-ups at the appropriate time. TNO Companies also sets up and facilitates joint ventures with strategic partners, both nationally and abroad.

FURTHER READING

The Rathenau Institute

http://www.rathenau.nl/en.html

The Netherlands Organization for Applied Scientific Research (TNO)

http://www.tno.nl/index.cfm

The UK's Foresight Program

ABSTRACT: The Foresight Program was created in 1994 to help the UK government develop its science and technology foresighting capability. Activities of the program are sponsored and directed at the ministerial level of government and have direct policy implications.

SPONSORING INSTITUTION: UK Government, Department for Business Innovation and Skills. Relevant departments sponsor appropriate research projects.

The purpose of the program is to advise government on how to ensure that decisions remain robust in the context of future uncertainties. The work of the program is intended to drive the development of more effective strategies, inform policies, and help set priorities at both the national and international levels, while maintaining a balance between long-term thinking and problems that require immediate action.

Early manifestations of the program focused on improving communications and links between the research community and those who translate research into products and services.

The program achieves its purpose in three ways:

1. Undertakes major foresight projects: two-year studies that are designed to create an extensive base of evidence for major issues 20-80 years in the future;
2. Policy futures projects: these are shorter projects that provide futures and evidence analysis to fill gaps in existing policies; and
3. Through the Foresight Horizon Scanning Centre: provide training, toolkits, and networks to strengthen foresighting capacity, and to share best practices within and across government.

Projects undertaken by the program deal with key issues for the economy, society, and the environment, particularly in areas where science and technology can offer insight and policy solutions, and typically last between 18 months to two years. Ideas for projects may originate within the Foresight Program, or they can be the result of consultation with government departments, or from the research community. Each project is directed by the Government's Chief Scientific Advisor along with a group of leading experts from academia.

New projects are required to compel government sponsorship and guidance at the ministerial level through the High Level Stakeholder Group, and must meet the following criteria:

1. In areas where outcomes are uncertain, the project's outlook must be at least 10 years in the future;
2. Projects must involve science and technology as drivers of change or as solutions;
3. They must cover topics where government can have significant influence on outcomes;
4. There must be an interdisciplinary, inter-sectoral approach to the science; and
5. Gain the support of the groups most likely to be affected in the future.

The High Level Stakeholder Group is chaired by a minister from a sponsoring government department, and is made up of senior-level decision-makers from relevant departments, research councils, and other relevant bodies. The group is responsible for agreeing on an action plan once the report has been published.

FURHTER READING

Foresight Programme

http://www.bis.gov.uk/foresight/about-us

http://www.bis.gov.uk/foresight/about-us/history

http://www.bis.gov.uk/foresight/our-work/projects

The Irish Innovation Board (Forfás) as a Government-Created Pro-Innovation Research and Policy Organization

ABSTRACT: Like other European countries, the Government of Ireland created Forfás in 1994 to act as Ireland's policy advisory board for enterprise, trade, science, technology, and innovation.

SPONSORING INSTITUTION: Government of Ireland, Department of Enterprise, Trade and Employment

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Forfás is an independent agency with the mandate to provide "ambitious, coherent and widely understood enterprise and science policy advice that supports growth". Policy advice is provided with the main intent of fostering success of Irish enterprises.

The five overarching policy areas on which Forfás advises are:

- Competitiveness;
- Enterprise (supporting the development of sustainable enterprise);
- Knowledge;
- People (with particular focus on education and training); and
- Sustainability.

The policy-supporting functions of Forfás are:

1. Providing independent and rigorous research, advice, and support in enterprise and science policy;
2. Ensuring coherence of policies across developmental agencies that support enterprise;
3. Evaluating enterprise policy interventions; and
4. Providing research and administrative support to independent advisory groups.

Within the governing board of Forfás are agencies that are responsible for the promotion of investment in Ireland (IDA Ireland) and for the development and promotion of indigenous businesses (Enterprise Ireland).

The governing board also includes Science Foundation Ireland, an agency that was created to provide strategic support to academic researchers on biotechnology, information communications technology, and sustainable energy and energy-efficient technologies.

Board members are appointed by the Minister for Enterprise, Trade and Innovation, and include high-level personnel from the department, as well as representatives from state agencies and specialists in business, economics and other fields.

FURHTER READING

Irish Innovation Board, Forfás

http://www.forfas.ie/aboutus/

The Netherlands Scientific Council for Government Policy (WRR)

ABSTRACT: Established in 1976, the Scientific Council of Government Policy advises the government on issues of social importance, though it is not limited to one policy sector. Reports of the WRR concern the long-term direction of government policy.

SPONSORING INSTITUTION: Government of the Netherlands.

The Netherlands Scientific Council for Government Policy is an independent advisory body of the Dutch government created to provide policy advice on a variety of long-term policy issues. The Council's work is characterized by a multidisciplinary approach. Council members are also university professors, allowing the Council to maintain ties with academia.

Projects can be on any issue the Council considers the government should, or does, deal with, or they can also be commissioned when the government seeks an advisory opinion. However, all studies performed by WRR have a social aspect and start based on the current state of scientific knowledge on each issue. From there, the Council "builds a bridge" to government policy.

Tasks of the Council include:

1. Presenting new perspectives and long-term directions for solutions;
2. Indicating conflicts and contradictions in government policy;
3. Flagging future bottlenecks;
4. Recognizing new problems; and
5. Making proposals for an integrated strategies approach to problem solving.

The organization works on the basis of "Council periods" which last for five years. At the start of these periods, the Council independently produces a work program, after consultation with the prime minister. This ensures the independence of the Council. The program can be modified and subjects added or removed based on new insight. More systematic reviews occur at the mid-point of the program and changes are made where necessary.

Project selection is dependent on the subject matter:

1. The subject should be of importance to long-term government policy;
2. The subject should concern a current or future socially relevant problem;
3. The subject should be challenging and be suitable for academic research;
4. The subject should be within the scope of government policy, or enter that area in the future;
5. The subject should have foresight; and
6. The subject should concern several sectors of government policy, it should be approachable from different perspectives, and it should allow for opportunities to make suggestions on potential actions.

The Council maintains ongoing communication with the political sphere of government, speaking with the prime minister, ministers, and junior ministers. In addition, contact is maintained with government departments, social and academic institutions, and advisory bodies. It increasingly collaborates with politicians and policymakers in order to be informed on the latest developments in policy.

Communication of the Council's findings occurs through the publication of reports to government; WRR surveys; working documents and pre-studies; dialogue with policymakers, discussion of current social issues through conferences, workshops and public forums; an information leaflet on the purpose and activities of WRR; articles and lectures written and presented by Council members; and through WRR lectures in which experts are invited to share their views on science and policy.

FURTHER READING

The Netherlands Scientific Council for Government Policy (WRR)

http://www.wrr.nl/english/content.jsp?objectid=2831

Finland's Government Foresight 2030 Report: Sustainable Development and Wellbeing

ABSTRACT: In March 2012, the Finnish Prime Minister's Office announced it was launching a project to report on Finland's long-term future, focusing on sustainable growth, the economy, and the wellbeing of both people and the environment. Preparation of the report will occur through the cooperation of experts and stakeholders.

SPONSORING INSTITUTION: Prime Minister's Office.

The Foresight 2030 Report of the Finnish Prime Minister's Office (PMO) places emphasis on collaboration between experts and stakeholders, and also on broad citizen consultation. The time scale of the report will cover the next 10-20 years. It aims to identify development trends and set objectives and strategic plans for government policy. The report will act as an operational strategy document used to support the decision-making capacity of various actors in society, including the different levels of government.

In addition to this report, an international research group has been commissioned to carry out research and analysis on changes to the world economy in order to provide options for promoting sustainable growth.

Preparation and promotion of the implementation of the report falls solely to the PMO. However, other government departments are involved, including: the Ministry of Employment and the Economy, the Finnish Innovation Fund (Sitra), the Academy of Finland, and the Finnish Funding Agency for Technology and Innovation.

Responsibility to monitor the work of the Foresight 2030 Report falls to a ministerial working group chaired by the Minister of Economic Affairs. The steering group is chaired by the State Secretary from the Ministry of Employment and the Economy.

Submission of the report to Parliament is expected Fall 2013.

FURTHER READING

Government Foresight 2030

http://government.fi/ajankohtaista/tiedotteet/tiedote/en.jsp?oid=353659

The EU Citizen Participation in Science and Technology (CIPAST) Project

ABSTRACT: Scheduled to last 3 years (from 2005 to 2008), the EU's Citizen Participation in Science and Technology (CIPAST) project was situated within the context of changes in the involvement of civil society in policy- and decision-making in science and technology, particularly in the wake of energy policy and biotechnology controversies.

SPONSORING INSTITUTION: The European Union.

The purpose of CIPAST was to bring together organizations with experience in participatory procedures in science and technology issues and task them with setting up a context-specific *training program* for decision-makers in the political sphere, research, non-profit organizations, and industry.

In order to fulfill this purpose, CIPAST program objectives were to set up and expand a network of actors working on participatory processes in science and technology; to develop communication and dissemination tools; and to elaborate on and test, through two training workshops, a body of tools for capacity building and training.

Discussion lists, a website and a bi-monthly newsletter were launched during the first year and maintained until the end of the project. In addition, an online database of case studies is still accessible on the CIPAST website.

Conception, preparation, and production of training materials was opened to approximately forty organizations that do not belong to the CIPAST consortium but that have significant experience in participatory initiatives. Training workshops were opened to sixty new partners or potential users, and training materials were made available for public use.

The Final Report of CIPAST made four recommendations:

1. Foster and support existing European cooperation and networking between actors involved in participation;
2. Support further organization of training sessions on citizen participation in science and technology;
3. Support an interdisciplinary group of researchers and practitioners to develop a database of case studies and investigate local cultures of participation; and

4. Document experiences of involvement of civil society in nanotechnologies.

FURHTER READING

Citizen Participation in Science and Technology (CIPAST) Project
http://www.cipast.org/

EU Public Engagement Program "Monitoring Policy and Research Activities on Science in Society in Europe" (MASIS)

ABSTRACT: In 2007, there was a paradigm shift within the research community of the European Union towards Science *in* Society, rather than science *and* society. In 2008, under the "2008 Capacities Work Programme: Science in Society" initiative of the European Commission, the Monitoring Policy and Research Activities on Science In Society (MASIS) project was created.

SPONSORING INSTITUTION: European Commission.

MASIS was created to answer the question: "what activities are being undertaken in EU member states (and associated partner states) with respect to *Science in Society*, increasing public engagement, and establishing linkages between *Science in Society* and policy?" The aim of the project was to develop structural links and interactions between scientists, policymakers, and society.

Activities encompassed within MASIS include public engagement, reporting on issues surrounding emerging technologies, and establishing pre-set reporting formats with set themes for member countries. These activities fall within the three main *Science in Society* research priorities: governance of science, public understanding of science, and science communication.

Membership in the MASIS initiative is comprised of 38 countries – 27 EU member states and 11 associated countries, each of which provides comprehensive reports and updates around four main themes:

1. National context: current and recent debates about the relationship between science and society, trajectories, and recent policy developments in science in society;
2. Priority setting, governance, and the use of science in policymaking: focusing on actors, processes and procedures for public involvement, and procedures for science-based medicine;
3. Science in society-related research activities: describe the scale and scope of research efforts; and
4. Activities related to science in society.

Among the most commonly identified national debates are issues of reforming higher education and national research and development strategies in order to better link

scientific institutions with societal needs, as well as specific discussions on "controversial" technologies such as bio- and nanotechnology.

At the conclusion on the MASIS project in 2013, a new European Union Framework Program for Research and Innovation, Horizon 2020, will begin. Scheduled to run from 2014 to 2020 with an €80 billion budget, the program is intended in part to drive new job creation in Europe. Within this program, €300 million has been allocated for research activities on the topic of science in society.

Challenging Futures of Science in Society: Emerging Trends and Cutting-Edge Issues (MASIS report, 2009).

The MASIS Expert Group was asked to examine the role of *Science in Society* in order to gain better understanding of the landscape within which research is being conducted. This allows for preliminary identification of emerging trends, policy patterns, and issues that may require cross-national and/or European level intervention.

The study found emerging challenges in the governance of scientific institutions, particularly given the sometimes competing pressures of driving innovation, democratizing science, and maintaining integrity and transparency. As a result, new trends in governance are emerging: discourse on responsible development (with attention to ethics and codes of conduct); interactive forms of technology assessment; and public engagement.

FURHTER READING

Monitoring Policy and Research Activities on Science in Society in Europe (MASIS)

http://www.masis.eu/english/aboutmasis0/

http://www.masis.eu/english/aboutmasis0/sisactivities/

http://www.masis.eu/english/aboutmasis0/nationalactivities0/

European Research Area (2009) Challenging Futures of Science in Society: Emerging Trends and Cutting-Edge Issues. European Commission. Downloaded from:

http://www.masis.eu/files/reports/Emerging_trends_in_SiS.pdf

AUSTRALIA & JAPAN

ISSP

The Australian National Enabling Technologies Strategy (NETS) and Associated Activities of the Expert Forum

ABSTRACT: In 2009, the Australian government established the four-year National Enabling Technologies Strategy (NETS) as a comprehensive process for developing foresighting capacity necessary for governance and regulation, and for understanding the application of emerging technologies and how they can address global and national strategies.

SPONSORING INSTITUTION: Government of Australia, Department of Industry, Innovation, Science, Research and Tertiary Education (DIISRTE).

The National Enabling Technologies Strategy (NETS) has two main focuses: coordination and public engagement. Through the establishment of an expert panel responsible for foresighting activities and a stakeholder advisory panel for stakeholder consultation, NETS emphasizes transparency and inclusiveness. In addition, NETS features a Public Awareness and Community Engagement Program with the mandate to engage with the public on issues of emerging technologies.

NETS was developed to improve the ability of government to prepare for the policy, social, economic, and environmental impacts of emerging technologies, and to engage stakeholders upstream of technology development and deployment.

The Strategy aims to help Australian industries capitalize on growth opportunities, benefit from emerging technologies and mitigate potential risks to health, safety and the environment. In total, funding for the Strategy is $38.2 million over four years.

The three major components of the Strategy are:

1. Supporting the development of *policy and regulatory frameworks* to ensure government fully considers the health, safety, environmental, economic, and social impacts of enabling technologies. Funding will also support industry uptake, international engagement and strategic research ($10.6 million). A Working Group of government agencies is designed to ensure a whole-of-government approach to these issues;
2. Raising *public awareness and engagement* to increase understanding of enabling technologies – focusing on health, safety and environmental issues ($9.4 million); and
3. Establishing the *National Measurement Institute* to improve measurement infrastructure, standards and expertise ($18.2 million).

Activities are national in scale, engaging all levels of government as well as a range of stakeholders through a Commonwealth/State Working Group established to promote collaboration and coordination to addressing issues. In addition, the Stakeholder Advisory Council provides advice on how the Strategy may address issues of importance to the broader community.

Expert Forum

Established in 2009, the Forum consists of eight people, established to guide NETS's technology foresighting activities.

The Forum was created to:

1. Prepare policymakers, regulators, industry and community for future developments in emerging technology;
2. Identify challenges and opportunities stemming from emerging technologies in the next five to ten years; and
3. Complement other foresighting activities undertaken by government departments and organizations, including the:
    - Prime Minister's Science, Engineering and Innovation Council (PMSEIC)
    - Future Manufacturing Industry Innovation Council
    - National Collaborative Research Infrastructure Strategy (NCRIS)
    - Department of Broadband, Communication and the Digital Economy.

Activities of the forum include public consultation; holding foresight workshops to facilitate uptake of enabling technologies (building products industry, aged care sector, food industry workshop); and developing future strategies. In addition, the Expert Forum is expected to:

1. Assist in identifying new and converging technologies;
2. Consider the implications of other foresighting activities in Australia and other places;
3. Consider the role of emerging tech in addressing issues of significance nationally and globally;
4. Suggest areas of further study; and
5. Participate in an annual open forum with a range of stakeholders.
6.

As one of its first outputs, the Forum produced a survey of the Australian technology landscape, known as Enabling Technologies Futures, for DIISRTE in 2011. The survey provides insight into the future of nanotechnology, biotechnology, and synthetic biology, and into the development of new applications with potential for influencing future strategies, products, markets and investment opportunities.

Short- and long-term outcomes of the activities of the Forum include: timely and accurate information to inform decision-making; support for a sustainable, resource-efficient, globally competitive, socially inclusive society; effective regulatory frameworks; and public confidence in products and services using enabling technologies and regulation of risks.

Enabling Technologies Futures: a survey of the Australian technology landscape (ETF)

The ETF follows the National Nanotechnology Strategy, and is intended as a survey of new and emerging technologies. Drafted by the Expert Forum, the survey takes into account public and key stakeholder feedback on the draft version of the report, which will be considered in the final version. The Study is presented in the context of five dimensions of analysis: drivers, opportunities, barriers, risks, and disruptive potential.

Public consultations on the draft version of the report ended on 23 February 2012. The final version of the report is pending.

The Enabling Technologies Futures document is intended to:

1. Provide guidance to the Expert Forum on new forms of nano- and biotechnologies (as well as areas of intersection) and technologies enabled by ICT and cognitive science;
2. Outline issues that might be raised by emerging technologies, particularly with respect to opportunities, risks, barriers, and potential disruptive impact; and
3. Assist in identifying prospects for emerging technologies to help address Australia's national challenges.

Foresighting is the main component of the study, with technologies being assessed according to three time frames:

- Horizon 1: Short term, technologies that are currently commercialized;
- Horizon 2: Medium term, technologies that are under development, or whose commercialization is expected within the next decade; and
- Horizon 3: Long-term, technologies and applications not expected to be developed or commercialized in less than 20 years.

Note that the ETF received some criticism as lacking in sensitivity to public values and as being a reactive document, that fails to provide proactive policy responses (see "Technology Roadmap Lacks in Public Values" article cited in Further Reading).

NETS Public Awareness and Community Engagement Program

The Program achieves its mandate of engaging the public on issues of enabling technologies through these objectives:

1. Increase awareness and understanding among the general public about enabling technologies;
2. Promoting informed public debate through improved awareness and understanding of social and ethical issues around enabling technologies;
3. Understanding the publics' knowledge, concerns and aspirations for enabling technologies;
4. Providing the public with updates on the Government's response to these technologies; and
5. Creating awareness and understanding of the regulatory bodies and practices relating to enabling technologies and the corresponding health and safety issues.

The program develops materials in the three broad streams of: Information, Education and Engagement, which include on-line resources, social media, schools resources, public attitude studies and public engagements.

FURTHER READING

NETS Framework
http://www.innovation.gov.au/Industry/Nanotechnology/NationalEnablingTechnologiesStrategy/Documents/NETSAnnualReport200910.pdf

Expert Forum
http://www.innovation.gov.au/Industry/Nanotechnology/NationalEnablingTechnologiesStrategy/Pages/FirstMeetingoftheNETSExpertForum.aspx
http://www.innovation.gov.au/Industry/Nanotechnology/NationalEnablingTechnologiesStrategy/Pages/NationalEnablingTechnologiesStrategyPlanningfortheFuture.aspx
http://www.innovation.gov.au/Industry/Nanotechnology/NationalEnablingTechnologiesStrategy/Pages/ExpertForumTermsofReference.aspx

Australian Enabling Technologies Roadmap
http://www.innovation.gov.au/Industry/Nanotechnology/NationalEnablingTechnologiesStrategy/Pages/ExpertForum.aspx

Technology roadmap 'lacks in public values'
http://www.abc.net.au/science/articles/2012/02/22/3436107.htm

NETS-PACE
http://www.innovation.gov.au/Industry/Nanotechnology/PublicAwarenessandEngagement/Pages/default.aspx

The Health, Safety, and Environment (HSE) Working Group of the Australian National Enabling Technologies Strategy (NETS)

ABSTRACT: Part of the Australian government's work on Enabling Technologies considers health, safety, and environmental issues. The Health Safety and Environment (HSE) Working Group was created in 2010 to provide information and advice to government on the impact of emerging technologies on these issues.

SPONSORING INSTITUTION: Government of Australia, Department of Innovation, Industry, Science and Research (DIISR).

The HSE Working Group achieves its goals through interdisciplinary, inter-sectoral consultations, international linkages, and public consultation.

The Working Group is comprised of policymakers, regulators and research agencies; draws on advice from HSE experts, researchers, industry, and community; maintains international linkages so Australian interests are promoted and international work can feed back and benefit the country.

The mandate of the Working Group is to:

1. Determine gaps in the system and knowledge, facilitate the development of a coherent research program through the examination of regulatory frameworks;
2. Facilitate a coordinated approach across government agencies to progress issues and increase evidence base with respect to potential health and environmental issues associated with nanotechnology;
3. Facilitate appropriate consultation and general communication with community on HSE matters; and
4. Support work to develop the capacity of agencies to respond to emerging technologies.

HSE Working Group Agencies: Department of Agriculture, Fisheries and Forestry, Department of Defense, Department of Education, Employment and Workplace Relations, Department of the Environment, Water, Heritage and the Arts, Department of Foreign Affairs and Trade, Department of Health and Aging, Department of Infrastructure, Transport, Regional Development and Local Government, Department of Innovation, Industry, Science and Research, Australian Competition and Consumer Commission, and Australian Customs and Border Protection Service.

FURTHER READING

Health Society and Environment Working Group

http://www.innovation.gov.au/INDUSTRY/NANOTECHNOLOGY/NATIONALENABLINGTECHNOLOGIESSTRATEGY/Pages/NationalEnablingTechnologiesStrategyBalancingRiskAndReward.aspx

Results of the Review of Health Technology Assessment (HTA) in Australia and Recommendations for Better Support and Reduced Regulatory Costs

ABSTRACT: The cost of government-provided health care programs in Australia has been rising over time due to factors such as population growth and aging, development of new technologies, and changing expectations of health care.

Health Technology Assessment is a tool for achieving safe, effective, efficient and fiscally sustainable health care. HTA provides a means by which new technologies can be assessed and prioritized against existing health care provisions and other government priorities. These technologies apply primarily to diagnostic tests, medicines, medical devices, prostheses, and surgical procedures.

SPONSORING INSTITUTION: Government of Australia, Ministry of Health and Aging and Ministry and the Ministry of Finance and Deregulation.

The Review has been conducted to identify issues and problems in the HTA system that must be addressed. The Australian HTA system is comprised of agencies with discrete functions responding to different needs, but there are areas of concern including duplication, differing methodologies, evidence requirements, transparency and communication across agencies.

The review also addresses the regulatory burden on business that results from the HTA process; ensures processes are efficient, measured, and proportionate; and identifies opportunities for reform of processes that might be poorly designed, duplicated or unnecessary, impose prohibitive costs and complexity on businesses, and discourage innovation.

The review will identify and discuss issues to be considered; prepare public discussion papers; conduct analysis of stakeholder submissions; hold internal consultations; establish the HTA Review website as the primary means of communication with stakeholders; engage public stakeholder focus groups; hold bilateral meetings between senior management and stakeholder organizations; and incorporate input from consumer consultations carried out by the Consumers Health Forum of Australia (CHF).

The scope of the activities of CHF encompasses:

- Initial consultations with consumers;
- Two teleconferences with 17 key senior consumer representatives; and

- Full-day national workshop with 28 key consumer representatives to explore views on what a future HTA model would look like.

FURTHER READING

Australian Government, Department of Health and Ageing (2009). Review of Health Technology Assessment in Australia. Commonwealth of Australia. Downloaded from: http://www.health.gov.au/internet/main/publishing.nsf/Content/hta-review

Japan Science and Technology Agency (JST) and its sub-agency, the Research Institute of Science and Technology for Society (RISTEX)

ABSTRACT: The Japan Science and Technology Agency is a massive quasi-governmental organization that exists to foster innovation through the development of infrastructure that facilitates research and development. It is a core, independent institution responsible for the implementation of science and technology policy in Japan, including the government's Science and Technology Basic Plan. Different manifestations of the Agency have existed since 1957, with the most current model being established in 2003.

SPONSORING INSTITUTION: Japanese Government, Ministry of Education, Culture, Sports, Science and Technology (MEXT).

JST is an independent institution that operates a large number of sub-agencies/departments responsible for a range of activities from administrative responsibilities (Department of Strategic Planning and Management, and Department of Audit and Research Integrity), innovation (Research Institute of Science and Technology for Society), to science communication (Center for Promotion of Science, and others).

The Agency has a broad range of activities, owing to the diversity of organizations it encompasses. It operates programs designed to facilitate technology transfer of new technologies from universities and public research institutions to industry, with the goal of ensuring that research has positive impact on the economy, society, and living standards.

JST also operates five basic research funding programs:

1. CREST: team-oriented research program, aims to generate research that has significant positive impact on science and technology and provide tangible benefits to society
2. PRESTO: targeted basic research program in which research proposals are selected after a call for proposals in an area that falls within the Strategic Sectors set by the Ministry (MEXT)
3. ERATO: research program aimed at developing key Research Areas that have high potential for seeding new technologies
4. ALCA: promotes continuous reduction of GHGs over medium- to long-term
5. RISTEX: projects aim to generate results that contribute to addressing issues facing society, such as environmental issues, safety and security

Research Institute of Science and Technology for Society (RISTEX)

Through collaboration with stakeholders of various backgrounds, RISTEX produces and applies “evidence-based, scientifically-grounded data, methods, theories, models, policy proposals and tools” in order to generate socially valuable outcomes.

The activities of RISTEX aim to promote socially beneficial research and development (R&D) through the following process:

1. Identify social issues: includes forecasting social issues, identifying experts and stakeholders, narrow the issues down to specific challenges;
2. Establish R&D focus areas;
3. Promote R&D: Under the management of Area Directors, establish R&D programs with clear goals, issue calls for proposals, and publicize adopted projects. Stakeholder engagement through each step of this stage is important to the resolution of the challenges identified;
4. Present results to society; and
5. Assist in the implementation of recommendations resulting from the R&D stage

This research cycle is designed so that there is constant collaboration between the science and technology community and the broader public.

FURTHER READING

Japan Science and Technology Agency (JST)

http://www.jst.go.jp/EN/about/content.html

Research Institute of Science and Technology for Society (RISTEX)

http://www.ristex.jp/EN/aboutus/principle.html

INTERNATIONAL

ISSP

International Symposium on "Opportunities and Challenges in the Emerging Field of Synthetic Biology"

ABSTRACT: Held in 2009 by the US National Academies, the UK Royal Society, and the Organization for Economic Cooperation and Development (OECD), the Symposium addressed the following challenge: synthetic biology is expected to impact many sectors of the economy and to contribute to economic growth, but it is also expected to have social and environmental impacts. Thus, there is a need to address the range of social, economic, ethical, and legal issues raised by emerging technologies as well as other science and technology challenges.

SPONSORING INSTITUTION: Intergovernmental and non-governmental organizations, OECD, US National Academies, and the UK Royal Society.

The Symposium brought together the scientific, engineering, policy, public and legal communities involved in synthetic biology to explore the opportunities and challenges posed by synthetic biology. The Symposium featured expert talks and discussions, and all content was made available online. It was hosted by the US National Academies, and the report was published by the OECD and the UK Royal Society.

The aim of the Symposium was to contribute to fostering safe and efficient development of synthetic biology by identifying issues and areas for future study and informing policymakers of the implications of these issues.

Key outcomes:

- It is crucial to invest in infrastructure to ensure the safe and efficient development of synthetic biology;
- In order to bridge the gap between applications and tools and techniques, some issues would benefit from investigation and/or policy intervention, such as: standardization, developing intellectual property models, as well as international collaboration and cooperation in the regulation and governance of synthetic biology and science and technology development;
- There is a need to create opportunities for public debate and discussion on emerging technologies, and to involve the public using methods other than relying on a simple communication strategy; and
- The science and policy communities must understand that communication between stakeholders is context-specific and depends on various complex factors.

FURTHER READING

Opportunities and Challenges in the Emerging Field of Synthetic Biology
http://www.oecd.org/document/28/0,3746,en_2649_34537_43106012_1_1_1_1,00.html

The Technopolis Group

ABSTRACT: The Technopolis Group is a large consulting firm that was established in the UK in 1989 to carry out policy research, development, and implementation, as well as development of governance and institutions. The Group focuses on emerging technologies, innovation, university and research institutes, industry, economic and social development, health and life sciences, and environment and sustainable development.

SPONSORING INSTITUTION: Global clientele.

Since its establishment in the UK, the Technopolis Group has carried out contract-based research and advisory activities that are international in nature. It began its expansion in 1996 and now has offices in 9 European countries.

The scope of the Group's activities continues to grow and now includes projects in Asia, Australia, North America, and South America.

The aim of the Technopolis Group is to provide practical research and evaluation results, advice, and management support services to policymakers and institutions responsible for policy implementation. In addition, the Group teaches and publishes on evaluation tools, some of which were developed by Technopolis.

Using both quantitative and qualitative tools, the Group focuses on science, technology and innovation (STI) and economic and social policy development, particularly in the fields of emerging technologies and innovation.

Support for policy development occurs through developing and fostering foresighing and mapping exercises that facilitate the prediction of future policy requirements.

Clients of the Technopolis Group include government departments (at federal, state, and municipal levels), research institutions, advisory bodies (including the Canadian Council of Science and Technology Advisors, CSTA), multinational research organizations (including several departments of the European Commission), and educational institutes.

FURTHER READING

Technopolis Group

http://www.technopolis-group.com/cms.cgi/site/group/index.htm

http://www.technopolis-group.com/cms.cgi/site/expertise/index.htm

Concluding Observations

Our menu of "interesting options" on how to address the governance of emerging technologies has a few features worth noticing:

1. The options are highly diverse and contextual

The unique characteristics of some jurisdictions are reflected in the choice of the instruments and processes we review. Variations in the approaches to dealing with emerging technologies can be attributed to cultural differences (particularly apparent during discussions of EU processes), history, environment, and governing institutions.

2. The options are often transient

In many cases, approaches come and go. Even highly regarded organizations such as the US Office of Technology Assessment (OTA) and the Science Council of Canada (SCC, not discussed here) have disappeared. In general, we found the landscape to be quite fluid – some structures went through several manifestations over the course of their history prior to achieving their current arrangements (e.g., the Japan Science and Technology Agency, JST).

3. The options are rarely well described in terms of their effectiveness

Performance measurement is difficult in this domain, particularly given that results of some of these interventions will generally not be apparent in the near future (for example the effectiveness of civil engagement initiatives on the altering the perception of controversial emerging technologies). Whether or not the extent of proactive work being done is sufficient is unknown, and perhaps unknowable.

4. High-level engagement is key to the success of initiatives

As in many other contexts, active engagement of high-level decision-makers such as heads of State and Ministers (Presidential Commission for the Study of Bioethical Issues, PCSBI, and the Australian National Enabling Technologies Strategy, NETS), or heads of agencies (the Emerging Technologies Interagency Policy Coordination Committee, ETIPC, FDA, EPA) was often cited as necessary for success. Without this engagement, there is a risk that quality analysis will remain unused.

5. Many options are new and have an almost experimental character

The novelty of some of these processes indicates that there are continuing, ongoing efforts to approach the problem from different perspectives (e.g. Finland's Government Foresight 2030 report, the EU's Horizons 2020 project to follow MASIS).

6. **Although proactive work is difficult, there are significant efforts being made in this domain**

This report represents a small snapshot of the hundreds, if not thousands, of activities undertaken world-wide by the public, private, and third sectors to deal with the implications of emerging technologies. Extensive efforts are made in this field along with sizeable monetary investments. We can note, however, that even a small investment, if well placed, can lead to tangible progress in this difficult domain (for example, the collaboration between the Woodrow Wilson Center for International Scholars and the DIYbio community to develop a DIYbio Code of Conduct).

As stated previously, what we provide here is a menu of options, and not a "how to" guide for choosing the best course of action for Canada. The selection of the most useful and helpful models for Health Canada and other governing bodies will be a highly contextual choice that is best made by government insiders. We hope that the menu provided will be useful as a basis for discussion and further research.

The Institute for Science, Society and Policy

The Institute for Science, Society and Policy offers a unique, holistic approach to understanding the social implications of science and technology. We're interested in how to use these different perspectives to inform science and technology policy.

Centered at the University of Ottawa, the ISSP carries out research, teaching and public outreach on the relationship between society and science, innovation and technology.

Institute for Science, Society and Policy
Simard Hall
60 University Private
Ottawa, Ontario, Canada
K1N 6N5

Address inquiries and comments to:
issp@uottawa.ca

uOttawa

issp.uottawa.ca