International Efforts to Govern Synthetic Biology

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Revolution:

"**Synthetic biology** is

A) the design and construction of new biological parts, devices and systems, and

B) the re-design of existing natural systems, for useful purposes."

(http://syntheticbiology.org)

"synthetic biology focuses on the design and synthesis of artificial genes and complete biological systems, and on changing existing organisms, aimed at acquiring useful functions."

(Rathenau Institute, 2006, *Constructing Life: Early Reflections on the Emerging Field of Synthetic Biology*, p.15. Quoting the Dutch Committee on Genetic Modification.)

Regulation

"International regulation has greater potential than regulation at other levels to contribute to a more even distribution of benefits and to establish measures to ameliorate negative impacts. It can play a role in introducing accountability and responsibility for management of transnational risks; help to balance the varying needs and interests of different countries; and promote transfer of technology, financial assistance, information and skills for capacity building."

(Rhodes, 2010, *International Governance of Biotechnology*, p.90)

"with gene synthesis firms springing up all over the world, and the underlying technology becoming cheaper and more widely available, it is unclear whether regulations enacted in any one country will be enough"

(Peter Aldhous, 09.11.05, 'The Bioweapon is in the Post', *New Scientist*, Issue 2525)

Arms Control			
Health	Human	Animal	Plant
	Disease control	Biosafety/biosecurity	Food safety
Environmental Protection			
Trade	Free trade	Intellectual property rights	Access to genetic resources
Drugs Control	Illicit trade	Anti-Doping	
Social Impacts (human genetics)			
Development			

Coverage by existing regulations

- Biological Weapons Convention – Article 1

  "(1) Microbial or other biological agents, or toxins, whatever their origin or method of production, of types and in quantities that have no justification for prophylactic, protective or peaceful purposes."

- Sixth Review Conference – Final Declaration

  "the Conference declares that the Convention is comprehensive in its scope and that all naturally or artificially created or altered microbial and other biological agents and toxins, as well as their components… are unequivocally covered by Article 1."

Coverage by existing regulations

- Convention on Biodiversity, Cartagena Protocol on Biosafety and Nagoya Protocol on Access to Genetic Resources

  "any technological application that uses biological systems, living organisms, or derivatives thereof, to make or modify products or processes for specific use" (Article 2, Convention on Biodiversity)

- World Health Organisation's *Laboratory Biosecurity Guidance*

  "scientifically, historically and economically important biological materials such as collection and reference strains… vaccines and other pharmaceutical products, food products, genetically modified organisms, non-pathogenic microorganisms, extraterrestrial samples, cellular components and genetic elements" (p.5)

- Agreement on Trade Related Aspects of Intellectual Property Rights (TRIPS)

"Article 27 – *Patentable Subject Matter*

… patents shall be available for any inventions, whether products or processes, in all fields of technology, provided that they are new, involve an inventive step and are capable of industrial application.

2. Members may exclude from patentability inventions, the prevention… of which is necessary to protect *ordre public* or morality, including to protect human, animal or plant life or health or to avoid serious prejudice to the environment…

3. Members may also exclude from patentability:

(b) plants and animals other than microorganisms, and essentially biological processes for the production of plants or animals other than non-biological and microbiological processes."

Activities of associated organisations

- Conference of the Parties to the Convention on Biodiversity

  Decision X/13, October 2010

  Invited governments and other organisations to submit information on synthetic biology to its Subsidiary Body on Scientific, Technical and Technological Advice and to apply the precautionary approach to field release of synthetic life, cell or genome.

- Ad Hoc Technical Expert Group on Risk Assessment and Risk Management to the Cartagena Protocol

  First meeting, April 2009

  Identified "risk assessment of living modified organisms produced through synthetic biology" as a priority topic for the development of guidance.

Activities of associated organisations

- World Health Organisation
  - Discussed within the 2007 and 2008 reports of its Scientific Working Group on Life Sciences Research and Global Health Security.
  - Mentioned in a 2005 report *Life Sciences Research: Opportunities and Risks for Public Health*.
  - Raised in the 11th meeting of its Advisory Committee on Variola Virus Research – which noted that developments in synthetic biology mean that the variola virus genome can no longer be considered as restricted to two WHO labs and that states need to be aware of the implications of this – and reported to the World Health Assembly in 2010.

Responsibilities

A different approach to governance

"since current biosafety and biosecurity paradigms address life sciences research conducted at research institutions, there may well be gaps in oversight resulting from the large numbers of synthetic biology practitioners who come from backgrounds that are not traditionally considered life sciences or who lack institutional affiliations."

(NSABB, April 2010, *Addressing Biosecurity Considerations Related to Synthetic Biology*, p.iii)

Approach emphasises the need for bottom-up design and implementation of oversight frameworks and for changes to scientific culture through education, training and codes of conduct.

A different approach to governance

- Recommendations:
  - Inclusion of relevant stakeholders in the design and implementation of oversight frameworks;
  - Ensure outcomes are usable, relevant and appropriate;
  - Tailor frameworks to national and institutional requirements;
  - Promote discussion and review of such measures at scientific conferences and workshops and relevant publications;
  - Involve all laboratory staff in design of local biosecurity programmes;
  - Expect all laboratory personnel to follow an ethical code of conduct; and
  - Combine considerations of biosafety, biosecurity and bioethics in the laboratory risk management culture.

"It is our declared intention to raise barriers for malign attackers through a number of measures that will combine to protect synthetic biology from abuse. We aim at encouraging continued improvements and harmonization in this field, as well as adoption and further evolution of this Code of Conduct and the Best Practice Guidelines in the future."

(International Association Synthetic Biology, 2009, *Code of Conduct for Best Practices in Gene Synthesis*, p.2)

Adequacy of current risk analysis approaches?

"the empirical data on the properties of synthetic organisms is inadequate to allow appropriate risk assessment to be undertaken…

Until the empirical data required for an appropriate risk evaluation of release trials is available, synthetic organisms are only to be handled in contained systems…

At present, given the lack of data, it is not possible to judge whether the more specific legal provisions already existing for the handling of genetically modified organisms are also sufficient to regulate the handling of synthetic organisms."

(Swiss Federal Ethics Committee on Non-Human Biotechnology, May 2010, *Synthetic Biology: Ethical Considerations*)

- Change to international regulations generally very slow and does not match pace of scientific developments.
- New approaches to governance may help and should enable greater scientific input into the development of regulation.
- In the biosecurity area a mixed-governance model seems likely.
- This may be less acceptable in other areas.

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