ESRC Innogen Centre

Series: Appropriate Governance of the Life Sciences

Date: Feb 2012

Briefing No 11

Governing Synthetic Biology

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This policy brief is one of a series describing Innogen's research on strategic innovation issues in life sciences, the governance and regulation of innovation and the resulting innovation trajectories determining which products are developed and which companies take the lead in developing them. It is based on a policy brief prepared for the International Risk Governance Council (www.irgc.org).

THE GOVERNANCE OF INNOVATIVE TECHNOLOGIES

The appropriate risk governance concept, developed by the Innogen Centre, is enabling of innovation, minimises risk to people and the environment, and balances the interests and values of all relevant stakeholders. Synthetic biology is one important illustration of how rapid advances in the life sciences are opening up potentially important new applications in medicine and healthcare, agriculture, industrial chemistry and energy production. Credible, effective and appropriate governance systems are a key part of ensuring that the benefits of synthetic biology are realised while minimising risks.

Policymakers thus need to make decisions that balance potential benefits and harms in the face of uncertainty about the eventual nature of products and processes and in this context they are increasingly shaping, rather than responding to, innovative science and technology. They influence the future development of the science, guide product development in certain directions, and either generate or diminish conflict between stakeholder groups.

Future governance of synthetic biology therefore should (i) avoid the mistakes made in setting up current regulatory systems that might be seen as precedents for synthetic biology, (ii) avoid foreclosure on future advances that could be of significant social benefit and (iii) be capable of evolving as scientific and technical knowledge expands and as lessons are learned about the most appropriate forms of regulation and governance. This requires flexibility in the face of uncertainty about the eventual applications, products, processes, benefits and risks, while recognising the dangers of irreversible harms.

CURRENT PERCEIVED RISK GOVERNANCE DEFICITS

Risk governance issues raised in the context of synthetic biology in policy reports include:

1. Insufficient knowledge about the potential risks posed by organisms that combine genetic elements from multiple sources, containing genes and proteins that have never existed together in a biological organism, or that perform biological functions that do not exist in nature.

2. Uncontrolled accidental or intentional release of novel organisms with potential environmental or human health implications.

3. Bio-terrorism and the construction of novel organisms designed to be hostile to human interests.

4. A 'bio-hacker' culture in which individuals could unintentionally develop dangerous organisms.

5. Patenting and the creation of monopolies, inhibiting basic research and restricting product development to large companies.

6. Trade and global justice, for example exploitation of indigenous resources by enabling chemical synthesis of valuable products in industrial countries.

7. Creation of 'artificial life' and related ethical and religious concerns.

The potential risks of synthetic biology should be weighed against the benefits, including recognising that there is an ethical dimension to any decision to forego scientific research (and therefore its potential benefits) in a particular area. For example, curtailing publicly funded research in synthetic biology provides no guarantee against potential abuses and Indeed misuses of the technology are likely to be most effectively prevented or remediated by the techniques of synthetic biology itself.

There is a history of decisions taken in early stages of product development, that are then difficult to change, and have unforeseen and counter-productive outcomes, particularly where regulation has been designed to reassure public opinion rather than to address genuine expected risks, as was the case for GM crops in Europe. Also, where a regulatory regime has evolved over a long period of time in response to earlier generations of scientific development, as for drug development, it can become inflexible and difficult to modify in ways that are appropriate to the latest advances and opportunities.

APPROPRIATE GOVERNANCE OF SYNTHETIC BIOLOGY

The appropriate risk governance of synthetic biology thus needs to be informed by an understanding of how governance and engagement approaches interact with innovation processes. It also needs to be capable of evolving as scientific and technical knowledge expand, requiring flexibility in the face of uncertainty about the eventual nature of products, processes, benefits and risks. Synthetic biology is already too broad a set of developments to be dealt with under one heading and this will require a diverse and flexible set of regulatory instruments tailored to a range of specific hazards and the needs of different industry sectors.

Regulating the risks of synthetic biology research

Regulation of basic research on synthetic biology should be considered separately from product regulation. However, given the role of gene sequences or bio-bricks, in basic synthetic biology research, trading in these products may be best dealt with using the regulatory initiatives also being developed to govern synthetic biology research. Policy-makers need to take a lead in developing standardised procedures for screening sequences and for mitigating bio-security risks, e.g. by promoting a 'culture of responsibility' in the life sciences, backed up by legal mechanisms, coupled with surveillance and improving intelligence on deliberate threats.

It is also important to recognise that using life science innovation itself to combat risks may be the best way to minimise harm. Using synthetic biology to develop improved disease diagnostics and vaccines would enable us to combat the risks from both naturally occurring and maliciously developed pathogens, and the population risks from naturally arising disease organisms are probably considerably greater than those arising from malicious use of synthetic biology.

Regulating the products of synthetic biology

Regulating the products of synthetic biology will build on current regulatory approaches. Thus products that have applications to human or animal medicine, agriculture or food production, or biofuels will come under the scrutiny of the relevant existing regulatory systems. Here it is important to consider relationships with current *innovation systems* and with current *regulatory systems.*

- The shape of emerging synthetic-biology industries will be influenced by their regulatory and investment environments and policy makers may not recognise some of the counter-intuitive implications that regulation can have for innovation. For example, expensive and lengthy regulation tends to favour very large companies by raising high barriers to new market entrants. Large companies are often highly innovative, but only within the restricted areas that support the prevailing sector strategy (see for example the difficulties in moving away from the blockbuster strategy in the pharmaceutical sector). Synthetic biology could offer the type of path-breaking opportunity that will be challenging to multinational companies and, where there is a choice of regulatory precedents, the most appropriate would be the one that favours the industry sector best placed to exploit the new technologies, which may be dominated by smaller companies.

- Considering relationships with current regulatory systems, the challenge is to choose the regulatory precedent that avoids reinforcing currently inadequate

regulatory systems. For example, there is an emerging consensus in Europe that regulatory systems for existing GMOs will be the appropriate precedent for crop and micro-organism-related developments using synthetic biology, despite the contentious differences between the US and EU approaches to GM risk governance, and the increasing evidence of the inadequacy of European risk governance, particularly of GM crops.

Because radical innovations often require infrastructure changes, paving the way for them may require policy initiatives to create markets and investment in infrastructure. Regulators could consider streamlining market authorisation, for example by setting up a 'fast track' for products that satisfy a particular public demand or are capable of reducing the risks presented by current products.

Synthetic biology also has the potential to support regulatory reform by replacing regulatory solutions with technological solutions. One example is the adoption of genetic use restriction technologies (GURTs) to prevent the multiplication and uncontrolled spread of engineered organisms. In the context of GM crops, this has become publicly contentious, but synthetic biology could greatly enhance the effectiveness of this approach, obviating the need for regulatory restrictions beyond requiring the use of this technology. GURTs therefore have potential value in developing containment strategies for organisms used in synthetic biology.

FEAR OF THE FEAR OF THE PUBLIC

Despite recent improvements in public engagement approaches, it is still challenging to find ways of reconciling conflicting values or ideologies around technologies such as GM or synthetic biology. Where there are strong ideologically based differences of opinion at the outset of a debate, it is hard to manage the process so as to avoid further polarisation and exacerbation of conflict. Apparently successful public engagement in the early stages of development of a new area of science and innovation cannot guarantee continued public support in future.

Research and innovation in synthetic biology is proceeding within a context of open dialogue about its potential benefits and its social, economic and ethical implications, but this is at a time when innovation outcomes are highly uncertain. There are unresolved questions around how and when to incorporate stakeholder concerns into decision-making about future technological developments, what power and influence various actors should have, and how widely the dialogue should be framed, e.g. beyond the usual dialogue around the nature of the science and technology itself to include the processes of innovation and technology development, the relevant regulatory regimes, and how they interact with one another.

The policy aim should be to enable people, organisations, policymakers and governments to make informed choices within the constraints of effective regulatory systems, and to foster debate in a way that does not empower one set of stakeholders to impose ideologically held opinions on the rest of society.

Notes:

This policy brief is one of a series dealing with Appropriate Governance of Life Sciences – http://tinyurl.com/7kslbsf

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