

Adaptive governance of synthetic biology

Joyce Tait

Synthetic biology has the potential to revolutionize the development of drugs, vaccines, biofuels and food crops, and to clean up environmental pollution, but the field is relatively young. It is too early to tell how it will deliver new fundamental understandings in the life sciences, how this understanding will create opportunities for innovation to satisfy human needs and the extent to which its applications might generate hazards to people or the environment.

Synthetic biology is now being linked by NGOs to genetically modified (GM) crop development with potentially similar results for its future development [1]. An NGO advocacy coalition has published a report on synthetic biology that echoes the arguments made against GM crops in the late 1990s [2] with the intention to "... reign [sic] in these new technologies", with an ideologically based framing of the technology as inherently hazardous, based on negative conjectures with little relationship to actual evidence.

The prospect of another polarized public debate had already convinced policy-makers and scientists to pay early attention to the governance of synthetic biology.

Reports from the US Presidential Commission for the Study of Bioethical Issues (PCSBI) and from the International Risk Governance Council (IRGC) [3,4] have attempted to develop principles of good governance that could be applied to synthetic biology, given the uncertainty about the nature of future developments. The reports recommend that policy-makers should aim for a governance approach that can adapt to changing innovation opportunities emerging from new scientific discoveries; encourage and promote innovation; minimize risk to humans and the environment; and balance the interests and values of all relevant stakeholders. The reports reject calls for a moratorium on synthetic biology until all risks are identified

and mitigated, but also reject unfettered freedom for scientific investigation. The governance of synthetic biology should achieve an equitable balance between promoting innovation and imposing constraints to ensure safety. Dialogue with stakeholders should be conducted in a manner that welcomes the respectful exchange of opposing views and encourages mutual accommodation of differing opinions. Dialogues should contribute to decisions being taken on the basis of the best available evidence. Considering potential dual-use risks of synthetic biology, both reports note that undue restriction might be counterproductive to safety and security, by preventing the development of effective safeguards against, for example, terrorist threats.

These principles of good governance are part of a long-term political and policy experiment that claims to use a lighter touch and be less top-down [5], but in effect has extended the regulatory process into areas that used to be left to market forces. It claims to be more democratic by involving a wider range of stakeholders in the decision-making process, but in effect has merely led to a shift in power away from industry and commerce towards advocacy groups with equally limited claims to represent 'society'. The impact of implementing this governance agenda on innovation has so far been more marked and damaging in Europe than in the USA, but the recent criticism by Friends of the Earth and other advocacy groups might signal a change of emphasis and put the balanced approach to the governance of synthetic biology, that has so far been achieved, at risk.

Indeed, the availability and quality of the scientific evidence used to support policy advice and decision-making, has been a major casualty of the new governance approach as applied in the EU to GM crops—as evidenced by the destruction of GM crop trials designed to evaluate the safety and efficacy of these crops. The role

of neutral, impartial evidence in political decision-making has been diminished in favour of evidence that suits the agendas of particular advocacy groups. Politicians themselves helped to create this situation by shying away from making difficult, unpopular decisions on the basis of hard evidence, in favour of trying to accommodate all opinions, including ideologically driven agendas. Arthur Miller describes the sense of liberation experienced when eschewing the role of evidence in decision-making: "It was as though the absence of real evidence was a release from the burdens of this world; [...] Evidence, in contrast, is effort; leaping to conclusions is a wonderful pleasure..." [6].

There is a need to reappraise both the role of scientific evidence in informing policy and political decision-making on new biotechnologies, and the legitimate context in which to accommodate value-based opinions as represented by NGOs.

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Joyce Tait is at the ESRC Innogen Centre, University of Edinburgh, UK.
E-mail: joyce.tait@ed.ac.uk

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