Eighth meeting, of the Synthetic Biology Leadership Council (SBLC) Governance Sub-group

13:30 – 17:00, Tuesday 7th June 2016.

BIS Conference Centre, 1 Victoria Street, London, SW1H 0ET.

Attendees

Chair: Joyce Tait (JT), Innogen Institute, University of Edinburgh (SBLC)

Governance Sub-group:

Alistair Kent (AK)	Genetic Alliance
Jackie Hinton (JH2)	BIS
Linda Brooks (LB)	Thermofisher
Tim Fell (TF)	BIA, SBLC
Julian Hitchcock (JH1)	Denoon Legal
Michael Paton (MP)	Health and Safety Executive
Janet Bainbridge (JB)	UK Trade & Investment, SBLC
Martin Cannell (MD)	DEFRA
Richard Kitney (RK)	Imperial College, SBLC
Patrick Middleton (PM) (for Matt Goode)	Research Councils

Apologies: Matt Goode, Lionel Clarke, Roland Jackson, Robert Doubleday, Hilary Sutcliffe

Agenda Items

1. Minutes of last meeting and feedback on recent activities

The minutes from the 7th meeting of the GSG on 2nd March 2016 were approved.

All actions had been completed with the exception (Agenda item 4) of issuing invitations to those working on RRI in SB Research Centres to give presentations to the SBLC, and the link to the list of RRI issues from the European Commission HS had mentioned. The request for feedback from Science, Technology and Innovation communities what issues they think the Governance Subgroup should be paying attention to is still ongoing.

Robert Doubleday, Centre for Science and Policy, has accepted our invitation to join the GSG and will be attending the next meeting.

Action 1 (JT): contact Stuart Hogarth with a view to organising presentations from SBRCs.

Action 2 (JT): Ask HS about the link to the list of RRI issues from the European Commission.

Action 3 (all): Ask contacts in Science, Technology and Innovation communities what issues they think the Governance Subgroup should be paying attention to.

2. Update on CBD related developments (MC and MP)

(Latest papers from CBD office, Papers 8.2 and 8.3)

In addition to the papers circulated for the meeting, MC circulated the AHTEG (Ad Hoc Technical Expert Group), May 2016, report (paper XX/8) on recommendations adopted by SBSTTA (Subsidiary Body on Scientific, Technical and Technological Advice).

Reporting on negotiations at SBSTTA20 (noted that the negotiations were tough):

- The main noteworthy outcome of the negotiations was regarding the operational definition of synthetic biology proposed by the synbio AHTEG. Two options will be discussed at COP in December: i) to note that more work needs to be done on the definition, particularly regarding inclusion and exclusion criteria; or ii) accept that it is appropriate to use the current definition as an operational definition (for the purposes of scientific and technical deliberations). Both recommendations will be discussed by the COP.
- Considering whether the question "Does synthetic biology meet the criteria for a "new and emerging issue" had been addressed, several Parties argued that there has so far been no systematic analysis against the relevant criteria. The AHTEG mandate has been extended to address this issue within the next year. It's worth noting that EU member states do not have their 'own voice' at the COP/MOP meeting. Instead negotiating positions are co-ordinated at EU level. In the lead up to COP/MOP, the EU will be developing a position paper with regard to these discussions. Defra will be involved in the drafting groups.
- There will be a future action for GSG to comment on these negotiations.

In discussion the following points were noted:

- The language including 'products' (i.e. non-living products) within the coverage of the CBD and its protocols is still there in the latest papers. It was seen as potentially risky for the future proportionate governance of synthetic biology to leave this language unchallenged.
- The NGO influence on EU debates was seen as being less than on CBD-related fora.
- There should be a requirement not to create new laws until those that are currently in place are being effectively implemented and are unable to cope with new circumstances.
- The new more precise techniques involved in synthetic biology actually reduce the uncertainties around the properties of the modified organism compared to 'old GM'.
- There was a brief discussion on the EU system for regulating synthetic biology and gene editing and whether both will be regarded as 'GM' from the point of view of EU regulations.

Action 4 (All): based on this discussion to feed back to the GSG any additional points they would like to make after reading the documents circulated.

Action 5 (JT): send a copy of the SB report prepared for UK and RoI Environmental Agencies when it becomes available

3. Synthetic Biology Strategy Paper – meeting the commitments
(Strategy paper 'Biodesign for the Bio-economy') (TF, AK, JB, JT)

This item considered the recommendations in the strategic plan, to be spread across future SBLC meetings as part of an annual agenda in the following order: Recommendation 4 (including RRI and Regulations) + Recommendation 1 (including investor interests following SynBioBeta) (July meeting); Recommendation 3 (Skills, training) plus Recommendation 5 (national and international coordination) plus updates and actions from Recommendation 4 and Recommendation 1 (Nov meeting); and Recommendation 2 (SBRC and wider infrastructure of foundries etc) plus review of all Recommendations (metrics), plans for next annual cycle, and budget needs (Mar 17 meeting).

The points raised on Recommendation 1 were:

- The momentum behind promotion of synthetic biology is not being maintained at a high enough level to enable the UK to capitalise on its initial competitive advantage – there is a need to reinforce the message that SB is the *foundation* of the bioeconomy and as such it needs much stronger financial support than it is currently getting.
- (Related to Recommendation 3) We need to ensure that we have the trained expertise to enable us to benefit from increased investment.

- The UK needs to give greater emphasis to the engineering aspect of synthetic biology, particularly through more high level involvement of EPSRC in discussions and decision making relevant to synthetic biology and the bioeconomy. The tools of automation and the ability to scale up production processes will be important aspects of such initiatives.
- The development of engineering-related standards will be an essential part of the supporting infrastructure to enable synthetic biology to deliver its potential contribution to the bioeconomy. Standards are also needed on working practices and safety, quality and efficacy.

The focus on governance was seen, among other things, as being about ensuring a receptive space for the technology that emerges from synthetic biology. The points raised on Recommendation 4 included some sent in by HS who was not able to be at the meeting:

- The idea was floated of asking investors and stakeholders what they want to see from the technology. This was seen as related to achieving balanced stakeholder representation through our meetings and in addition paying greater attention to the full range of stakeholder perspectives including those who advocate a strongly precautionary approach.
- Any SBLC initiative involving an increased effort on stakeholder engagement would need to be funded. BBSRC funded some research last year on mapping the stakeholder community and will send the GSG the outcomes of that research.
- The UK biosecurity strategy, covering dual use research of concern (DURC) and research integrity is currently being revised with a view to publication.
- Attention was drawn to the US enlightened approach to biosecurity where very well-qualified FBI personnel engage actively with the research community, including 'garage biology'. There is no equivalent in the UK and SBLC should encourage such an approach to be developed.
- In catering for needs related to biosecurity aspects of synthetic biology, it is important to ensure that any governance mechanisms introduced do not inhibit our ability to deal with an actual biosecurity threat (or a naturally occurring pandemic) by the rapid development of diagnostic tools, vaccines and antibiotics.

Action 6 (GSG): (i) to urge the SBLC to emphasise the role of synthetic biology in future planning for the bio-economy and to seek significantly enhanced funding to enable us to build on our current advantage; (ii) to seek (through RCUK) stronger representation from EPSRC in fora where discussions are held and decisions are taken that are relevant to the role of synthetic biology in the bioeconomy.

Action 7 (RK and TF): to prepare a note for the next SBLC meeting on where future funding needs to be directed to deliver the greatest benefit for the bioeconomy and on the role of standards in complementing that investment.

Action 8 (PM): to send GSG members the results of the BBSRC funded stakeholder mapping initiative.

Action 9 (JH2): to send GSG members the UK Biosecurity Strategy when it is available.

Action 10 (SBLC): to encourage those working on biosecurity in the UK to engage more proactively with those working on synthetic biology outside the mainstream of research funding and innovation support.

4. Tabled for future consideration – Paper on "Public dialogue on genome editing"
(http://nuffieldbioethics.org/blog/2016/public-dialogue-on-genome-editing-why-when-who/)

Due to the absence of Roland Jackson (RJ), it was decided that the discussion will be pushed back to the next meeting, when RJ is back. RJ had provided the link to a paper on genome editing, presumably in response to the action point in item 4 in the previous minutes, in lieu of the paper on

the Robotics dialogue. It was noted that Nuffield is going to produce a report soon on genome editing.

The need for public engagement will have to be discussed again at the next SG meeting, but in the meantime the following remarks were made:

- There seemed to be conflicting views about the need for public engagement at the last meeting organised by Nuffield and Sciencewise, between the legal regulators and everybody else.
- Due to the expense involved, a public dialogue makes sense only if there is an actual demand for it from the community, and the timing is important.
- There is a need for a properly informed public debate with clear and accurate language so people get both the science and the language right (something like a thesaurus of terms was suggested); also the public needs to be educated about what is good evidence and what is not. This need for clarity and understanding is important not only for the public, but for the regulators as well.
- Greater mediatisation on what's happening in SB in the UK should be encouraged, as journalists tend to focus on science made in the US.

Action 11 (GSG): full discussion on the topic at the next meeting.

5. BSI project on Proportionate and Adaptive Governance of Innovative Technologies

This item discussed a report from a recent project at the Innogen Institute, funded by the British Standards Institution (BSI). In the context of the need for more proportionate and adaptive regulatory systems and a pro-innovation government agenda, this project considered how standards could be integrated more purposively alongside regulations and regulatory guidelines to deliver such an outcome (including a focus on Responsible Research and Innovation). A key outcome of this project was an outline framework for application to future developments in synthetic biology, and life sciences more generally.

The BSI is proposing to fund a second phase of this research to consider two case studies in more depth and to take them to a point where they can be used as a starting point for the actual delivery of future standards. This will be supplemented by a grant from the ESRC Knowledge Transfer Fund held at the University of Edinburgh. We have proposed that one of the case studies should be on the future governance of synthetic biology, assuming that the regulatory precedent will be the systems currently in place for GMOs.

We are suggesting that this could be a contribution to Actions 4.1 and 4.2 in 'Biodesign for the Bioeconomy'.

The GSG was asked to comment on this proposal prior to its being discussed at the next SBLC meeting. The discussion covered the following points (including comments sent in advance from HS who was unable to attend):

- The overall approach outlined in the proposed framework was seen to be useful, i.e. the regulatory approach itself should be goal-setting (make sure the environment is not harmed) with the emphasis on achieving that through the adoption of guidelines and standards.
- The issue is not to attempt to amend the EU regulations (seen as unrealistic) but to add a preliminary phase to the current regulatory system that would simplify and speed up the regulation of organisms that could be demonstrated to comply with standards to demonstrate safety to people and the environment.
- Discussion included the choice of case study, and the arsenic biosensor that has been going through the EU regulatory system for a number of years was one choice considered. However, for the UK to influence the EU in the context of judging the relative safety of

different organisms including GM plants and other organisms planned to be released into the environment, the Annex to the Directive would need to be changed given that it currently only applies to contained use micro-organisms and this would be problematic.

- This would be a useful choice of case study but there would need to be careful management of expectations. If the arsenic biosensor was chosen as an example in this case study, it could be a useful way of building on the experience of those who have been working on it to date, whether the outcome is positive or negative in terms of gaining approval for the technology. This could potentially also bring in consideration of DNA/biobrick type standards.
- The emphasis on the interactions between regulation of innovative technology and economic benefits should be extended to take account of the need to protect health and safety and to provide reassurance to those who may lack trust in businesses and other groups.
- There was agreement on the need for stakeholder involvement in the design of behavioural approaches.
- There was also support for the need for aspirational/behavioural standards, but with emphasis on the cost of delivery of a standard.
- Overall there was agreement from GSG members with the proposal that governance of synthetic biology should be one of the case studies to be used in the next BSI-funded project on Proportionate and Adaptive Governance of Innovative technologies.

Action 12 (MP): to send the EFSA Report on the arsenic biosensor.

Action 13 (JT): to take the proposal to SBLC that synthetic biology governance should be one of the case studies addressed in the forthcoming project at the Innogen Institute, funded by BSI and ESRC, with the agreement of the GSG.

6. AOB

- The regulation of probiotics in the EU was discussed but it was not clear whether this was an example related to synthetic biology.
- The Harvard closed meeting on creating a synthetic human genome was also raised as an issue to be considered, potentially with some urgency, depending on the extent to which it continues to have high profile media coverage.